IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, MERCY HEALTH MUSKEGON, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER, and YORK HOSPITAL, *Plaintiffs*, v. ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *Defendant*.	)	Civil Action No. 1:18-cv-2841

REPLY IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

AND

MEMORANDUM IN OPPOSITION TO
DEFENDANT'S CROSS-MOTION TO DISMISS OR FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs' opening brief explained the clear limits that Congress imposed on the ability of the Centers for Medicare & Medicaid Services (CMS) to change Medicare payment rates for hospital outpatient clinic visit services from year to year: The agency may make targeted cuts to the Medicare payment rates for specific items or services, but it must do so in a budget-neutral fashion. And CMS must respect the statutory exemption that Congress explicitly provided to protect certain grandfathered ("excepted") off-campus provider-based departments (PBDs) from a statutory change that effectively reduced payment rates for non-excepted off-campus PBDs.

CMS's Final Rule ignored both of these clear statutory mandates. By selectively cutting payment rates for certain off-campus PBD clinic visit services, CMS violated the Medicare statute's clear prohibition on non-budget-neutral cuts to specific categories of services. And by setting the payment rate for excepted off-campus PBDs as though they were *not* excepted—purportedly to fix a problem created by Congress's selected approach—CMS has engaged in a clear usurpation of legislative authority from Congress.

In response, the Government does not contest that the statutory provision authorizing the agency to make annual adjustments to hospital outpatient payment rates—Subsection (t)(9)—prohibits the agency from making non-budget-neutral payment cuts to selected services. Instead, CMS is left to argue that its authority derives from a separate statutory provision—Subsection (t)(2)(F)—that, when triggered, provides the agency with authority to make adjustments to an across-the-board "conversion factor." But that conversion factor is not implicated here. And in trying to defend its decision to override the statutory separateness of excepted and non-excepted off-campus PBDs, the Government effectively admits that its goal

was to address a policy concern that Congress has already addressed through a different legislative solution. That is *ultra vires*. This Court should right the agency's clear wrong.

Not to be deterred, the Government suggests—but does not expressly argue—that this Court lacks jurisdiction to review the Final Rule. Not so. There is nothing in the Medicare statute that precludes this Court from holding the agency to account when it has clearly exceeded the bounds Congress imposed on its delegated authority. Indeed, this Court has recently affirmed as much in two closely analogous cases that the Government simply fails to acknowledge. Review of Plaintiffs' *ultra vires* claim is available and appropriate now.

I. THE FINAL RULE IS *ULTRA VIRES*.

The statutory provision authorizing CMS to make annual adjustments to payment rates for specific outpatient hospital services requires those adjustments to be budget-neutral: a downward adjustment for one service must be offset by upward adjustments for the other OPPS services to ensure that total spending remains the same. 42 U.S.C. § 1395l(t)(9)(A) and (B). The alternative statutory source of authority claimed by the Government here—Subsection (t)(2)(F)—must be applied as an across-the-board adjustment of the conversion factor, an adjustment that applies broadly to payments for all covered services under the OPPS. *See* 42 U.S.C. § 1395l(t)(9)(C). Congress's decision to divide CMS's authority in this fashion ensured that service-specific payment cuts would not disproportionately target a subset of disfavored providers and beneficiaries. Disagreement with Congress's solution does not give CMS license to ignore a statutory directive.

For the same reason, CMS cannot legislatively override Congress's decision to except certain grandfathered off-campus PBDs from changes that were made to the statute in 2015. In that year, Congress explicitly and deliberately tackled the very problem that CMS now purports

to address, and it chose a different legislative fix: Going forward, off-campus PBDs could be paid at a different payment rate from the main campuses of hospitals. But grandfathered off-campus PBDs would be protected from those payment cuts through a statutory exemption. Again, CMS cannot ignore Congress's statutory mandate simply because it disagrees.

A. CMS Cannot Justify Its Failure To Observe Budget Neutrality By Claiming That The Final Rule's Service-Specific Adjustments Are A "Method."

The Government does not dispute that the statutory provisions authorizing CMS to make annual adjustments to payment rates for specific outpatient hospital services require those adjustments to be budget-neutral. 42 U.S.C. § 1395l(t)(9)(A) and (B). Instead, it argues that a separate statutory provision—Subsection (t)(2)(F)—allows CMS "to develop a method to control unnecessary increases in volume for a specific service," and then in turn contends that the word "method" could be defined to "include creating parity between the OPPS and [Physician Fee Schedule]-equivalent payment rates." Gov. Br. 15–16.

To begin with, the Government's argument—that the Final Rule was necessary to respond to an "unnecessary" increase in volume of clinic visits, *see* Gov. Br. 5–9, 20–21, 23—depends on two logical fallacies. First, an increase in the number of PBD clinic visits does not mean those services are "unnecessary." An increase in utilization could equally mean the opposite, that there is simply more need for them. Second, the patients who visit off-campus PBDs and those who visit physician offices are not fungible. Patients who visit off-campus PBDs tend to be sicker than those who visit physician offices and ambulatory surgical centers (ASCs) (which, like physician offices, also are not hospital-affiliated and do not need to meet the Medicare Conditions of Participation). *See* Am. Hosp. Ass'n, Comparison of Medicare Fee-for-Service Beneficiaries Treated in ASCs and Hospital Outpatient Departments (2019), *available at*

https://bit.ly/2FK9ytK; *see also* Watson Policy Analysis, 2016 Medicare Carrier 5 percent Standard Analytic File (2018).

But this Court need not decide whether the Government actually found an unnecessary increase in the volume of clinic visits. Even assuming that it did, as Plaintiffs pointed out in their opening brief, the statute spells out precisely what CMS may do in the event it finds such "unnecessary increases in volume" after developing the specified method: "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. § 1395l(t)(9)(C) (emphases added). Section (t)(9)(C) thus clarifies two critical points: (i) the "method" referenced in (t)(2)(F) is merely an analytical mechanism for CMS to "*determine*" whether there is an unnecessary increase in volume (and does not itself authorize, as the Government argues, implementation of a payment adjustment to address any such increase); and (ii) if CMS applies the (t)(2)(F) methodology and determines the existence of an unnecessary increase in volume, the appropriate fix is an adjustment to the conversion factor.

The Government did not adjust the conversion factor to effectuate the clinic visit payment cuts at issue in this case. The conversion factor, which is updated annually, is applied to the relative weight of each service paid under OPPS to translate the relative weights into dollar payment rates. 42 U.S.C. § 1395l(t)(3)(C) and (D). The challenged cuts, of course, do *not* apply across-the-board to all services under the OPPS.

To sidestep this problem, the Government turns to a creative reading of the statute.[1] It argues that while Subsection (t)(9)(C) says that CMS *may* adhere to Congress's sole enumerated manner for implementing such method, the agency *may also*—at its unfettered discretion—decline to do so, and instead may formulate any combination of service-specific and across-the-board cuts it desires. Gov. Br. 15–16. That is quite something. Coupled with the Government's position on the breadth of the judicial-review bar, the authority claimed by CMS under Subsection (t)(2)(F) would be both virtually limitless and unreviewable. That cannot be.

The Government argues that if Congress intended Subsection (t)(9)(C) to be an exclusive remedy for an unnecessary increase in the volume of services, it would have used the word "shall" or "may only" instead of "may." Gov. Br. 16. But if Congress had used "shall," the statute would have an entirely different meaning—the agency would be powerless to *refrain* from adjusting the conversion factor in the face of an unnecessary increase in volume. And Congress did not need to explicitly state that CMS "may *only*" implement a method defined under Subsection (t)(2)(F) by making changes to the conversion factor, because that is implicit in the interplay between Subsection (t)(2)(F) and Subsection (t)(9) (C). "If A, then B" implies that C is no longer on the table. The "may" here gives the agency the discretion to do the thing

[1] The Government also points to "Congress's silence" as to whether methods implemented under Subsection (t)(2)(F) "must be budget neutral." Gov. Br. 18–19. To be clear, Plaintiffs agree that the methods under Subsection (t)(2)(F) may lead to adjustments that need not be budget-neutral—but they *do* need to be implemented across-the-board by adjustments to the conversion factor under Subsection (t)(9)(C), not just adjustments to selected services. The issue here is that CMS asserts the power to make service-specific adjustments under Subsection (t)(2)(F) without regard to that constraint.

prescribed, or not to do the thing prescribed—not the discretion to do an infinite number of other things not mentioned.[2]

The Government concedes that "CMS has not previously determined the extent of its authority under Subsection (t)(2)(F)." Gov. Br. 20. It is true that CMS has never read Subsection (t)(2)(F) to provide it the broad legislative powers it now claims. But CMS *has* addressed this statutory provision before. Plaintiffs' Br. 16. The agency previously acknowledged that "possible legislative modification" would be necessary before it could use its authority under Subsection (t)(2)(F) to adopt measures other than adjustment to the conversion factor. 63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998). The agency also has described the interplay between Subsection (t)(2)(F) and Subsection (t)(9)(C) almost precisely as Plaintiffs do here. 66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2001). The Government's response is thin at best, resorting to the conclusory statement that "none of the language Plaintiffs cite is contrary to CMS's position in the Rule." Gov. Br. 20. That is not accurate and not enough. Nowhere in the record—and not even in its litigation brief, where it is too late to do so anyway—has CMS offered an adequate explanation for its change in position regarding the scope of its authority under Subsection (t)(2)(F). That, in and of itself, is an APA violation, and it renders any claimed deference to the agency's construction of the statute improper. *See, e.g.*, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

[2] The plain language of the statute is clear enough. But that is also what the legislative history reveals. Balanced Budget Act of 1997, H.R. Rep. No. 105-217, at 784 (Conf. Rep.). The Government's response—that here, too, Congress simply meant to describe one remediable option available to the agency, Gov. Br. 17—is no more plausible than its argument regarding the language of the statute itself. There would be no point in specifying one and only one remedial measure if the agency were intended to retain limitless discretion to make adjustments.

The Government tries to salvage its flawed reading of the statute by falling back on freestanding policy arguments. The Government claims that there is "no logical reason why Congress would have wanted CMS" to make across-the-board cuts to reduce unnecessary increases in the volume of specific covered outpatient services. Gov. Br. 15. True, there is no one logical reason; there are many. To name a few: The OPPS payment methodology is designed to be based on claims data, with payment rates established on a relative basis. The more CMS eschews that methodology for particular items and services, the less the system retains its integrity. The agency's umbrage at the fact that its hands are bound is properly directed at the concept of budget neutrality itself, which permeates the statute. Also, as Plaintiffs have already explained, Congress limited CMS's authority to make selective payment reductions in part to protect individual providers and services from targeted, draconian cuts. Plaintiffs' Br. 12–13. But this Court need not guess *why* Congress restricted CMS's remedies; the important thing is that it did. "The question here is not whether Congress could have drafted" the statutory framework "differently or even better, but what the statutory language provides." *Citizens for Responsibility & Ethics in Wash. v. Fed. Election Comm'n*, 316 F. Supp. 3d 349, 398 (D.D.C. 2018). What is not "logical" here is the Government's position—in the face of a carefully crafted statute imposing bright-line limits on the exercise of CMS's authority—that the agency may nevertheless make any desired cuts to selected services simply by calling the desired outcome a "method."

The Government's interpretation also flies in the face of the rest of the Medicare statute. When the "statutory context" renders the meaning of statutory language clear, Congress need not further enumerate its intent to remove any specter of ambiguity. *See Indep. Ins. Agents of Am., Inc. v. Hawke*, 211 F.3d 638, 644 (D.C. Cir. 2000). And here, the Government's argument fails

because it "would render" the budget-neutral restraint on service-specific adjustments "meaningless"; it would allow CMS "to constantly expand" its claimed authority to effect cuts to Medicare payments by labeling any desired non-budget-neutral cut part of a "method" "without congressional action." *See id.* at 643–645. Because the statute is clear when its provisions are read together, this case is in stark contrast to the legal authority cited by the Government. *Cf. Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697, 700 (D.C. Cir. 2014) (rejecting challenge to agency action that required reading statutory provisions "in isolation" when the "only certainty that we can discern from the statutory scheme is that it is unclear").

The Medicare statute provides CMS a choice: If the agency is concerned about the volume of covered outpatient services, it may either make targeted cuts to specific services in a budget-neutral fashion under Subsection (t)(9)(B); *or* it may "develop a method" under Subsection (t)(2)(F) and then implement that method through a non-budget-neutral adjustment of the conversion factor for all OPPS services under Subsection (t)(9)(C). Because the Government has failed to show that any statutory grant of power authorizes CMS's cuts to clinic visit service payments, this Court should "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." *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 328 (2014).

B. CMS Cannot Treat Excepted And Non-Excepted PBDs The Same When Congress Instructed They Be Treated Differently.

The Medicare statute, as amended, creates two distinct categories of off-campus PBDs: excepted ones, which satisfy certain grandfathering requirements, and non-excepted ones, which do not. 42 U.S.C. § 1395l(t)(21). Congress created that distinction in order to allow entities that had been billing before November 2015 to continue billing under the OPPS payment system, while non-excepted entities would be subject by a different payment system (later determined by

CMS to be the Medicare Physician Fee Schedule). *Id*. § 1395l(t)(21)(C); H.R. Rep. No .114-604, at 10 (2016). And because CMS has long treated the statutory reference to a payment *system* as a proxy for payment *rates*, Plaintiffs' Br. 18, the Medicare statute requires CMS to pay excepted and non-excepted PBDs differently.

By intentionally cutting the payment rate for grandfathered off-campus PBDs so that it now magically equals the payment rate for non-excepted PBDs, CMS has effectively overridden Congress's policy directives with its own. The Government's brief admits as much. Gov. Br. 1 (arguing that the Final Rule was necessary because Congress "did not address once and for all the problem of Medicare having to pay significantly more for certain services" since it left in place "payment disparity [that] creates a perverse incentive to increase utilization of clinic visits furnished in off-campus OPDs.").

Recasting Plaintiffs' arguments as "essentially an extension of the *expressio unius* canon of construction," the Government claims that nothing in the 2015 amendments prevents the agency from exercising its authority under Subsection (t)(2)(F) to control unnecessary increases in the volume of covered services. Gov. Br. 22–23. But Congress decided to create a grandfathered category of PBDs, and CMS is bound by the statutory framework as written. If the grandfathering provision set forth in Section 603 were intended to be of limited duration only, or subject to being overridden by Subsection (t)(2)(F) whenever CMS deemed it necessary, Congress would have said so. *See, e.g.*, *Validata Chem. Servs. v. U.S. Dep't of Energy*, 169 F. Supp. 3d 69, 78 (D.D.C. 2016) (Congress enacted "sunset provision" in government-contracts jurisdictional statute as "a 'compromise'" and, following a " 'test' period," declined "to extend the period").

CMS's invocation yet again of Subsection (t)(2)(F) as a wellspring of boundless authority highlights the danger of the agency's power grab here. When CMS finds unnecessary volume increases under Subsection (t)(2)(F), CMS is permitted to make adjustments to the conversion factor. 42 U.S.C. § 1395l(t)(9)(C). It is not a hall pass that permits the agency to undermine the statute whenever it wants to, including by abrogating Subsection (t)(21)(C)'s excepted/non-excepted distinction. Fundamentally, CMS fails to explain why Congress would draw the statutory distinction between excepted and non-excepted PBDs in the first place if the agency were free to ignore it. Whether framed as an issue of surplusage, as Plaintiffs maintain, or a violation of *expressio unius* principles, as the Government asserts, that failure is dispositive. *See Hawke*, 211 F.3d at 645 (explaining that in administrative law "the canons of avoiding surplusage and *expressio unius* are at their zenith when they apply in tandem").

The Government purports to justify its position by arguing that the statutory separation between excepted and non-excepted entities "continues to have import" for the payment rates applicable to other services because the Final Rule undermines the statutory separation for "only a single type of service": covered clinic visits. Gov. Br. 23–24. But there is nothing in Section 603 to suggest that Congress intended to permit CMS to carve out exceptions for specific types of services. The general includes the specific, and the grandfathering provision in Section 603 codifies disparate treatment for *all* services covered by the statutory provision—among which clinic visits have by far the greatest financial impact. *See* Gov. Br. 5–6, 8–9 (explaining the financial impact of OPPS clinic visits). By the Government's logic, it could do the exact same thing next year to all but one of the remaining covered services. But that kind of asserted authority-by-encroachment simply is not permitted by the plain language of the statute.

Because the Final Rule purports to override Congress's specific policy choice to protect grandfathered off-campus PBDs from being paid at the same payment rate as physician offices, CMS's conduct is *ultra vires* for this reason as well.

II. THIS COURT HAS JURISDICTION OVER PLAINTIFFS' CLAIMS.

Perhaps cognizant that its position is weak on the merits, the Government attempts to shield CMS's extra-statutory conduct from judicial review, on two principal grounds. First, the Government suggests—but curiously does not quite argue—that the Medicare Act expressly precludes judicial review, even of *ultra vires* challenges. And second, the Government briefly asserts that the Medicare Act's generally applicable "channeling" requirement also bars Plaintiffs' challenge for want of exhaustion of administrative remedies. Gov. Br. 11 n.5 (citing 42 U.S.C. § 405(h) and *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 9 (2000)). Both arguments are wrong.

A. Plaintiffs' Claims Are Not Precluded.

The Government rarely shrinks from a jurisdictional challenge. Except now. Rather than affirmatively arguing that this Court lacks jurisdiction, the agency asserts instead that by bringing *ultra vires* claims, "Plaintiffs impliedly concede that the agency acted within the scope of its authority." Gov. Br. 10. In other words, if a plaintiff challenges the agency as having acted *ultra vires*, it effectively concedes that the agency did not act *ultra vires*. That is a perfect Catch-22.[3] It is also wrong.

[3] There was only one catch and that was Catch-22, which specified that a concern for one's safety in the face of dangers that were real and immediate was the process of a rational mind. Orr was crazy and could be grounded. All he had to do was ask; and as soon as he did, he would no longer be crazy and would have to fly more missions. Orr would be crazy to fly more missions and sane if he didn't, but if he was sane he had to fly them. If he flew them he was crazy and didn't have to; but if he didn't want to he was

The reason that the Government does not argue head-on that this Court lacks jurisdiction is that it cannot. Two recent decisions of this Court—neither of which appears in the Government's brief—belie the Government's argument that *ultra vires* challenges to CMS's authority under the Medicare statute are "self-defeating." Gov. Br. 13. *See Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 83 (D.D.C. 2018) (holding reviewable and *ultra vires* unauthorized reduction to drug-reimbursement rate); *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 12 (D.D.C. 2018) (same for failure to promulgate statutorily mandated cancer-hospital adjustment). The D.C. Circuit itself has said as much as well. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 114 (D.C. Cir. 2004) (reviewing HHS's authority to alter pass-through payments despite Government's assertion of judicial-review bar because if "the Secretary is not so authorized, even a procedurally proper and reasonably explained decision would be contrary to law because it would be *ultra vires*").

The inescapable implication of the Government's argument would be to immunize from judicial review the most egregious of administrative-agency overreaches.[4] That is not the law.

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sane and had to. Yossarian was moved very deeply by the absolute simplicity of this clause of Catch-22 and let out a respectful whistle.

"That's some catch, that Catch-22," he observed.

"It's the best there is," Doc Daneeka agreed.

Joseph Heller, *Catch-22* 52 (1961).

[4] The Government never explains *why*, as it appears to imply, its justiciability theory would be any different had Plaintiffs instead brought an APA claim and raised only an *ultra vires* theory. Indeed, the Government moved to dismiss claims doing precisely this in the related case. But if it were indeed true that the Government's purported concern could be cured by simply granting leave for Plaintiffs to reframe their non-statutory *ultra vires* claim as one brought instead under the APA, this Court should simply do that instead. *See, e.g.*, *Flaherty v. Pritzker*, 322 F.R.D. 44, 48 (D.D.C. 2017).

"Were such unauthorized actions to go unchecked, chaos would plainly result. When an executive acts *ultra vires*, courts are normally available to reestablish the limits on his authority." *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988). The Government notably fails to cite any authority to the contrary.

To demonstrate that Congress meant to remove the Final Rule from this Court's purview, the Government faces a "heavy burden." *Id.* at 221. Courts "apply a presumption in favor of judicial review of agency action" when addressing arguments that particular conduct has been placed beyond the reach of Article III supervision, and thus "read statutory bars on judicial review narrowly." *See Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 518 (D.C. Cir. 2016). An agency's conduct will be subject to judicial review unless there is "clear and convincing evidence" Congress intended otherwise. *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967). For good reason. "Otherwise, agencies could characterize reviewable or unauthorized action as falling within the scope of no-review provisions whose application to such action Congress did not intend." *Amgen*, 357 F.3d at 113. Courts thus use a critical eye to "determine whether the challenged agency action is of the sort shielded from review." *See id.* at 112 (construing neighboring judicial-review bar, Subsection (t)(12)(E), to "extend[] no further than the Secretary's statutory authority to" impose "'other adjustments'"). That concern is at its height when the challenge implicates a " 'serious constitutional question,' " such as an agency's violation of the separation of powers, were the statute "construed to preclude all judicial review of a constitutional claim." *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 n.20 (1994) (citation omitted).

The Government's preclusion argument presumes that Congress's statutory limits on judicial review of Medicare challenges apply to non-statutory claims. That presumption is

infirm. Plaintiffs' challenge turns on whether the Medicare Act applies to CMS's unauthorized conduct *at all*. As the D.C. Circuit has explained, when the question "whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action," the proper path forward is to "address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review." *Amgen*, 357 F.3d at 113. This inquiry is a targeted one, looking only to whether the agency "is authorized" to undertake the challenged conduct and rendering "irrelevant" the normal APA concerns that the agency's conduct "was arbitrary, capricious, and procedurally deficient." *Id.* at 114.

And as this Court has recently affirmed, when CMS has "committed a facial violation of the statute" contrary to Congress's instruction, immediate "*ultra vires* review" is the proper recourse. *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 12. Because Plaintiffs' challenge does not "arise under" the Medicare Act, that statute's limitations on judicial review do not apply. Full stop.

B. Plaintiffs' Claims Are Not Subject To Medicare Channeling, But Plaintiffs Satisfied Its Requirements Regardless.

The Medicare channeling provision, which applies only "with respect" to other provisions of the Medicare Act, 42 U.S.C. § 1395ii, does not apply to CMS's *ultra vires* conduct. But even if it did, that channeling provision does not foreclose judicial review because Plaintiffs satisfied its requirements. *See Council for Urological Interests v. Sebelius*, 668 F.3d 704, 709 (D.C. Cir. 2011) ("Critical to our analysis, the Supreme Court has understood section 405(h) as having only channeling force, not, as the government would have it, foreclosing force.").

The Medicare channeling provision comprises two discrete requirements: (1) presentment and (2) exhaustion. Presentment is done. Plaintiffs submitted specific claims

for payments under the Clinic Visit Policy after that policy took effect,[5] and they did so prior to filing the First Amended Complaint, thus satisfying the presentment requirement to the extent it even applies to *ultra vires* challenges.[6] *See Action All. of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010).

Nor is there an exhaustion barrier here. As an initial matter, the Government (at 11 n.5) has waived any argument on exhaustion by advancing it "only in a footnote." *Animal Welfare Inst. v. Feld Entm't, Inc.*, 944 F. Supp. 2d 1, 23 (D.D.C. 2013) (quoting *Hutchins v. District of Columbia*, 188 F.3d 531, 539 n.3 (D.C. Cir. 1999) (en banc)). Moreover, even if this Court were to forgive that default and reach the question head on, exhaustion is not required when further administrative process would be futile. And here, the Hospital Plaintiffs appealed beyond the first level of appeal and have been told by CMS that there is no further review available.[7] Courts do not require plaintiffs to invoke "wholly formalistic" agency procedures when "the Secretary gives no reason to believe that the agency machinery might accede to plaintiffs' claims." *Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). Because Plaintiffs' *ultra vires* claim will not "turn on any disputed facts" and assessing the lawfulness of CMS's extra-statutory conduct requires considering "nothing more than the statute, its legislative history, and the regulation," "nothing indicates that administrative appeals might result in the agency

[5] Dkt. 13 ¶ 15; Dkt. 14-4 ¶16 & Ex. A; Dkt. 14-5 ¶ 9 & Ex. A; Dkt. 14-6 ¶ 10 & Ex. A.

[6] The Government recognizes as much, attempting to preserve in a footnote an as-yet-unspecified argument about the timing of that presentment. Gov. Br. 13 n.7. But the Government correctly acknowledges that binding D.C. Circuit precedent precludes this line of attack. *See Scahill v. District of Columbia*, 909 F.3d 1177, 1184 (D.C. Cir. 2018).

[7] Requiring Plaintiffs to undertake, needlessly, further administrative process without any chance of success would also confront them with the "serious obstacles from the colossal backlog in Medicare appeals and HHS's ostensibly Sisyphean attempts to combat the problem." *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 505 (5th Cir. 2018).

overturning" the Final Rule. *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 112 (D.D.C. 2015).

All the more so because the Final Rule is "even more embedded" than most agency interpretations, having been promulgated "after notice and comment rulemaking" in which the agency rejected commentators' concerns that that policy would exceed the limited scope of the agency's authority. *See id.*; *see also Hall v. Sebelius*, 689 F. Supp. 2d 10, 24–25 (D.D.C. 2009) (recognizing that "exhaustion may be excused where 'an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law' " and when "plaintiffs 'do not challenge an individual … decision by the agency where agency expertise would be important' " but rather "challenge the agency's 'policy, pattern, and practice' or 'systemic failure to comply with' federal law."). And because all "laws and regulations pertaining to the Medicare and Medicaid programs" are "binding" on HHS adjudicators, there is no lawful avenue of relief for Plaintiffs under the administrative-appeals process. *See* 42 C.F.R. § 405.1063(a).

As this Court recently affirmed in a challenge to one aspect of the CY 2018 OPPS payment rate rule, "the futility of requiring Plaintiffs to exhaust their administrative remedies" in these circumstances "is readily apparent." *See American Hosp. Ass'n*, 348 F. Supp. 3d at 75. The Medicare channeling provision—to the extent it even applies to *ultra vires* claims—thus does not preclude this Court's review either.

III. THE RELIEF SOUGHT IS AVAILABLE AND APPROPRIATE.

Finally, the relief Plaintiffs seek is both available and appropriate. Because CMS's conduct is *ultra vires*, the proper recourse is not a mere remand; there is nothing to correct that can be corrected. Instead, the proper remedy is to vacate the offending portions of the rule, remand, and direct CMS to observe its statutorily imposed obligations. *See, e.g.*, Order Granting

Summ. J., *H. Lee Moffitt Cancer Ctr. v. Azar*, No. 16-2337 (TJK), Dkt. No. 23 (July 18, 2018) (directing HHS to, "as promptly as practicable and in a manner consistent with the Court's Opinion, provide for an appropriate adjustment under 42 U.S.C. § 1395l(t)(2)(E) to reflect those higher costs identified in the study performed under 42 U.S.C. § 1395l(t)(18)(A) effective for services furnished on or after January 1, 2011, through December 31, 2011, as provided by Section 3138 of the Patient Protection and Affordable Care Act," and to pay "interest to the extent required by 42 U.S.C. § 1395oo(f)(2).").

The Government's contrary assertion that "the only appropriate remedy would be to remand to the agency for further consideration" fails to account for the magnitude of CMS's overreach in promulgating the Final Rule. Gov. Br. 25. The established two-part standard for vacatur forecloses the open-ended remand the Government seeks. *See Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993) (directing courts to (1) analyze "the possibility" that an agency "may be able to justify the Rule" on remand and (2) "the disruptive consequences of vacating"). Because "the Final Rule's deficiency is not merely procedural," as "the agency acted outside of the scope of its statutory authority" under the Medicare Act, this is not a case where the agency could conceivably "be able to substantiate its decision on remand." *Children's Hosp. Ass'n of Texas v. Azar*, 300 F. Supp. 3d 190, 211 (D.D.C. 2018) (quoting *Allied–Signal*, 988 F.2d at 151). Similarly, given that Plaintiffs have moved swiftly in bringing their challenge, "the Final Rule only became effective" mere months ago, and the agency may instead make payments at the previously prevailing rates, any disruption to vacating the Government's unsalvageable rule would be, at most, minimal. *See id.* (nine months between the challenged rule's effective date and the Court's vacatur order).

CONCLUSION

For these reasons, and those in Plaintiffs' opening brief, this Court should grant summary judgment in Plaintiffs' favor, vacate the relevant portions of the Final Rule, enjoin CMS from enforcing the Clinic Visit Policy, and order CMS to provide immediate repayment of any amounts improperly withheld as a result of the agency's unauthorized conduct.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 5, 2019, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson
Catherine E. Stetson