UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:19-cv-00132-RMC
ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services,	)	Oral Argument Requested
Defendant.	)	

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

When it considered Section 603 of the Bipartisan Budget Act of 2015, Congress was faced with competing concerns. On the one hand, many hospitals bring needed hospital services to their communities through off-campus hospital departments. These facilities provide valuable services that would not otherwise be available for vulnerable patient populations; for example, off-campus hospital departments typically operate for longer hours, and provide a broader array of services, than freestanding physicians' offices do. Hospitals also treat costlier Medicare, Medicaid and uninsured patients, while many physician practices self-select less costly patients with private insurance. Moreover, off-campus hospital departments incur higher operating costs than freestanding physicians' offices, because these facilities are subject to the regulatory and licensure requirements that apply to hospitals; physicians' offices are not. In recognition of the value of these services and their higher costs, the Medicare program has historically paid for outpatient services performed at off-campus hospital departments at the rate specified under the Outpatient Prospective Payment System (OPPS).

One the other hand, because freestanding physicians' offices are paid at lower rates under a different Medicare fee schedule, some commenters have raised concerns that the payment differential gives hospitals the incentive to buy physicians' offices and to convert them into off-campus hospital departments simply to obtain higher payment rates. When a payment policy creates both beneficial and unwanted behavior, it is up to Congress to make the call. And Congress did just that by carefully balancing both of these competing concerns when it enacted Section 603. As to new off-campus hospital departments, Congress provided that the lower payment rate would apply, so as to counter the incentive for new acquisitions of physicians' offices. But Congress also understood that it was preserving OPPS payment rates for existing facilities, in order to protect the Medicare beneficiaries who have come to rely on those facilities for their medical services.

Congress underscored this balance the following year when it enacted the 21st Century Cures Act, which confirmed this difference in treatment between existing and new off-campus hospital departments.

The Secretary does not like how Congress made the call. He now seeks to erase the line that Congress drew, cutting payment rates for evaluation and management (E/M) services performed at existing off-campus hospital departments by 60% over two years so that the same rate would apply for those services at old and new facilities. None of the Secretary's explanations for his Final Rule, in the Federal Register, or in his brief in this Court, suffices to justify his departure from the statute. The Secretary, first, attempts to discount Congress's careful compromise in Section 603 as mere "legislative silence" that he is free to disregard. He ignores, however, that Congress has legislated twice on this topic, and that Congress explicitly based its second enactment, the 21st Century Cures Act, on the premise that OPPS payment rates would be preserved for existing off-campus hospital departments.

The Secretary, next, attempts to invoke his authority under the OPPS statute to develop a "method" to control "unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395*l*(t)(2)(F). That authority, however, has nothing whatsoever to do with the calculation of payment rates for any one particular outpatient service. That calculation is governed instead by Section (t)(4) of the OPPS statute, 42 U.S.C. § 1395*l*(t)(4), which requires that the payment for any one service "is determined … as follows" in that paragraph. The paragraph goes on to describe a nested series of internal cross-references within the OPPS statute, in which Section (t)(2)(F) plays no role. The Secretary's attempt to treat his authority to develop "methods" as carte blanche to tinker with payment rates for particular services, then, cannot be squared with the actual statute that Congress wrote.

Even if a payment adjustment were otherwise a "method" within the meaning of Section (t)(2)(F), the Secretary still could only invoke that provision to address "unnecessary" increases in the volume of outpatient services. But Congress has expressed its views, quite recently, as to the propriety of services performed at existing off-campus hospital departments, and specifically chose to preserve OPPS payment rates for those services. Here, as in *Hays v. Sebelius*, 589 F.3d 1279, 1282 (D.C. Cir. 2009), the Secretary may not rely on a generally-worded authority to address "necessary" or "unnecessary" services to override Congress's judgment on this score. What is more, the Secretary plainly misread Section (t)(2)(F) to authorize him to address increases in costs; that statute refers only to increases in volume, but the Secretary, by his own telling, issued his Final Rule with the hope that the same volume of services would be performed at lower costs.

At all events, perhaps the Secretary's most glaring error was his decision to issue his Final Rule without making an offsetting budget-neutrality calculation. The OPPS statute is quite explicit that any adjustment to payment amounts must be performed in a budget-neutral fashion. The Secretary's only explanation for his departure from this rule is that he chose to describe his payment cut as a "method," not as an "adjustment." The Secretary may not so easily avoid his statutory constraints simply by a choice of nomenclature.

The Secretary's Final Rule is contrary to the statutory scheme that Congress has designed. The Rule is *ultra vires*, and should be vacated.

ARGUMENT

I. This Court Has Jurisdiction to Review the Legality of the OPPS Rule

A. The OPPS Rule is *Ultra Vires*

"There is a strong presumption that Congress intends judicial review of administrative action." *Amgen, Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004) (internal quotation omitted). This presumption applies with particular force in favor of "judicial review of agency action taken

in excess of delegated authority." *Id*. at 111–12. In light of this presumption, a statute that precludes the review of particular agency actions "does not repeal the review of *ultra vires* actions." *Aid Ass'n for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1173 (D.C. Cir. 2003).

The Secretary invokes 42 U.S.C. § 1395*l*(t)(12)(A), which precludes administrative or judicial review of a variety of the agency's determinations under the OPPS system, including "the development … of … methods described in paragraph (2)(F)." But as the D.C. Circuit recognized when the Secretary cited the same statute to block review of an exercise of his adjustment authority, Section (t)(12)(A) prevents "review only of those 'other adjustments' that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of 'other adjustments' extends no further than the Secretary's statutory authority to make them." *Amgen*, 357 F.3d at 112. Section (t)(12)(A), then, "merges consideration of the legality of the [Secretary's] action with consideration of this court's jurisdiction." *COMSAT Corp. v. FCC*, 114 F.3d 223, 227 (D.C. Cir. 1997).[1] For the reasons explained below, the Secretary lacked the authority under the OPPS system to adopt a "method" that overrides Congress's judgment, or that targets one particular medical service that he disfavors for a payment cut. This Court has jurisdiction to hear this challenge.

B. Exhaustion Is Not Required for this Purely Legal Challenge

The Secretary also asserts that this Court lacks jurisdiction under 42 U.S.C. § 405(g). In the ordinary case, Section 405(g) would require the channeling of a claim under the Medicare statute through the agency's process for administrative review. *See* 42 U.S.C. §§ 405(g), (h),

[1] Whether review of *ultra vires* agency action is distinct from *Chevron* review raises "questions [that] are abstractly interesting, but ultimately unimportant in the resolution of this matter." *Aid Ass'n for Lutherans*, 321 F.3d at 1174. Because both doctrines focus on the limits of the authority that Congress has delegated to an agency, the scope of *ultra vires* review "is in all important respects perfectly consistent with *Chevron* and *Mead*." *Id.* (citing *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984), and *United States v. Mead Corp.*, 533 U.S. 218 (2001)).

1395ii; *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 17 (2000). There are two elements to this channeling requirement. "First, the plaintiff must have presented the claim to the Secretary; this requirement is not waivable, because without presentment, there can be no decision of any type, which § 405(g) clearly requires." *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018) (internal quotations omitted). "Second, the plaintiff must fully exhaust all available administrative remedies, though this more demanding requirement is waivable." *Id*. at 826. The Secretary does not dispute that the Plaintiff Hospitals have presented their claims to the agency. *See* ECF No. 7-5 (Declaration of Daniel W. Peters), ¶ 11 & Att. A.

The Secretary instead faults the Plaintiff Hospitals for not pursuing those administrative claims to their inevitable conclusion within the agency. But the Secretary's administrative adjudicators are bound by his regulations, *see* 42 C.F.R. § 405.1063, and thus could not grant the Plaintiff Hospitals the relief that is sought here—vacatur of the Final Rule. What is more, those adjudicators could not even accept the Plaintiff Hospitals' claims for a hearing, as Section (t)(12)(A) precludes "administrative or judicial review" of methods that the Secretary develops under Section (t)(2)(F), and the adjudicators would be bound by his reasoning that the payment cuts falls within his "methods" authority. 42 U.S.C. § 1395*l*(t)(12)(A); 42 C.F.R. § 419.60(a)(4). Here, as in *Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992), "it seems wholly formalistic not to regard further appeals as completely futile." *See also Hall v. Sebelius*, 689 F. Supp. 2d 10, 23–24 (D.D.C. 2009) (exhaustion is futile "where the agency has indicated it does not have jurisdiction over the dispute" (internal quotation omitted)).[2]

[2] Indeed, the Secretary's contractors have already begun to inform hospitals that they will not accept requests for redetermination that challenge the Final Rule at issue here. "[R]edeterminations **are not** available for review of the payment rates or reductions in payment rates under OPPS. If redeterminations are received for this purpose, the request will be dismissed." First Cost Service Options, Inc., *Redeterminations for HCPCS G0463 paid under OPPS* (Apr. 2,

The Secretary offers no reason to doubt the futility of further administrative proceedings. He does not contend that delay is needed for "the agency's efficient functioning," *Tataranowicz*, 959 F.2d at 275; to the contrary, the sooner that the correct OPPS payment rules are established, the better for all interested parties, the Secretary included. Nor does he contend that waiving exhaustion would "thwart any effort at self-correction," *id.*; he has been clear that he will not alter his rule unless he is ordered to do so. There is no reason to hold administrative hearings to gain "the benefit of the agency's experience or expertise," *id.*; the Secretary has already fully explained his reasoning in the Federal Register. And waiver of exhaustion would not "curtail development of a record useful for judicial review," *id.*; the Plaintiff Hospitals raise a purely legal challenge to the Final Rule.

Further exhaustion would be particularly pointless given the stakes here. Off-campus hospital departments provide important services to the public that are not offered by freestanding physician's offices, such as extended hours for urgent care services. For example, plaintiff Sarasota Memorial Hospital's off-campus hospital departments performs many of its services for patients who were referred to those facilities by independent physicians that do not offer necessary services like on-site laboratory, imaging, or surgical services. *See* ECF No. 7-5 (comment letter of Sarasota Memorial Hospital) at 2–3. No purpose would be served by requiring further exhaustion within the agency, then, other than to continue to jeopardize the ability of the Plaintiff Hospitals to provide needed services to their communities. *See, e.g.*, ECF No. 7-5 (Peters Decl.),

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2019), https://medicare.fcso.com/Appeals/0432991.asp (emphasis in original). *See also* Noridian Healthcare Solution, Jurisdiction E, *G0463 Has No Appeal Rights* (Mar. 22, 2019), https://med.noridianmedicare.com/web/jea/article-detail/-/view/10521/g0463-has-no-appeal-rights ("CMS has provided direction to the Medicare Administrative Contractors (MACs) to dismiss requests appealing the reimbursement of HCPS G0463. No further appeal rights will be granted at subsequent levels due to the statutory guidance supporting the pricing of this HCPCS code.").

¶ 7. All of the relevant factors point in favor of waiving further exhaustion. *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).

II. Congress Unambiguously Provided that Excepted Off-Campus Hospital Departments Must Be Paid at OPPS Rates

To hear the Secretary tell the tale, Congress inexplicably dropped the ball when it enacted Section 603. The cost of services performed at off-campus hospital outpatient departments had been skyrocketing for years; the Secretary, MedPAC, and others had repeatedly urged Congress to fix the problem; yet, for some unknowable reason, Congress fell short of the mark by lowering the payment rate for outpatient services only for newly-constructed off-campus facilities. *See* Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 598 (2015).

It is true that Congress was concerned about the incentives that hospitals may have to purchase freestanding physician's offices, and so it tailored its remedy to target that particular problem by adjusting the payment rates for newly-acquired off-campus hospital departments. But that was not Congress's only concern. It also sought to preserve the critical services that patients, particularly those in underserved communities, have grown to rely upon from existing off-campus departments. The Secretary entirely ignores this other side of the coin.

The Plaintiff Hospitals have explained that off-campus hospital departments provide necessary medical services for their communities that would not otherwise be provided by independent physicians' offices, and have also explained how these facilities must meet more rigorous regulatory requirements, and thus must incur greater operating costs, than freestanding physician offices do. *See* Mem. in Supp. of Pls.' MSJ (ECF No. 7-1) at 5–6. The Secretary agrees, or at least he used to. *See* 73 Fed. Reg. 66,187, 66,191 (Nov. 7, 2008) (noting the "high facility

overhead expenses that are associated with the delivery of services unique to an outpatient hospital or a department of an outpatient hospital").

Though hospital departments and physician offices both bill using the E/M code, they often offer vastly different services to their patients during an E/M visit. *See* ECF No. 7-5 (comment letter of Sarasota Memorial Hospital) at 3. The Secretary's attempt to treat E/M services performed at either location as the same thing is no more persuasive than the suggestion that a Ford Pinto is the same as a Ford Mustang. When it considered Section 603, however, Congress recognized that hospitals provide superior care and that off-campus hospital departments provide services that are not otherwise available in the community for vulnerable populations. *See Hearing with MedPAC to Discuss Hospital Payment Issues, Rural Health Issues, and Beneficiary Access to Care: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 114th Cong. 38 (2015) (statement of the Am. Hosp. Ass'n). Congress was also aware that, in light of the greater costs that these facilities incur, an across-the-board cut to payment rates for existing off-campus facilities could "result in the closure of some [existing PBDs] and the reduction of services in others, greatly affecting the vulnerable populations—especially those with complex medical problems—that receive care there, and limiting the ability to train the next generation of health professionals in these outpatient settings." Letter from Atul Grover, Chief Pub. Policy Officer, Ass'n of American Medical Colleges, to the Honorable John Barrasso, et al. (Jan. 13, 2012) https://www.aamc.org/download/271334/data/aamccommentletteronproposedhopdcuts.pdf.

The Secretary fails even to acknowledge these reliance interests, discussing only his cost concern as if that were the only relevant factor in Congress's choice of reimbursement rates. Unlike the Secretary, Congress did not have the luxury of focusing exclusively on one side of the scale (*i.e.*, the increased costs associated with off-campus departments) while ignoring altogether

the other side (*i.e.*, the unique and important benefits these facilities offer to patients). Rather, Congress sought to balance these interests by addressing the incentive to purchase physician offices by cutting OPPS payments for new off-campus PBDs while also preserving these higher payments for already operating off-campus PBDs. *See* 83 Fed. Reg. 58,818, 59,023 (Nov. 21, 2018) ("we believe the section 603 amendments to section 1833(t) of the Act are intended to prevent" the payment of OPPS rates for services at "newly purchased physician practices," so as to counter the trend favoring the "acquisition of standalone or independent practices and facilities by hospitals").

The Secretary now dismisses Congress's concern for preserving services for vulnerable populations as "vastly overstat[ing] what Congress actually did," Def.'s Mem. in Opp. to Pls.' MSJ (ECF No. 17-1) at 18, but the text and structure of the statute, as well as the prevailing policy debate at the time, all reinforce the conclusion that Congress took pains to strike a balance, targeting what it saw as hospitals' incentive to purchase new physicians' offices, while at the same time protecting the reliance interests of hospitals and beneficiaries who have relied on existing facilities for their medical services.

The Secretary, moreover, ignores that Congress has legislated *twice* on this issue. The same Congress that enacted Section 603 also enacted the 21st Century Cures Act, Pub. L. No. 114-255, § 16001, 130 Stat. 1033, 1324 (2016)—a statute that goes entirely uncited in the Secretary's brief. Congress was concerned that the Secretary had been undermining the careful balance it had drawn in Section 603 by denying OPPS payment rates for off-campus departments that were being built at the time that Section 603 was enacted. Congress accordingly enacted 21st Century Cures to clarify that these "mid-build" departments would receive the same OPPS rates that existing off-campus departments were entitled to receive. In so doing, Congress explained its understanding

of its prior year's enactment, explaining that Section 603 has "effectively grandfathered any off-campus PBD [hospital outpatient department] that was billing outpatient services before [the] date of [its] enactment." H.R. Rep. No. 114-604, at 10 (2016). Based on this understanding of Section 603, Congress explained that its new enactment would guarantee that existing "[o]ff-campus facilities … continue to receive the higher payment rates that apply to an outpatient department on the campus of a hospital." *Id.* at 20. Congress, in other words, did not leave the treatment of existing off-campus hospital departments to the Secretary's discretion, but instead explicitly assured that OPPS payments for those facilities would be protected. *See Nat'l R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 419 (1992) (subsequent amendments "confirm[ed]" the statute's meaning); *see also EEOC v. Blinded Veterans Ass'n*, 128 F. Supp. 3d 33, 40 (D.D.C. 2015).

The Secretary attempts to discount all of the foregoing by characterizing the Plaintiff Hospitals' argument as one falling under the *expressio unius* canon, which, he asserts, cannot override his reading of his own statutory authority. Def.'s Mem. in Opp'n to Pls.' MSJ (ECF No. 17-1) at 17 (citing *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014)). "This is not entirely correct." *Indep. Ins. Agents of Am., Inc. v. Hawke*, 211 F.3d 638, 644 (D.C. Cir. 2000). The canon, like any of the canons of statutory interpretation, does not automatically dictate a particular result one way or the other; instead, it must be examined together with "the text, structure, legislative history, and purpose of the statute." *Adirondack Med. Ctr. v. Sebelius*, 891 F. Supp. 2d 36, 47 (D.D.C. 2012), *aff'd*, 740 F.3d 692 (D.C. Cir. 2014).

That examination points in favor of confirming Congress's understanding that it was preserving OPPS payment rates for existing off-campus hospital departments. Congress was directly presented with proposals to cut payment rates for all such departments, but it made the

deliberate choice to target its remedy to address what it saw to be the problem, the incentive that hospitals would otherwise have going forward to purchase physician's offices. As to the proposals that it extend the statute to cut payment rates for existing facilities and new facilities alike, "Congress considered the unnamed possibility and meant to say no to it." *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003); *see also EchoStar Satellite L.L.C. v. FCC*, 704 F.3d 992, 999 (D.C. Cir. 2013).

This case, then, is the mirror image of *Adirondack*. That case involved, first, a broad grant of authority to the Secretary to adjust payment rates for the Inpatient Prospective Payment System (IPPS), and, second, a later-enacted provision granting the Secretary further adjustment authority in a more targeted manner. After examining the statute's text, structure, history, and purpose, the D.C. Circuit rejected the hospitals' argument that the second grant of authority somehow cabined the scope of the first grant, reasoning that it was likely that Congress meant instead "to clarify and complement the Secretary's existing authority—i.e., to make assurance double sure." 740 F.3d at 698 (internal quotation omitted).

This case, however, does not involve a second grant of authority on top of an existing grant of authority. Rather, the statute that Congress enacted in Section 603 and confirmed in the 21st Century Cures Act *limits* the discretion that the Secretary would otherwise enjoy with respect to payment rates for off-campus hospital departments. In a case like this, the more specific provision that limits the agency's discretion—Section 603—controls over any more general grant of discretionary authority in the OPPS statute. "It is a commonplace of statutory construction that the specific governs the general. That is particularly true where … Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (internal quotation

and citation omitted). This canon "is perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission." *Id.*

In sum, when it enacted Section 603 and when it refined that enactment the following year in 21st Century Cures, Congress crafted a careful compromise that addressed the "specific problem" that it saw "with specific solutions"—a targeted payment cut that applied only to newly-acquired off-campus hospital departments. Congress did not mean to leave the treatment of existing facilities to the Secretary's whims, but instead understood that it had preserved OPPS payment rates for those facilities, so as to ensure that vulnerable populations would continue to have access to the medical services that those facilities provide. The Secretary's contrary reading cannot be squared with the statute that Congress actually enacted in Section 603.

III. The Secretary's Targeted Payment Cut Is Not a "Method to Address Unnecessary Increases in the Volume of Covered OPD Services"

A. A Payment Cut Targeted to a Particular Outpatient Service Is Not a "Method" within the Meaning of Section (t)(2)(F)

In his attempt to override the payment rules that Congress established in Section 603 of the Balanced Budget Act, the Secretary relies on 42 U.S.C.§ 1395*l*(t)(2)(F), which authorizes him to "develop a method for controlling unnecessary increases in the volume of covered OPD services." He asserts that the Final Rule announces such a "method" by targeting the rate for one particular medical service—the rate for E/M services performed at excepted off-campus hospital departments—for a 60% cut. He can only attempt to justify his theory, however, by ignoring the actual language of Section (t)(2)(F), which refers to a method to address the volume of "covered OPD *services*," in the plural. That plural phrase is defined in the statute to mean the full basket of outpatient services that are paid for under the OPPS system. *See* 42 U.S.C. § 1395*l*(t)(1)(B); *cf. Digital Realty Tr., Inc. v. Somers*, 138 S. Ct. 767, 776–77 (2018) (courts must follow explicit statutory definitions). The Secretary repeatedly paraphrases Section (t)(2)(F), however, to suggest

that it grants him the authority to address the volume of any one covered OPD "service," in the singular. *Compare* 42 U.S.C. § 1395*l*(t)(2)(F) *with* ECF No. 17-1 at 3 ("an unnecessary increase in the volume of a covered OPD service").[3] His paraphrases do violence to the statute.

Section 1395*l*(t) draws a sharp delineation between: (1) the calculation of the total amount of funds available to pay for the entire basket of "covered OPD services" in a given year, and (2) the divvying up of those funds to determine how much is paid for any one particular "covered OPD service." The Secretary's "methods" authority plays a role only in the first calculation, not the second. As to the second calculation, Section (t)(4) specifies in precise detail which internally cross-referenced provisions in the OPPS statute go into the determination of the payment amount for any one individual service; the statutory scheme allows for adjustments to the payment amount under Section (t)(2)(D) and (t)(2)(E) (which must be budget-neutral), but makes no mention of any "methods" authority to adjust payment amounts under Section (t)(2)(F).

First, the total pool of money to be paid for all of the "covered OPD services" in the OPPS system is established by taking "the total amounts that would [have been] payable from the Trust Fund … for covered OPD services in 1999," 42 U.S.C. § 1395*l*(t)(3)(A), which figure is then used to calculate the "conversion factor," that is, a set dollar amount that is used as the basis for calculating payments for all of the covered OPD services, *id.* § 1395*l*(t)(3)(C). An "OPD fee schedule increase factor" is then applied to the conversion factor for each subsequent year that is equal to the "market basket percentage increase," *id.* § 1395*l*(t)(3)(C)(iv)—that is, "the pure price change of goods and services used by a provider in supplying [health care] services," *Banner*

[3] *See also* ECF No. 17-1 at 3 ("an unnecessary increase in the volume of an isolated type of service"); 17 ("volume of a specific OPD service"); 20 ("volume of a single covered OPD service"); 21 ("volume of a single, specific type of service" and "volume for a specific service"); 23 ("volume of a covered service").

Health v. Price, 867 F.3d 1323, 1354 (D.C. Cir. 2017), *cert. denied*, 138 S. Ct. 1318 (2018). That amount is then reduced by a statutorily-specified "productivity adjustment" or "other adjustment," 42 U.S.C. § 1395*l*(t)(3)(F), (G), to arrive at the conversion factor for a given year. Through this formula, the total amount of funds available to pay for all of the covered OPD services in a given year equals the amount available for the first year that the OPPS operated, increased each year by a factor that accounts for inflation, and decreased each year by a factor that represents improvements in productivity, or any other considerations that caused Congress to seek to reduce total OPPS payments.

This is where Section (t)(2)(F) enters the picture. As noted, it authorizes the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services." If the Secretary first develops such a method, but later finds that his method has not succeeded, then—and only then—he "may appropriately adjust the update to the conversion factor," but only for the factor "otherwise applicable in a subsequent year." 42 U.S.C. § 1395*l*(t)(9)(C). Because the conversion factor is a set dollar figure that applies to all of the services paid for under OPPS, this subsequent-year adjustment authority would affect payment rates in that later year for all covered OPD services equally.

Second, the statute sets forth a different formula for the calculation of individual payment amounts for any one covered OPD service. Section (t)(4) governs this calculation: "The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year *is determined*, subject to paragraph (7), *as follows*[.]" 42 U.S.C. § 1395*l*(t)(4) (emphasis added).[4] The amount of payment is determined, first, by finding

[4] The referenced paragraph, 42 U.S.C. § 1395*l*(t)(7), deals with transitional payments at the onset of the OPPS system, as well as payments for rural hospitals and cancer hospitals. It is not relevant here.

"[t]he medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year," *id.* § 1395*l*(t)(4)(A). The cross-referenced provision, Section (t)(3)(D), then leads to a series of further cross-referenced provisions that, together, result in the calculation of a "medicare OPD fee schedule amount for each covered OPD service" that is the product of the "conversion factor" described above and the "relative payment weight … for the service or group." 42 U.S.C. § 1395*l*(t)(3)(D).

Returning to Section (t)(4), this amount is then adjusted "for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E)." *Id.* § 1395*l*(t)(4)(A).[5] Section (t)(4), then, specifies the particular adjustments that the Secretary may apply to tinker with the amount of payment for any one covered OPD service—the wage, outlier, transitional pass-through, and "other" adjustments under Sections (t)(2)(D) and (t)(2)(E), each of which must be budget neutral. The Secretary's "methods" authority under Section (t)(2)(F) is not included in this list.

The Secretary's attempt to shoehorn Section (t)(2)(F) into this second formula, then, must be rejected. Congress laid out the structure of the OPPS statute in elaborate detail, "and relied on [that structure] to make precise cross-references." *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 938–39 (2017). *See also United States v. Brockamp*, 519 U.S. 347, 350 (1997) (the statute "sets forth its limitations in a highly detailed technical manner, that, linguistically speaking, cannot easily be read as containing implicit exceptions"). Congress specified that the payment amount for a particular service "is determined … as follows" in Section (t)(4) and in the particular provisions that Section (t)(4) cross-references, including the Secretary's budget-neutral "adjustment"

[5] That amount is then reduced to reflect a separate calculation of the amount of deductibles and co-payments for which the beneficiary is responsible, *id.* § 1395*l*(t)(4)(B), (C), resulting in a net amount that the Medicare Trust Fund will pay for the covered service.

authorities under Section (t)(2)(D) and (t)(2)(E), but excluding his "methods" authority under Section(t)(2)(F). That "methods" authority, then, plays no role in the calculation of any one particular covered OPD service; it only enters the equation if the Secretary elects to make an adjustment under Section (t)(9)(C) to the conversion factor that applies across the board to all covered OPD services. The Secretary is not at liberty to rewrite the statutory scheme to treat Section (t)(2)(F) as a free-floating "adjustment" authority.

B. The Secretary Cannot Override Congress's Judgment as to Which Outpatient Services Are "Necessary"

Even if the Secretary otherwise were empowered to use Section (t)(2)(F) to target payment rates for any one outpatient service, he still would only be able to do so upon a finding that there had been an "unnecessary increase" in the volume of the service. But, here, Congress has recently considered the issue, and has made its own determination as to whether services performed at off-campus hospital departments are necessary. The Secretary's theory that there has been an "unnecessary increase" in the volume of E/M services at off-campus hospital departments is explicitly premised on his disagreement with Congress's decision to continue to pay for those services at full OPPS rates. *See* 83 Fed. Reg. at 59,008 (because Section 603 pays existing hospital off-campus departments at OPPS rates, "[t]herefore, the current site-based payment creates an incentive for an unnecessary increase in the volume of this type of OPD service."). In short, the Secretary believes that Congress left the payment rate too high.

The Secretary may not use Section (t)(2)(F) to perform "an end-run around the statute" to set the payment rate he prefers. *Hays*, 589 F.3d at 1282. The OPPS statute, like the Part B drug statute at issue in *Hays*, establishes statutorily required payment rates. When faced with a payment request for these services, the Secretary's choice is "binary." *Id.* at 1283. He may decide not to cover the service because it is medically unnecessary, but if it is, he must reimburse at the

statutorily prescribed rates. It is "quite unlikely that Congress, having minutely detailed the reimbursement rates for covered items and services, intended that the Secretary could ignore these formulas whenever she determined that the expense of an item or service was not reasonable or necessary." *Id.* (internal quotation omitted).

The Secretary's only response on this point is to deny that this case is similar to *Hays* because Congress has not "minutely detailed the reimbursement rates" for outpatient services here. ECF No. 17-1 at 19. This argument is difficult to follow; if the OPPS statute does not qualify as "minutely detailed," it is hard to imagine what statute would qualify. And Congress went to great lengths to describe the payment rules for services performed at off-campus hospital departments, setting forth in elaborate terms the precise definitions for "mid-build" off-campus departments that should be grandfathered, as well as specific rules for audits to ensure the accuracy of the line drawing between excepted and non-excepted departments. *See* 42 U.S.C. § 1395*l*(t)(21)(A), (B). It is doubtful that Congress would have engaged in that exercise if it had thought that all of its handiwork was subject to the Secretary's thumbs down merely on his recitation that Congress had "unnecessar[ily]" kept the payment rate too high. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (Congress does not "hide elephants in mouseholes").

C. The Secretary Improperly Sought to Address the Cost, Not the "Volume," of Covered OPD Services

In issuing the Final Rule, the Secretary forthrightly acknowledged that he sought to address unnecessary costs, not unnecessary services. *See* 83 Fed. Reg. at 59,006 ("We consider these shifts in the sites of service unnecessary if the beneficiary can safely receive *the same services* in a lower cost setting but instead receives care in a higher cost setting."); *id.* at 59,008–09 (same); 59,010 (same). Section (t)(2)(F), however, is not a cost-control measure; instead, by its explicit terms, it authorizes the Secretary to address "unnecessary increases in the volume" of services. For the

reasons explained above, Section (t)(2)(F) does not give the Secretary the authority to target specific payments on his belief that they are "too high." And it certainly gives the Secretary no authority to tinker with payment rates where his goal is to address only costs, not the volume of services.

The Secretary's only response in this score is to recite his findings that the volume of outpatient services has increased in recent years. ECF No. 17-1 at 19. Not only does this not address the point, it proves nothing. The volume of services can increase or decrease for any number of "necessary" reasons, such as population growth, advances in medical technology, or beneficiaries' preference to visit a location closer to their home for a service that would otherwise be provided at a hospital's main campus. To assert that the volume of services has increased is not to say that they have increased "unnecessarily." The Secretary has studiously avoided drawing that latter conclusion, seeking only to establish a lower cost for "the same services." 83 Fed. Reg. at 59,006. The Secretary, then, simply invoked Section (t)(2)(F) for the wrong purpose. *See Hays*, 589 F.3d at 1282–83 ("To be sure, Congress could have written the Medicare Act to authorize the least costly alternative policy," so that "the phrase 'reasonable and necessary' would indeed modify 'expenses' [rather than modifying 'items or services.']" …. "But this is not the statute Congress wrote.").

IV. Even if the Secretary Had the Power to Adopt a Targeted Payment Cut, He Could Only Do So in a Budget-Neutral Manner

For all of the reasons described above, the Secretary lacked the authority under Section (t)(2)(F) to target a particular outpatient service for a payment cut. But if he did have that authority, he could only exercise it in a budget-neutral manner. The OPPS statute requires budget neutrality "[i]f the Secretary makes adjustments under subparagraph (A)." 42 U.S.C. § 1395*l*(t)(9)(B). That subparagraph applies to "the wage and other adjustments described in paragraph (2)." *Id.*

§ 1395*l*(t)(9)(A). Section (t)(2)(F), of course, falls within paragraph (2) of the OPPS statute. It follows that, if Section (t)(2)(F) gives the Secretary the authority to adjust payment rates for a particular outpatient service, he must follow the budget-neutrality rules to do so. *See NLRB v. SW Gen., Inc.*, 137 S. Ct. at 938–39.

The Secretary acknowledges that he would be required to follow budget neutrality rules if he called his adjustment in payment rates an "adjustment," but contends that he may avoid those rules through the simple measure of calling the same payment-rate adjustment a "method." *See* ECF No. 17-1 at 23. This will not do. When two provisions of the same federal statute overlap, courts must give effect to both, if possible. *See FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 304 (2003). If Section (t)(2)(F) overlaps with Section (t)(2)(E) to also authorize an adjustment to particular payment rates—again, it does not—then the Secretary would be obliged to give effect to both provisions, including the rule in Section (t)(2)(E) that "other adjustments" are subject to budget neutrality.

Without refuge in the statute itself, the Secretary appeals to a pure policy argument: Why, he asks, shouldn't he be allowed to cut payments for particular services to save money, without making up the shortfall somewhere else in OPPS? The answer, of course, is that the budget neutrality rule is a two-edged sword. It does not exclusively serve the Secretary's interest in controlling costs; it also protects providers' interests in the predictability of payment and in a guarantee that OPPS payments, at least in the aggregate, will be adequate to cover the costs of providing those services. *Cf. Cape Cod. Hosp. v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011) (requiring upward adjustment in payment rates to ensure proper budget-neutrality calculation). This is why Congress designed the OPPS system the way that it did, with a precise formula defining how much overall OPPS payments will grow from year to year, and with instructions to

the Secretary as to how to allocate that pool of funds. *See* H.R. Conf. Rep. No. 105-217, 784, 1997 U.S.C.C.A.N. 176, 405 (1997) (describing calculation for the total amount of Medicare OPD fee payment amounts for the OPPS's first year of operation and for subsequent years). The Secretary's invocation of Section (t)(2)(F) here cannot be squared with the statute that Congress actually enacted. The Final Rule, accordingly, should be vacated.

V. Remand for Further Rulemaking Would Be Futile

The Hospital Plaintiffs have sought vacatur of the Final Rule, and an order directing the Secretary to pay them at OPPS rates. The Secretary, wisely, does not dispute that vacatur would be required if the Hospital Plaintiffs prevail. "Vacatur is the normal remedy" in an APA action, *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014), although the government may seek a departure from that normal rule upon a showing that the "disruptive consequences of vacatur" outweigh the "seriousness of the order's deficiencies," *id.* (internal quotations omitted). No such showing would be possible here. The Final Rule is fatally flawed, and vacatur would not be the least bit disruptive. The Final Rule applies to one specific HCPCS code that providers to use to report E/M services performed at excepted off-campus hospital outpatient departments. *See* 83 Fed. Reg. at 59,013–14. To comply with the vacatur, the Secretary would simply pay the normal OPPS rate for services reported under that one code.

The Secretary argues, however, that vacatur should be accompanied by a "remand to the agency for additional investigation or explanation." ECF No. 17-1 at 26 (quoting *INS v. Ventura*, 537 U.S. 12, 16 (2002)). He is correct that remand is the general rule. This Court, however, may forgo the futile gesture of a remand to the agency "where there is not the slightest uncertainty as to the outcome of an agency proceeding." *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1489 (D.C. Cir. 1995). Remand would be pointless here, because the Secretary is legally required to pay OPPS rates to the Hospital Plaintiffs for the E/M services performed at their facilities. And even if the

Secretary would have had some discretion in that regard when he first issued his rule, the calendar year has now begun, and given budget-neutrality constraints the Secretary could not now adopt a different rule without revisiting all of the payment calculations for OPPS services for 2019. This would be both a practical impossibility, *see Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1169 (D.C. Cir. 2015); *Amgen*, 357 F.3d at 112, as well as a legal one, *see* 42 U.S.C. § 1395hh(e) (prohibiting retroactive rulemaking absent a showing that the retroactive rule is legal required or necessary for the public interest). Because "[o]nly one conclusion would be supportable" here, *Fogg v. Ashcroft*, 254 F.3d 103, 111–12 (D.C. Cir. 2001) (internal quotation omitted), there is no need for a remand for the agency to arrive at a pre-ordained result.

CONCLUSION

The Secretary exceeded his statutory authority in issuing his Final Rule adjusting OPPS payment rates for excepted off-campus hospital outpatient departments. The Plaintiff Hospitals accordingly respectfully request that their motion for summary judgment be granted, that the Final Rule be vacated, and that the Secretary be directed to pay them for the services they perform at their excepted off-campus hospital outpatient departments at the OPPS rates that would otherwise apply in the absence of the Final Rule.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day served the foregoing via the Court's CM/ECF on all counsel of record.

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April 5, 2019