APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 19-5352

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
Appellees

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES,
Appellant

Consolidated with 19-5353, 19-5354

Appeals from the United States District Court
for the District of Columbia

(No. 1:18-cv-02841)
(No. 1:19-cv-00132)
(No. 1:19-cv-01745)

Argued April 17, 2020

Decided July 17, 2020

Alisa B. Klein, Attorney, U.S. Department of Justice, argued the cause for appellant. With her on the briefs were *Mark B. Stern*, Attorney, *Robert P. Charrow*, General Counsel, U.S. Department of Health & Human Services, *Janice L. Hoffman*, Associate General Counsel, *Susan Maxson Lyons*, Deputy Associate General Counsel for Litigation, and *Robert W. Balderston*, Attorney.

Howard R. Rubin and *Robert T. Smith* were on the brief for amici curiae Digestive Health Physicians Association, et al. in support of appellant.

Catherine E. Stetson argued the cause for appellees. With her on the brief were *Susan M. Cook*, *Katherine B. Wellington*, *Mark D. Polston*, *Joel McElvain*, *Christopher P. Kenny*, and *Michael LaBattaglia*. *Kyle Druding* entered an appearance.

Before: SRINIVASAN, *Chief Judge*, GARLAND and MILLETT, *Circuit Judges*.

Opinion for the Court filed by *Chief Judge* SRINIVASAN.

SRINIVASAN, *Chief Judge*: Many hospitals provide outpatient care at off-site facilities known as "off-campus provider-based departments," or PBDs. Certain services offered by hospitals at off-campus PBDs, such as routine clinic visits, can also be provided by independent physician practices unaffiliated with a hospital. Although off-campus PBDs and independent physician practices can offer the same service, Medicare until recently reimbursed those providers at different rates: because off-campus PBDs are considered hospitals for regulatory

purposes, they were paid a higher rate applicable to hospitals instead of a lower rate applicable to physician practices. The result was that, for the same outpatient service, off-campus PBDs obtained up to twice as much per patient in Medicare reimbursements as did physician practices.

The Department of Health and Human Services determined that the payment differential gave rise to an economic incentive that induced unnecessary growth in the volume of outpatient care provided at off-campus PBDs. HHS thus reduced the rate it paid hospitals for the most common off-campus PBD service, "patient evaluation and management," to equal the rate paid to physician practices for that service. HHS justified that reimbursement cut as an exercise of its statutory authority to adopt "method[s] for controlling unnecessary increases in the volume" of covered outpatient services. 42 U.S.C. § 1395*l*(t)(2)(F).

A group of hospitals brought these consolidated actions, claiming that HHS's rate reduction for off-campus PBDs falls outside of the agency's statutory authority. The district court agreed and set aside the regulation implementing the rate reduction. Because we conclude that the regulation rests on a reasonable interpretation of HHS's statutory authority to adopt volume-control methods, we now reverse.

I.

A.

Medicare Part B health insurance covers outpatient hospital care, including same-day surgery, preventive

and screening services, and physician visits. *See* 42 U.S.C. §§ 1395j, 1395k. The Department of Health and Human Services (HHS) sets the rates at which Medicare will reimburse hospitals for providing such services according to an intricate statutory system known as the Outpatient Prospective Payment System (OPPS). *See* 42 U.S.C. § 1395*l*(t).

Under the OPPS, hospitals are not reimbursed for the actual costs incurred in providing care. Instead, to help control Medicare expenditures, the statute calls for HHS to set predetermined payment amounts for each covered outpatient service. *See* H.R. Rep. No. 106-436, at 33 (1999). Hospitals then receive that amount for every instance in which they provide the service. OPPS rates are revised each year via notice-and-comment rulemaking and are published before they go into effect. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004).

HHS generally sets the rates using a complex statutory formula. First, each covered outpatient service (or group of related services) is assigned an Ambulatory Payment Classification (APC). 42 U.S.C. § 1395*l*(t)(2)(B). HHS then establishes "relative payment weights" for each APC based on the median cost of providing the relevant services. *Id.* § 1395*l*(t)(2)(C). In that relative weighting process, HHS may decide, for instance, that given the cost to the hospital, a certain service should be reimbursed at twice the rate of a different service. Next, each APC's relative weight is multiplied by a number known as the "conversion factor." *Id.* § 1395*l*(t)(3)(D). The same conversion factor applies to all APCs. *Id.* Multiplying an APC's relative payment weight by the conversion

factor produces a dollar amount, which is the base "fee schedule amount" for that APC. *Id.* § 1395*l*(t)(4)(A). That amount is subject to a variety of possible further adjustments, such as adjustments reflecting regional wage differences, *id.* § 1395*l*(t)(4)(A), or "outlier adjustments" for hospitals facing unusually high operating costs, *id*. § 1395*l*(t)(5).

When setting rates each year, HHS is required to reassess its choices: what services or groups of services should make up each APC, what an APC's relative payment weight should be, and what statutory adjustments (such as for labor cost differences) should be applied. *Id.* § 1395*l*(t)(9)(A). Changes to any of those inputs will alter the payment rate for a particular service. Any change HHS makes in those respects, however, must not cause overall projected expenditures for the next year to increase or decrease. *Id.* § 1395*l*(t)(9)(B). Under this "budget-neutrality" requirement, an increase or decrease in projected spending must be offset by other changes.

HHS must also update the conversion factor each year in order to keep up with inflation in general health care costs. *Id.* § 1395*l*(t)(3)(C)(ii), (t)(3)(C)(iv). Increases to the conversion factor, of course, proportionately increase overall OPPS outlays. But adjustments to the conversion factor need not be implemented in a budget-neutral manner—indeed, it would make little sense to do so in light of the objective of keeping pace with inflation.

The OPPS is designed to advance Congress's goal of controlling Medicare Part B costs in two ways. First, the OPPS encourages hospital efficiency by setting

payment rates prospectively and basing the amount on median cost. Second, because of the budget-neutrality requirement, overall OPPS expenditure growth should closely track annual increases to the conversion factor. Those increases are modest and their amount is prescribed by statute.

Although HHS has significant control over the rate it will pay hospitals for a specific service under the OPPS system, the agency has little control over how frequently hospitals will provide that service. Consequently, even if payment rates remain constant, an increase in the amount of services provided will cause an increase in overall Medicare expenditures.

Congress addressed that possibility in subparagraph (2)(F) of the OPPS statute, the provision centrally in issue in this case. Subparagraph (2)(F) directs HHS to "develop a method for controlling unnecessary increases in the volume of covered [outpatient] services." *Id.* § 1395*l*(t)(2)(F). Relatedly, Congress also authorized HHS to reduce the conversion factor, thereby shrinking projected overall expenditures, if it "determines under methodologies described in [sub]paragraph (2)(F) that the volume of services paid for . . . increased beyond amounts established through those methodologies." *Id.* § 1395*l*(t)(9)(C).

B.

Some hospitals provide outpatient care at facilities known as off-campus provider-based departments (PBDs), which are located away from the physical site of the hospital. Off-campus PBDs are considered part of the hospital for regulatory purposes. *See* 42 C.F.R.

§ 413.65. For that reason, services provided at off-campus PBDs are reimbursed through the OPPS system. HHS thus has generally paid hospitals the same amount for outpatient care provided at an off-campus PBD as for outpatient care provided in the main hospital.

At least some services provided at off-campus PBDs can also be provided by freestanding physician offices, i.e., medical practices unaffiliated with a hospital. Physician offices are generally reimbursed at a lower rate for a given service than hospitals, because hospitals receive a separate "facility" rate inapplicable to freestanding physician practices. *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, 37,142 (July 31, 2018).

Consider the amounts Medicare paid for a service commonly provided by off-campus PBDs: "evaluation and management of a patient," or E&M. In 2017, the E&M reimbursement rate for off-campus PBDs under the OPPS was $184.44 for new patients and $158.24 for established patients. By contrast, the 2017 E&M rate for freestanding physician offices—paid under a separate system known as the Physician Fee Schedule—was $109.46 for new patients and $73.93 for established patients. *See id.* Hospital-affiliated outpatient departments thus received between 68% and 114% more in reimbursements per patient for the same service.

According to the Medicare Payment Advisory Commission (MedPAC), which was established by

Congress to advise HHS, *see* Pub. L. No. 105-33 § 4022, 111 Stat. 251, 350, hospitals reacted to the incentive created by the payment differential between off-campus PBDs and independent physician practices. Almost a decade ago, hospitals began buying freestanding physician practices and converting them into off-campus PBDs, without much change in the facility or the patients served. MedPAC, *Report to the Congress: Medicare Payment Policy* 53, 59–61, 75–76 (Mar. 2014), https://go.usa.gov/xdCzV. MedPAC documented substantial increases in the provision of E&M services at hospital outpatient departments and little to no growth in the provision of the same services at physician offices. *See id.* at 42. From 2011 to 2016, the provision of E&M services at off-campus PBDs grew by 43.8%. MedPAC, *Report to the Congress: Medicare Payment Policy* 73 (2018), https://go.usa.gov/xdCzu. By comparison, the provision of E&M services at freestanding physician practices grew by only 0.4%. *Id.*

In 2015, Congress attempted to address the substantial growth in services provided at off-campus PBDs by enacting section 603 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, 129 Stat. 584, 597–98 (codified at 42 U.S.C. § 1395l(t)(21)). Section 603 adopted something of a compromise approach. On one hand, it did not touch the reimbursement rates for existing off-campus PBDs. On the other hand, it established that off-campus PBDs coming into existence after the statute's enactment would no longer be paid under the OPPS, but instead would be paid under the "applicable payment system under this part," which HHS interpreted to be a rate equivalent

to the Physician Fee Schedule. 42 U.S.C. § 1395l(t)(21)(C). That change applied to every service—not just E&M services—provided at new off-campus PBDs.

After section 603's enactment, though, HHS still continued to observe steady growth in the volume of hospital outpatient services. 83 Fed. Reg. at 37,139. For the years 2016 through 2018, the volume and intensity of services grew annually by 6.5%, 5.8%, and 5.4%, respectively. *Id.* And in its proposed OPPS rule setting rates for 2019, the agency projected that, without changes, volume would again increase by 5.3% in that year, leading to $75.3 billion in overall OPPS expenditures. *Id.* Outlays had been nearly $20 billion less only a few years earlier. *Id.*

HHS determined that, despite the 2015 enactment of section 603, "the differences in payment for . . . services" continued to be "a significant factor in the shift in services from the physician's office to the hospital outpatient department, . . . unnecessarily increasing hospital outpatient department volume." *Id.* at 37,142. HHS believed that the "higher payment that is made under the OPPS, as compared to payment under the [Physician Fee Schedule], [was] likely to be incentivizing providers to furnish care in the hospital outpatient setting." *Id.* at 37,141. Thus, although section 603 had removed the incentive for hospitals to purchase physician practices and convert them into off-campus PBDs on a going-forward basis, the statute did not remove the incentive to provide care in off-campus PBDs already in existence.

In its rule proposing 2019 OPPS rates, HHS announced that it "consider[ed] the shift of services" it had observed to be "unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives." *Id.* at 37,142. The agency concluded that E&M services, which are routine clinic visits, fit the bill, and thus that "the growth in clinic visits paid under the OPPS is unnecessary." *Id.*

Having found an "unnecessary increase[] in the volume of covered [outpatient] services," HHS proposed to exercise its subparagraph (2)(F) authority to "develop a method for controlling" the increase. 42 U.S.C. § 1395*l*(t)(2)(F); 83 Fed. Reg. at 37,142. Specifically, the agency proposed to cut E&M reimbursement rates to off-campus PBDs to the amount HHS pays to freestanding physician offices for providing the same service. "[C]apping the OPPS payment at the [Physician Fee Schedule]-equivalent rate," the agency explained, "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 [would] be removed." 83 Fed. Reg. at 37,142.

Notably, HHS proposed to implement the E&M reimbursement cut in a non-budget-neutral manner. In other words, the agency would reduce payments without offsetting increases in reimbursements for other covered outpatient services. *Id.* at 37,142–43. Although the OPPS statute generally requires annual rate adjustments to be budget-neutral, *see* 42 U.S.C. § 1395*l*(t)(9)(B), the agency did not believe that

requirement applied to methods for controlling volume under subparagraph (2)(F). 83 Fed. Reg. at 37,142–43. HHS chose not to apply the reimbursement cut in a budget-neutral manner because doing so "would not appropriately reduce the overall unnecessary volume of covered [outpatient] services, and instead would simply shift the movement of the volume within the OPPS system in the aggregate." *Id.* at 37,143. HHS estimated that the proposed rule would reduce Medicare's expenditures by approximately $610 million in 2019 alone, with an additional $150 million saved by Medicare beneficiaries in the form of reduced coinsurance payments. *Id.*

After receiving comments, the agency adopted its proposal as a final rule, with the only change that the E&M reimbursement cut would be phased in over two years. *See* 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).

C.

The American Hospital Association and various hospitals (whom we will refer to collectively as the Hospitals) challenged the 2019 rule in these actions, which were consolidated in the district court for purposes of addressing the parties' cross-motions for summary judgment. *See Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142, 146 (D.D.C. 2019). The Hospitals first argued that HHS's reduction in reimbursement for E&M services exceeded the agency's statutory

authority because the reduction does not qualify as a "method for controlling unnecessary increases in . . . volume" under subparagraph (2)(F) of the OPPS statute. *See id.* at 150–51. The Hospitals also argued that HHS's decision to cut reimbursement to preexisting off-campus PBDs contravened Congress's decision to leave preexisting facilities unaddressed in section 603 of the Bipartisan Budget Act of 2015. *See id.*

The district court agreed with the Hospitals' first argument. *Id.* at 161. The court accordingly vacated as *ultra vires* the part of the challenged rule that reduced E&M reimbursement rates. *Id.* This appeal followed.

II.

We must first consider whether we have jurisdiction to review the Hospitals' claim. Subparagraph (12)(A) of the OPPS statute provides that "[t]here shall be no administrative or judicial review of" certain specified actions HHS takes in implementing the OPPS, including "the establishment of . . . methods described in paragraph (2)(F)." 42 U.S.C. § 1395*l*(t)(12)(A). The government contends that HHS's cut to E&M reimbursement qualifies as such a "method." Thus, the government argues, judicial review of that reimbursement cut is precluded by statute, and we should dispose of the case on that basis at the threshold without examining HHS's authority to implement the rate reduction.

We are unpersuaded. Although subparagraph (12)(A) forecloses judicial review of the agency's "establishment of methods described in paragraph

(2)(F)," the Hospitals' claim is that the payment reduction at issue is *not* a "method[] described in paragraph (2)(F)" within the meaning of the statute. As a result, to determine whether the judicial-review bar applies in this case, we must decide whether the challenged agency action counts as a "method for controlling unnecessary increases in the volume of covered [outpatient] services." *Id.* § 1395*l*(t)(2)(F). And that latter question is the merits issue presented here.

Subparagraph (12)(A) therefore is a preclusion-of-review provision that "merges consideration of the legality of [agency] action with consideration of the court's jurisdiction in cases in which the challenge to the [agency's] action raises the question of the [agency's statutory] authority." *Amgen*, 357 F.3d at 113–14 (quoting *COMSAT Corp. v. FCC*, 114 F.3d 223, 226–27 (D.C. Cir. 1997)). In such cases, if the court "find[s] that [the agency] has acted outside the scope of its statutory mandate, we also find that we have jurisdiction." *COMSAT*, 114 F.3d at 227. Put differently, "the jurisdiction-stripping provision does not apply" if the agency's action fails to qualify as the kind of action for which review is barred. *Southwest Airlines Co. v. TSA*, 554 F.3d 1065, 1071 (D.C. Cir. 2009). As a practical matter, then, the court can simply skip to the merits question in its analysis. *See, e.g.*, *id.*; *Amgen*, 357 F.3d at 114; *COMSAT*, 114 F.3d at 227.

This court has already construed the provision at issue here as "merging" the preclusion and merits analysis in that way. In *Amgen*, we stated that subparagraph (12)(A)'s preclusion on review of "other

adjustments" to rates by HHS "extends no further than the Secretary's statutory authority to make" such adjustments. 357 F.3d at 112. Accordingly, we concluded that subparagraph (12)(A) "precludes judicial review of any adjustment made by the Secretary pursuant to [his statutory] authority . . . but not of those for which such authority is lacking." *Id.* at 113. We then proceeded to the merits question, ultimately holding that the challenged adjustment was within the agency's statutory authority and that we thus lacked jurisdiction. *Id.* at 114, 118. The government contends that *Amgen*'s treatment of subparagraph (12)(A) was dicta, but regardless, we fully agree with *Amgen*'s approach, under which we analyze the merits to decide whether we have jurisdiction.

The government attempts to sidestep that result by pressing us to analyze the Hospitals' claim under the '*ultra vires* review' doctrine often attributed to *Leedom v. Kyne*, 358 U.S. 184, 79 S.Ct. 180, 3 L.Ed.2d 210 (1958). That doctrine, which we have likened to a "Hail Mary pass," "permits, in certain limited circumstances, judicial review of agency action for alleged statutory violations even when a statute precludes review." *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009). The government submits that the Hospitals' challenge presents such a circumstance and thus must satisfy the stringent requirements set out in *DCH Regional Medical Center v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019)—among them, that the agency plainly acted in excess of its delegated powers and contrary to a

specific, clear, and mandatory prohibition in the statute. *Id.*

The Hospitals' challenge does not implicate the *Kyne* framework. We are not asked to remedy a "statutory violation[] even when a statute precludes review." *Nyunt*, 589 F.3d at 449. Instead, the Hospitals argue that the "same agency error . . . simultaneously ma[kes] the jurisdictional bar inapplicable and compel[s] setting aside the challenged agency action." *DCH Regional*, 925 F.3d at 510 (quotation marks omitted). Put differently, the Hospitals' claim is that subparagraph (12)(A)'s bar on judicial review does not apply if their merits argument is correct, not that their merits argument is so obviously correct that we should consider it despite an applicable bar on our review. *DCH Regional* itself recognized the distinction between cases involving a "*Kyne* exception" and cases such as this one in which "the relevant statutory bar . . . [is] effectively coextensive with the merits." *Id.* at 509–10.

In sum, subparagraph (12)(A)'s bar on judicial review is inapplicable unless HHS's challenged action qualifies as a "method for controlling unnecessary increases in . . . volume" under subparagraph (2)(F). Subparagraph (12)(A) then ultimately does not preclude judicial scrutiny of HHS's action for consistency with subparagraph (2)(F). To be sure, subparagraph (12)(A) still forecloses inquiry into "whether [the] challenged agency decision is arbitrary, capricious, or procedurally defective." *Amgen*, 357 F.3d at 113. But such claims are not before us here. As to the claim the Hospitals do raise, the question whether the Hospitals are correct and

the question whether the preclusion provision bars review of their claim are one and the same. We thus turn to assessing whether HHS had statutory authority to implement the challenged E&M reimbursement reduction.

III.

A.

We examine that question under the traditional *Chevron* framework, under which we defer to the agency's reasonable interpretation of an ambiguous statute. *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). HHS is generally entitled to *Chevron* deference on judicial review of its interpretations of the Medicare statute. *See Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 414, 113 S.Ct. 2151, 124 L.Ed.2d 368 (1993); *Baystate Franklin Med. Ctr. v. Azar*, 950 F.3d 84, 92 (D.C. Cir. 2020). The Hospitals urge us not to apply *Chevron* in this case for several reasons, none of which is persuasive.

First, we disagree that HHS forfeited any right to *Chevron* deference. To the contrary, HHS explained in the district court why its interpretation was entitled to *Chevron* treatment, invoked the doctrine twice in its opening brief in our court, and argued for it again in its reply brief. And in any event, our decisions hold that *Chevron* deference is not subject to forfeiture based on an agency's litigation conduct if the agency's challenged action "interpret[ed] a statute it is charged with administering in a manner (and through a process) evincing an exercise of its lawmaking authority." *SoundExchange, Inc. v.*

Copyright Royalty Bd., 904 F.3d 41, 54 (D.C. Cir. 2018). That is the case here. *See* 83 Fed. Reg. at 59,009, 59,011.

Second, the Hospitals contend that HHS's interpretation of subparagraph (2)(F) in the challenged rule is inconsistent with earlier agency pronouncements, such that the rule is arbitrary and unworthy of *Chevron* deference. *See Encino Motorcars, LLC v. Navarro*, —— U.S. ——, 136 S. Ct. 2117, 2126, 195 L.Ed.2d 382 (2016). But HHS has never taken a definitive position on the scope of subparagraph (2)(F). The Hospitals point to one sentence in the agency's first OPPS rulemaking cautioning that "[a]dditional study, analysis, and possible legislative modification would be necessary before [the agency] could consider implementing" a volume-control method involving direct changes to reimbursement. Medicare Program; Prospective Payment System for Hospital Outpatient Services, 63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998). Even assuming that statement amounted to an announcement of agency policy, which is far from clear, its meaning is ambiguous. As the district court concluded in its decision, the agency might well have thought that a "possible legislative modification would be necessary" because its proposed volume-control method would have required amending a separate statutory formula pertaining to its proposal, not because it believed that direct rate changes could never qualify as a "method for controlling" volume under (2)(F). *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 157 n.8.

Nor, contrary to the Hospitals' contention, has HHS long viewed subparagraph (2)(F) to require volume-control methods to be budget-neutral. It is true that the agency previously implemented a volume-control method called "packaging," which bundles related services together into a single payment group, in a budget-neutral manner. *See* Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, 72 Fed. Reg. 66,580, 66,615 (Nov. 27, 2007). That example, though, does not establish that HHS viewed (2)(F) as requiring budget-neutrality. The agency implemented "packaging" via other statutory authorities, including its power to alter the composition of APC groups and their scaled weights. *See id.* at 66,611, 66,615; 42 U.S.C. § 1395*l*(t)(2)(B)–(C), (t)(9)(A). Those adjustment authorities require budget-neutrality. *See* 42 U.S.C. § 1395*l*(t)(9)(B). HHS implemented packaging in a budget-neutral way not because it was a (2)(F) method, but because it involved other statutory adjustments that call for budget-neutrality. *See* 72 Fed. Reg. at 66,615 (budget-neutrality implicated because of "changes in APC weights and codes" and resulting "shifts in median costs" of those APCs).

Finally, we reject the Hospitals' argument that *Chevron* does not apply when, as here, our consideration of the agency's statutory authority merges with our consideration of the applicability of a preclusion provision. *See* Part II, *supra*. That result would mean that Congress's decision to enact a preclusion provision operated to enhance judicial scrutiny and restrict the agency's leeway. In

precluding judicial review of certain HHS actions, though, Congress necessarily intended the opposite outcome. *See Amgen*, 357 F.3d at 112 (noting "havoc that piecemeal [judicial] review of OPPS payments could bring about").

B.

Having rejected the Hospitals' arguments against applying *Chevron*, we proceed to review HHS's interpretation of subparagraph 1395*l*(t)(2)(F) under *Chevron's* two-step framework. We first ask whether "Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842, 104 S.Ct. 2778. If so, our work is done, for we "must give effect to the unambiguously expressed intent of Congress." *Id.* at 843, 104 S.Ct. 2778. But if the statute is "silent or ambiguous with respect to th[at] specific issue," *id.*, we assume "Congress has empowered the agency to resolve the ambiguity," and we defer to the agency's interpretation as long as it is reasonable. *Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 315, 134 S.Ct. 2427, 189 L.Ed.2d 372 (2014).

The question at issue is whether HHS may reduce the OPPS reimbursement for a specific service, and may implement that cut in a non-budget-neutral manner, as a "method for controlling unnecessary increases in the volume of" the service. 42 U.S.C. § 1395*l*(t)(2)(F). In our view, Congress did not "unambiguously forbid" the agency from doing so. *Barnhart v. Walton*, 535 U.S. 212, 218, 122 S.Ct. 1265, 152 L.Ed.2d 330 (2002); *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1125 (D.C. Cir. 2013). We further conclude that the agency reasonably read

subparagraph (2)(F) to allow a service-specific, non-budget-neutral reimbursement cut in the circumstances we consider here. We therefore hold that the agency acted within its statutory authority.

1.

At step one of *Chevron*, "the court begins with the text, and employs 'traditional tools of statutory construction' to determine whether Congress has spoken directly to the issue." *Prime Time Intern. Co v. Vilsack*, 599 F.3d 678, 683 (D.C. Cir. 2010) (quoting *Chevron*, 467 U.S. at 842–43 & n.9, 104 S.Ct. 2778). Applying those tools, we conclude that the OPPS statute does not directly foreclose HHS's challenged rate reduction.

To begin with, a service-specific, non-budget-neutral rate reduction falls comfortably within the plain text of subparagraph (2)(F). Reducing the payment rate for a particular OPPS service readily qualifies, in common parlance, as a "method for controlling unnecessary increases in the volume" of that service. The lower the reimbursement rate for a service, the less the incentive to provide it, all else being equal. Reducing the reimbursement rate thus is naturally suited to addressing unnecessary increases in the overall volume of a service provided by hospitals. As for whether a rate reduction under subparagraph (2)(F) can be non-budget-neutral, the provision simply says nothing about budget-neutrality. The text Congress enacted thus lends considerable support to the agency's reading of the statute at *Chevron* step one. *See Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 4 (D.C. Cir. 1999) (because operative "language d[id]

not preclude the [agency's] interpretation," the contrary "inference petitioner would draw as to the statute's meaning [was] not inevitable").

The broader statutory context bolsters the agency's view that subparagraph (2)(F) authorizes service-specific rate cuts. Under our decision in *Amgen*, the agency can alter the reimbursement rate for a particular service under its subparagraph (2)(E) authority to make "adjustments [it] determine[s] to be necessary to ensure equitable payments," 42 U.S.C. § 1395*l*(t)(2)(E); *see* 357 F.3d at 117 (upholding use of equitable-adjustment authority to change "payment amount for a single drug"). If the agency can adjust payment rates in furtherance of the expansive purpose of achieving equitable payments, it stands to reason that the agency can also adjust rates to accomplish the more focused goal of controlling unnecessary volume growth. Indeed, as the *Amgen* court saw it, HHS's robust "discretion" to adjust payment rates is a central feature of the statutory scheme. 357 F.3d at 114 (quoting H.R. Rep. No. 105-149, at 1323 (1997) and H.R. Conf. Rep. No. 105-217, at 785 (1997)).

The statutory context also supports construing subparagraph (2)(F) to allow non-budget-neutral adjustments. If the statute otherwise permits the agency to make a discretionary rate reduction as a method of volume control, it would be anomalous for the law to require the rate cut to be implemented budget-neutrally. That would require HHS to redistribute the costs traceable to the provision of unnecessary services throughout the OPPS, resulting in no net savings to Medicare and largely negating the

point of reducing reimbursement in the first place. *See* 83 Fed. Reg. at 37,142–43.

The Hospitals warn that, on that reading, nothing "prevents [HHS] from engaging in cost-control measures that will disproportionately affect only some service providers and beneficiaries." Hospitals Br. 7. But budget-neutrality offers little protection against such outcomes. If HHS reduces reimbursements for cardiac catheterizations and then redistributes the savings across the OPPS, that still hurts cardiologists much more than orthopedists even if cardiologists would get some money back in the form of slightly elevated reimbursements for other services they provide. The agency's ability to advance Congress's apparent goals in both budget-neutrality and subparagraph (2)(F)—namely, keeping growth in overall OPPS expenditures modest and predictable year to year, *see generally supra* pp. 5–6—would be undermined, not advanced, by requiring the savings from (2)(F) volume-control methods to be redistributed across the OPPS.

The Hospitals also contend that, budget-neutrality aside, subparagraph (2)(F) unambiguously does not encompass service-specific rate adjustments. The Hospitals argue in that regard that subparagraph (2)(F) does no more than enable the agency to develop an "analytical mechanism for determining whether there is an unnecessary increase in volume." Hospitals Br. 31 (formatting modified). That argument rests on reading subparagraph (2)(F) in conjunction with subparagraph (9)(C), which provides that:

> If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

42 U.S.C. § 1395*l*(t)(9)(C).

According to the Hospitals, subparagraph (9)(C) is the exclusive way for HHS to implement subparagraph (2)(F). On that understanding, (2)(F) empowers the agency to "develop a method" for diagnosing whether there has been too much growth in outpatient service volume, and if the agency decides there has, then it can respond by—and only by—using its (9)(C) authority to reduce the across-the-board conversion factor. (Recall that the conversion factor is the number by which relative payment weights for services are translated into actual reimbursement amounts. *See supra* pp. 4–5.) Subparagraph (2)(F), under the Hospitals' argument, does not itself authorize the agency to act on an unnecessary increase in volume upon finding that one exists, much less to do so on a service-specific basis. Rather, the agency can act only by reducing the overall conversion factor under (9)(C).

That interpretation of subparagraph (2)(F) is difficult to square with the provision's language. Subparagraph (2)(F) directs the agency to develop "a method for *controlling* unnecessary increases" in volume, not just a method for *assessing* whether

unnecessary increases exist. And we think it unlikely that Congress would have confined the agency's volume-control arsenal to the very blunt instrument of reducing the across-the-board conversion factor. The Hospitals identify no reason to suppose that Congress would have been concerned only about *overall* OPPS volume growth, which the conversion factor can suitably address, but not about unwarranted growth in the volume of a single service, which the conversion factor cannot. Cutting the conversion factor would reduce reimbursement equally for every OPPS service, a poorly tailored, ineffectual "method" of controlling undesirable volume growth in a specific service.

The Hospitals respond that HHS's reading of (2)(F) renders subparagraph (9)(C) redundant, because cutting the conversion factor fits textually as a "method for controlling" unnecessary volume. We do not see the redundancy. Subparagraph (9)(C) appears to come into play only after the agency first attempts to address unnecessary volume increases through methodologies implemented under subparagraph (2)(F): "If the Secretary determines under methodologies described in paragraph (2)(F) that" volume has "increased *beyond amounts established through those methodologies*, the Secretary may appropriately adjust the update to the conversion factor applicable in a *subsequent* year." 42 U.S.C. § 1395*l*(t)(9)(C) (emphases added). Because the (9)(C) authority thus kicks in only after the (2)(F) authority has been attempted and found inadequate, the former necessarily is not redundant of the latter.

At any rate, even if subparagraph (9)(C) did amount to surplusage under HHS's reading of (2)(F), that would not necessarily compel rejecting the agency's interpretation of (2)(F) at *Chevron* step one. "[A]t times Congress drafts provisions that appear duplicative of others—simply, in Macbeth's words, 'to make assurance double sure.'" *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 520 (D.C. Cir. 2016) (citation omitted)). There may have been particular reason for Congress to do so here. In specifying how HHS is to calculate the conversion factor, the statute envisions that the conversion factor will generally be "increased" each year, 42 U.S.C. § 1395*l*(t)(3)(C), (t)(3)(C)(ii). In that light, Congress could have thought it desirable to confirm the agency's power to *reduce* the conversion factor in response to volume growth, as subparagraph (9)(C) does.

Next, the Hospitals argue that subparagraph (2)(F)'s silence on budget-neutrality is itself evidence that Congress could not have intended the provision to allow direct rate adjustments. As noted, subparagraph (2)(F) does not address whether volume-control "method[s]" under that provision must be implemented in a budget-neutral fashion. Yet the OPPS statute nearly always specifies, one way or the other, whether a rate-adjustment authority must be exercised budget-neutrally. *See Am. Hosp. Ass'n*, 410 F. Supp. 3d at 159 (citing provisions). To the Hospitals, subparagraph (2)(F)'s comparative silence indicates that Congress did not intend the provision to authorize changes to payment rates.

But subparagraph (2)(F) undisputedly authorizes actions *other* than direct rate adjustments, and for at least some of those actions, a budget-neutrality requirement would make no sense. For example, the Hospitals do not dispute that subparagraph (2)(F) would allow HHS, as a volume-control method, to require additional paperwork from hospitals seeking reimbursement for certain outpatient procedures. That kind of volume-control method, of course, is insusceptible to a budget-neutrality mandate. Thus, (2)(F)'s silence on budget-neutrality tells us little about whether (2)(F) includes the authority to reduce a particular OPPS rate.

Lastly, the Hospitals make a similar argument based on paragraph 1395*l*(t)(4), which sets out how "[t]he amount of payment made from the Trust Fund under this part for a covered [outpatient] service . . . furnished in a year is determined." 42 U.S.C. § 1395*l*(t)(4). Paragraph (4) makes no mention of subparagraph (2)(F). But it expressly allows payment amounts to be "adjusted" under other provisions, such as subparagraphs (2)(D) and (2)(E), which authorize various adjustments including labor-cost adjustments and equitable adjustments. That, the Hospitals contend, is strong evidence that Congress did not intend direct modification of OPPS payment rates via subparagraph (2)(F).

Text and precedent, however, indicate that not all changes to OPPS rates must flow through paragraph (4). A number of provisions in the OPPS statute authorize HHS to set or adjust reimbursement rates for specific outpatient services but are unaddressed by paragraph (4). *See* 42 U.S.C. § 1395*l*(t)(14) (providing

separate formula for calculating "amount of payment under this subsection for a specified covered outpatient drug"); *id.* § 1395*l*(t)(15) (prescribing "amount [to be] provided for payment for [an ungrouped] drug or biological under this part"); *id.* § 1395*l*(t)(16)(D) (requiring payment reduction for a certain surgical procedure performed by certain hospitals); *id.* § 1395*l*(t)(16)(F)(i)–(ii) (requiring payment reductions for various imaging services); *id.* § 1395*l*(t)(22) (authorizing Secretary to make "revisions to payments" "made under this subsection for covered [outpatient] services" in order to decrease opioid prescriptions). Consequently, paragraph (4) is best understood to set out only the general mechanism—not the exclusive mechanism—by which specific OPPS rates for covered services are "determined."

Our decision in *Amgen* supports that understanding of paragraph (4). In that case, HHS used its equitable-adjustment authority under subparagraph (2)(E) to reduce a "transitional pass-through" payment for a drug to zero dollars. 357 F.3d at 107. The drug's manufacturer complained that HHS could not make that sort of equitable adjustment because paragraph (t)(6) lays out a specific formula for determining the "amount of the [transitional pass-through] payment." *See* 42 U.S.C. § 1395*l*(t)(6)(A), 1395*l*(t)(6)(D). *Amgen* rejected that argument, holding that (t)(6)'s seemingly "mandatory" provisions establish only "default OPPS rate calculations subject to later adjustment." 357 F.3d at 115. Under *Amgen*, then, although (t)(6) specifies in detail how pass-through payments must be calculated without mentioning subparagraph

(2)(E), the agency can nonetheless adjust the results of the (t)(6) formula using its (2)(E) authority. The same, we think, is true—or at least, not unambiguously untrue—of (t)(4) and (2)(F), respectively.

We thus conclude that the OPPS statute does not unambiguously foreclose HHS's adoption of a service-specific, non-budget-neutral rate cut as a "method for controlling unnecessary increases in" volume. 42 U.S.C. § 1395*l*(t)(2)(F). The statute is at least ambiguous as to whether that sort of rate adjustment lies within the agency's (2)(F) authority.

2.

At *Chevron* step two, we ask whether the agency's interpretation "is based on a permissible construction of the statute." *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1128 (D.C. Cir. 2013) (quoting *Chevron*, 467 U.S. at 843, 104 S.Ct. 2778). "A 'reasonable' explanation of how an agency's interpretation serves the statute's objectives is the stuff of which a 'permissible' construction is made." *Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 151 (D.C. Cir. 2005) (citation omitted).

The challenged rule meets that standard. The agency explained that recent growth in the volume of E&M services provided at off-campus PBDs was "unnecessary because it appears to have been incentivized by the difference in payment for each setting rather than patient acuity." 83 Fed. Reg. at 59,007. The agency further concluded that reducing payments in order to eliminate that incentive "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 59,009.

That interpretation of subparagraph (2)(F) is both "textually defensible" and "fits 'the design of the statute as a whole and . . . its object and policy.'" *Good Samaritan Hosp.*, 508 U.S. at 418, 419, 113 S.Ct. 2151 (quoting *Crandon v. United States*, 494 U.S. 152, 158, 110 S.Ct. 997, 108 L.Ed.2d 132 (1990)). It is reasonable to think that Congress, which cared enough about unnecessary volume to instruct the agency to "develop a method for controlling" it, would have wanted the agency to avoid causing unnecessary volume growth with its own reimbursement practices. We thus defer to the agency's conclusion that (2)(F) allowed it to address that problem by reducing a specific rate.

Sustaining HHS's challenged reduction in this case would not necessarily leave the agency free "to set any payment rate for any service, without regard to the fine-grained statutory scheme enacted by Congress." Hospitals Br. 45. It is one thing for HHS to use its subparagraph (2)(F) authority to eliminate a volume-growth incentive created, in the agency's view, by a differential in its own payment rates. It may be another thing for the agency to reduce payment for a service under (2)(F) merely because doing so would decrease volume that HHS decides is "unnecessary." We have no occasion to decide whether an action of that kind would rest on a reasonable interpretation of the OPPS statute. *Cf. Nat. Res. Def. Council v. EPA.*, 777 F.3d 456, 469 (D.C. Cir. 2014) (agency's interpretation cannot be "untethered to Congress's

approach" at *Chevron* step two); *Amgen*, 357 F.3d at 117 (equitable adjustments may not "work basic and fundamental changes in the scheme Congress created in the Medicare Act" (quotation omitted)).

In short, we conclude under *Chevron* that HHS's reduction in reimbursement for E&M services provided by off-campus PBDs qualifies as a "method for controlling unnecessary increases in the volume of covered [outpatient] services." 42 U.S.C. § 1395*l*(t)(2)(F). Because the challenged rate cut is thus a "method[] described in paragraph (2)(F)," judicial review of that action is precluded by the statute. *See id.* § 1395*l*(t)(12)(A). Consequently, neither we nor the district court has jurisdiction over the Hospitals' challenge.

IV.

The Hospitals argue in the alternative that HHS's decision to reduce E&M reimbursement to off-campus PBDs contravenes section 603 of the Bipartisan Budget Act of 2015. As explained, Congress enacted that provision in response to reports that the payment differential between off-campus PBDs and freestanding physician practices had induced hospitals to purchase those practices. Section 603 established that services performed at off-campus PBDs would no longer be paid under the OPPS but instead would be paid under a scheme approximating the Physician Fee Schedule. *See* 42 U.S.C. § 1395*l*(t)(1)(B)(v), 1395*l*(t)(21)(C). But the law exempted "department[s] of a provider . . . that [furnished covered outpatient services] prior to November 2, 2015." *Id.* § 1395*l*(t)(21)(B)(ii). In the

Hospitals' view, Congress's decision to leave the rates paid to preexisting off-campus PBDs unaddressed in section 603 means that the statute should be read to bar HHS from cutting reimbursement rates for those facilities.

Because the Hospitals' section 603 argument targets agency action we have already determined qualifies as a "method[] described in paragraph (2)(F)," we are doubtful we have jurisdiction to consider it. *See id.* § 1395*l*(t)(12)(A). In any event, we reject the argument on the merits. (The law of our circuit allows a court to assume hypothetical *statutory* jurisdiction even if we cannot assume Article III jurisdiction. *See Kramer v. Gates*, 481 F.3d 788, 791 (D.C. Cir. 2007).) Nothing in the text of section 603 indicates that preexisting off-campus PBDs are forever exempt from adjustments to their reimbursement. Rather, the text of the law exempts those providers from the change mandated by section 603 itself, leaving the exempted providers subject to all the provisions of the OPPS statute, including subparagraph (2)(F). It bears noting, moreover, that section 603's exemption of preexisting off-campus PBDs from the reimbursement reductions effected by that statute retains practical effect for all OPPS services except the one type of service (E&M services) addressed by the challenged rule.

Trying a different approach, the Hospitals contend that section 603 demonstrates Congress's judgment that increases in volume at preexisting off-campus PBDs are not "unnecessary" in the sense contemplated by subparagraph (2)(F). But even assuming that were true for increases in volume

occurring by 2015, when section 603 was enacted, it would not mean that Congress considered acceptable the continued volume increases later taking place in 2016, 2017, or 2018, on which HHS relied in adopting the challenged rule. *See* 83 Fed. Reg. at 37,139; MedPAC, *Report to the Congress: Medicare Payment Policy* 73 (Mar. 2018), https://go.usa.gov/xdCzu. Section 603 thus does not stand in the way of the agency's challenged rate reduction under (2)(F).

* * * * *

For the foregoing reasons, we reverse the judgment of the district court.

So ordered.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
Plaintiffs,

v.

ALEX M. AZAR II, SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendant.

Civil Action No. 18-2841 (RMC)

Signed 09/17/2019

MEMORANDUM OPINION

ROSEMARY M. COLLYER, United States District Judge

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

[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.

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 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

---

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

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

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-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

---

[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").

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 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, 106 S.Ct. 2505, 91 L.Ed.2d 202 (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 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

---

[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.

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, 106 S.Ct. 2333, 90 L.Ed.2d 921 (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, 104 S.Ct. 2778, 81 L.Ed.2d 694 (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, 104 S.Ct. 2778. 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, 104 S.Ct. 2778. 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, 104 S.Ct. 2778). 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, 131 S.Ct. 871, 178 L.Ed.2d 716 (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, 104 S.Ct. 2778; *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, 121 S.Ct. 2164, 150 L.Ed.2d 292 (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, 125 S.Ct. 2688, 162 L.Ed.2d 820 (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, 114 S.Ct. 2381, 129 L.Ed.2d 405 (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.

---

[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.

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 Corp. 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).*

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, 104 S.Ct. 2450, 81 L.Ed.2d 270 (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

[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 Lutherans 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.

exhaustion should be waived because further administrative review would be futile.

"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, 95 S.Ct. 2457, 45 L.Ed.2d 522 (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 62, 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. v. EPA*, 573 U.S. 302, 321, 134 S.Ct. 2427, 189 L.Ed.2d 372 (2014) (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341, 117 S.Ct. 843, 136 L.Ed.2d 808 (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, 108 S.Ct. 626, 98 L.Ed.2d 740 (1988)); *see also King v. Burwell*, —— U.S. ——, 135 S. Ct. 2480, 2483, 192 L.Ed.2d 483 (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, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000)); *see also Util. Air Regulatory Grp.*, 573 U.S. at 320, 134 S.Ct. 2427. 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, 134 S.Ct. 2427. ("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.

---

[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).

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 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, 121 S.Ct. 903, 149 L.Ed.2d 1 (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.*

---

[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?

§ 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 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

---

[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.

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 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 preset 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, 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

[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.

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.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 19-5352

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
Appellees

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES,
Appellant

Consolidated with 19-5353, 19-5354

September Term, 2020

1:18-cv-02841-RMC

Filed On: October 16, 2020

BEFORE: Srinivasan, Chief Judge; and Henderson, Rogers, Tatel, Garland, Millett, Pillard, Wilkins, Katsas, Rao*, and Walker, Circuit Judges.

* Circuit Judge Rao did not participate in this matter.

O R D E R

Upon consideration of appellees' petition for rehearing en banc, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Michael C. McGrail
Deputy Clerk

APPENDIX D

STATUTORY PROVISIONS INVOLVED

1. **42 U.S.C. § 1395*l* provides in pertinent part:**

* * * * *

(t) Prospective payment system for hospital outpatient department services

* * * * *

(2) System requirements

Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), 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;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional passthrough payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

* * * * *

(12) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395*oo* 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);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

* * * * *