IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services, *Defendant.*	)	Case No. 1:20-cv-00080-RMC

PLAINTIFFS' OPPOSITION TO DEFENDANT'S
MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

AND

REPLY IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

In the words of Yogi Berra, "It's déjà vu all over again." Just six months ago, this Court struck down as unlawful CMS's "Clinic Visit Policy" in the 2019 Final Rule that reduced the Medicare payment rate for certain clinic-visit services provided at excepted off-campus provider based departments (PBDs) to make it equal to payment rates for services provided at non-excepted off-campus PBDs. *See Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 3d 142 (D.D.C. 2019) (*AHA I*). And yet CMS copied-and-pasted the same unlawful policy into its 2020 Final Rule, claiming authority under the same statutory provisions. The same policy should meet the same fate as its 2019 twin—vacatur—for the same reasons—it exceeds CMS's authority. The agency may make targeted cuts to Medicare payment rates for specific items or services, but it must do so in a budget-neutral way. And CMS may not override the explicit statutory exemption Congress created to protect certain excepted off-campus PBDs from a statutory change that effectively reduced payment rates for non-excepted off-campus PBDs.

CMS has no new arguments in response, *compare* Gov. Br. *with AHA I*, ECF No. 21, and its old arguments remain unpersuasive. CMS still asserts authority for the Final Rule under Subsection (t)(2)(F), which, when triggered, allows the agency to make adjustments to an across-the-board "conversion factor." But that conversion factor is not implicated here. And the agency defends its decision to override Congress's statutory distinction between excepted and non-excepted off-campus PBDs by essentially arguing that it rewrote Congress's legislative mandate only *a little bit*. That is a *lotta* bit *ultra vires*. This Court should reaffirm its holding that CMS's Clinic Visit Policy is unlawful and vacate the policy a second time.

I. THE FINAL RULE IS *ULTRA VIRES*.

This Court said it best: The Clinic Visit Policy "developed by CMS to cut costs is impermissible and violates [the agency's] 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." *AHA I*, 410 F. Supp. 3d at 160.

A. CMS May Not Circumvent the Statute's Budget Neutrality Requirement By Claiming the Final Rule's Service-Specific Adjustments Are A "Method."

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. § 1395*l*(t)(9)(A) and (B). To avoid that budget neutrality requirement, CMS asserts authority to implement the Clinic Visit Policy under a different statutory provision—Subsection (t)(2)(F)—that allows CMS "to develop a method to control unnecessary increases in volume for a specific service." "Method," the agency contends, could be defined to "include creating parity between the OPPS and equivalent payment rates under the Medicare Physician Fee Schedule (PFS)." Gov. Br. 6-7.

This Court has already rejected that definition of "method" outright. "[C]ontext . . . 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." *AHA I*, 410 F. Supp. 3d at 156. Rather, the "method" referenced in (t)(2)(F) is simply an analytical mechanism for CMS to determine whether there is an unnecessary increase in volume for a specific service. *See* 42 U.S.C. § 1395*l*(t)(9)(C). If CMS applies the (t)(2)(F) methodology and determines there has been an unnecessary increase in volume, then it may adjust the conversion factor. *Id.*; *see also AHA I*, 410 F. Supp. 3d at 157 ("CMS can adopt volume-control methods under paragraph (t)(2)(F) which affect payment rates indirectly, even if those methods cannot affect them directly."). But CMS did not adjust the conversion factor to effectuate the clinic visit payment rate cuts at issue here.

CMS stresses that Subsection (t)(9)(C) states that the Secretary "*may* appropriately adjust the update to the conversion factor" if he determines under the (t)(2)(F) methodology that there has been an unnecessary increase in volume. According to CMS, "may," as used in Subsection (t)(9)(C), really means "may also." *See* Gov. Br. at 7. So the agency argues that adjusting the conversion factor is one tool for implementing such method, but the agency "may also"—at its unfettered discretion—*not* do so, and instead may formulate any combination of service-specific and across-the-board cuts it chooses. What is the agency's proposed limit, then, on the tools at its disposal for implementing Subsection (t)(2)(F)? None. That belies the elaborate and detailed statutory scheme Congress created. *See AHA I*, 410 F. Supp. at 156 ("CMS cannot shoehorn a 'method' into the multi-faceted congressional payment scheme when Congress's clear directions lack any such reference."). Instead, "may" in Subsection (t)(9)(C) gives CMS the discretion to do the thing prescribed, or not to do the thing prescribed. It does not grant the agency carte blanche to do any manner of *other* things, including formulate any combination of service-specific and across-the-board cuts it desires.[1]

Finally, CMS's reliance on "Congress's silence" as to whether methods implemented under Subsection (t)(2)(F) "must be budget neutral" is misplaced. Gov. Br. at 8. It's true 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 as CMS has done here. Indeed, CMS previously acknowledged that "possible legislative modification" would be

[1] The statute's plain language is clear, but if there was any doubt, the legislative history crystalizes Plaintiffs' interpretation. *See* Balanced Budget Act of 1997, H.R. Rep. No. 105-217, at 784 (Conf. Rep.). CMS's interpretation of the legislative history, Gov. Br. at 9, fails for the same reason as its interpretation of the statute's plain text; it is implausible that Congress meant to specify one and only one remedial measure—while also giving the agency unfettered discretion to make adjustments.

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 (Sep. 18, 1998); *see also* 66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2001). CMS asserts that it "ha[d] not previously determined the extent of its authority under paragraph (2)(F)." Gov. Br. at 9. Not so, and CMS's failure to offer an adequate explanation for its change in position regarding the scope of its authority independently violates the APA. *See, e.g., Encino Motorcars, LLC v. Navarro*, 126 S. Ct. 2117, 2127 (2016).

B. CMS May Not Override Congress's Decision to Treat Excepted and Non-Excepted PBDs Differently.

In 2015, Congress created 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. § 1395*l*(t)(21). That scheme allows entities that had been billing before November 2015 to continue billing under the OPPS payment system, while non-excepted entities are subject to a different payment system—later determined by CMS to be the Medicare Physician Fee Schedule (PFS). *Id* § 1395*l*(t)(21)(C). The Clinic Visit Policy effectively overrides that mandate: *both* excepted and non-excepted PBDs are paid for clinic visits only under the PFS.

That is okay, CMS suggests, because the 2015 amendments do not prevent the agency from exercising its bottomless font of power under Subsection (t)(2)(F) to control unnecessary increases in the volume of covered services. *See* Gov. Br. at 10. According to CMS, Subsection (t)(2)(F) empowers it to pick and choose the aspects of Congress's directive it wishes to follow: the agency maintains that the 2020 Final Rule is consistent with the statutory distinction between excepted and non-excepted off-campus PBDs because excepted off-campus PBDs continue to receive the congressionally prescribed standard OPPS payment rate for services "*other* than the clinic visit." *Id*. (emphasis added). CMS suggests that so long as

excepted off-campus PBDs continue to receive OPPS payment rates for *some* services the agency is otherwise free to ignore Congress's mandate thanks to Subsection (t)(2)(F). *Id.*

So by the agency's logic, it could implement a policy requiring that excepted off-campus PBDs be paid non-OPPS payment rates for all but one covered service. That would render Congress's explicit statutory distinction essentially meaningless. The grandfathering provision codifies differing treatment for excepted off-campus PBDs for *all* services covered by the statutory provision—the general includes the specific. Nothing in that provision suggests that Congress intended to permit CMS to carve out exceptions for specific types of services or to allow CMS's authority-by-encroachment. CMS simply misunderstands Subsection (t)(2)(F). Again, that subsection allows CMS to make adjustments to the conversion factor. 42 U.S.C. § 1395*l*(t)(9)(C). It is not a ticket to undermine Congress's statutory scheme, including abrogating Subsection (t)(21)(C)'s excepted/non-excepted distinction. And CMS is bound by the statutory framework as written. Thus, the 2020 Final Rule is also *ultra vires* because it purports to override Congress's specific policy choice to permit grandfathered off-campus PBDs to continue to bill under the OPPS system.

II. VACATUR IS THE APPROPRIATE REMEDY.

As with the prior iteration of the Clinic Visit Policy, "[v]acatur and remand are the correct remedies." *Am. Hosp. Ass'n v. Azar*, 2019 WL 5328814, at *3 (D.D.C. Oct. 21, 2019). Indeed, the Government sought reconsideration of this part of the Court's previous order on just this ground, and the Court denied it. *Id.*

The D.C. Circuit has "made clear that '[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated.'" *Nat'l Min. Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989)). CMS's contrary assertion that "the

appropriate remedy would be to remand to the agency for further consideration without vacatur" fails to account for the magnitude of CMS's overreach. Gov. Br. at 11. This is particularly true in light of CMS's brazen decision to ignore the substance of this Court's prior decision and to "set the agency above the law." *Am. Hosp. Ass'n v. Azar*, 415 F. Supp. 3d 1, 5 (D.D.C. 2019). CMS cannot substantiate or justify this rule any more than it could the last, which is why it relies on the same grounds this Court rejected before. Any disruption due to vacatur is the fault of the Government for disregarding this Court's Order. Thus, the two-part standard for vacatur forecloses the open-ended remand CMS seeks. *See Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993).

CONCLUSION

For these reasons, and those in Plaintiffs' opening brief and their briefing in *AHA I*, this Court should grant summary judgment in Plaintiffs' favor, vacate the relevant portions of the Final Rule, enjoin CMS from enforcing the 2020 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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