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. 1:20-80

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

In September 2019, this Court issued a decision finding portions of the CMS rulemaking governing Medicare payments for hospital outpatient services for Calendar Year (CY) 2019 to be *ultra vires*, vacating those portions of the 2019 Final Rule. CMS filed a motion to modify the Court's order to permit remand without vacatur, which the Court denied. Notwithstanding this Court's rulings, CMS proceeded with a fresh rulemaking for CY 2020, in which it implemented the same payment rate reduction that this Court had already declared unlawful.

For the same reasons this Court articulated in vacating the relevant portions of the 2019 Final Rule, the payment reductions contemplated by the 2020 Final Rule contravene the clear statutory safeguards crafted by Congress to constrain CMS's authority. As this Court has already noted, CMS's decision to proceed with implementing payment reductions for CY 2020 even after this Court declared them unlawful "appears to set the agency above the law." *American Hospital Ass'n v. Azar*, No. 18-2841 (D.D.C.) (RMC) (*AHA I*), ECF No. 50 at 7. Plaintiffs request an expedient decision on summary judgment finding the 2020 Final Rule to be *ultra vires* for the same reasons as the 2019 Final Rule—especially since CMS has now recommenced paying hospital claims at the lower, unlawful payment rate in CY 2020.

FACTUAL BACKGROUND

The 2019 OPPS Final Rule

In July 2018, CMS issued a proposed rule that would reduce Medicare payments under the hospital outpatient prospective payment system (OPPS) for CY 2019, titled *Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs* (CY 2019 Proposed Rule). As relevant here, the agency proposed that the Medicare payment rate for certain clinic-visit services provided at excepted off-campus

provider based departments (PBDs) would be reduced to render it equal to the payment rate for services provided at *non*-excepted off-campus PBDs. 83 Fed. Reg. 37,046, 37,142 (July 31, 2018). CMS estimated that this change—referred to as the "Clinic Visit Policy"—would result in a decrease in overall payments to hospitals under the OPPS by $760 million in CY 2019. *Id.* at 37,143.

The 2019 OPPS Final Rule was published in the Federal Register in November 2018. 83 Fed. Reg. 58,818 (Nov. 21, 2018). Like the Proposed Rule, the 2019 Final Rule adjusted the payment rate for services provided by excepted off-campus PBDs so that it was "equal to" the payment rate for services provided by non-excepted off-campus PBDs. *Id.* at 58,822, 59,013. However, in response to public comments, CMS announced that the payment reduction would now be phased in over a two-year period. 83 Fed. Reg. at 59,014.

This Court Vacates The Unlawful Portion of the 2019 OPPS Final Rule

Shortly after publication of the 2019 OPPS Final Rule, Plaintiffs filed a lawsuit, challenging the agency's site neutral payment policy as unlawful. Following cross-motions for summary judgment, this Court held the Clinic Visit Policy to be *ultra vires* and vacated that portion of the 2019 Final Rule.

In its 2019 Opinion, this Court recognized that the Clinic Visit Policy is "manifestly inconsistent" with the OPPS crafted by Congress. *AHA I*, ECF No. 31 at 19. In order to sidestep the budget neutrality requirement of 42 U.S.C. § 1395*l*(t)(9)(B), CMS purported to have developed a "method for controlling unnecessary increases in the volume of covered OPD services" under 42 U.S.C. § 1395*l*(t)(2)(F). But this Court appropriately found that this purported "method" was in reality "a selective cut to Medicare funding which targets only certain services and providers"—in other words, a "price-setting tool." *AHA I*, ECF No. 31 at

17.[1] That was (and is) unlawful, for two main reasons. First, the Court explained that given the number of tools that Congress gave to CMS as the "base ingredients of an Outpatient Prospective Payment System payment over which CMS has discretion," such as wage adjustments and the generally applicable conversion factor, the not-similarly-included "method" provision in subsection (t)(2)(F) "cannot affect" those payment-rate factors "directly" in a non-budget-neutral fashion. *Id.* at 19–22. As the Court noted, "CMS cannot shoehorn a 'method' into the multi-faceted congressional payment scheme when Congress's clear directions lack any such reference." *Id.* at 20. Second, CMS's expansive interpretation of the term "method" as used in a "single sentence" to allow the agency, at its sole discretion, to make virtually unlimited payment cuts that are both targeted and non-budget-neutral would be similarly inconsistent with the "great detail" and "granularity" in Congress's "extraordinarily detailed scheme" governing relative payment weights across different covered services. *Id.* at 22–26.

Following the Court's decision vacating portions of the 2019 Final Rule, CMS moved to modify the Court's order and/or to stay its effect. The Court denied that motion, concluding that "vacatur was appropriate and that a stay was not." *See AHA I,* Orders, ECF No. 39 (Oct. 21, 2019) and ECF No. 50 (Dec. 16, 2019). The Government has appealed to the D.C. Circuit, and briefing is under way.

CMS Readopts The Clinic Visit Policy In The 2020 Final Rule

While Plaintiffs' lawsuit challenging the 2019 Final Rule was still pending in this Court, CMS issued its proposed OPPS rule for CY 2020. 84 Fed. Reg. 39,398 (Aug. 9, 2019). Cross-referencing the basis given in the 2019 Final Rule and with little further elaboration, the agency

[1] This Court also rejected the Government's argument that judicial review of the Clinic Visit Policy was precluded under 42 U.S.C. § 1395l(t)(12)(A). *See AHA I*, ECF No. 31 at 14.

announced that "CY 2020 will be the second year of the 2-year transition of this policy" instituted in 2019. 84 Fed. Reg. 39,512–513.

CMS published the 2020 Final Rule in November 2019, almost two months after this Court vacated the agency's 2019 Final Rule in relevant part. 84 Fed. Reg. 61,142 (Nov. 12, 2019). Rather than retreating from its *ultra vires* conduct, CMS doubled down by completing the two-year phase-in contemplated by the 2019 Final Rule. In response to comments reiterating that the agency lacked statutory authority to implement the rule, the agency asserted: "We respectfully disagree with the district court and continue to believe the Secretary has the authority to address unnecessary increases in the volume of outpatient services." 84 Fed. Reg. 61,142. Once the 2020 Final Rule became effective in January, CMS began paying hospitals at the lower payment rate contemplated by the 2020 Final Rule.

Absent Judicial Relief, Plaintiffs Will Suffer Concrete and Imminent Harm

The 2020 Final Rule became effective on January 1, 2020. The Plaintiff-Hospitals and the members of the American Hospital Association and Association of American Medical Colleges have already begun to feel the effects of CMS's patently *ultra vires* conduct—and are suffering under the even steeper payment cut in CY 2020. Many hospitals rely heavily on the structure of Medicare payments established by Congress to provide critical outpatient services for the vulnerable populations in their communities, many of whom have been historically underserved. AHA Decl. ¶ 8; Declaration of Janis M. Orlowski (AAMC Decl.) ¶ 6; Declaration of Eric Lewis (Olympic Decl.) ¶¶ 9–14; Declaration of Kristi K. Nagengast (Mercy Decl.) ¶¶ 7–8; Declaration of Jud Knox (York Decl.) ¶ 7. By reducing the payment rate for covered services provided at excepted off-campus PBDs, the Final Rule will force serious payment reductions on affected hospitals, which in turn may cause those hospitals to make difficult decisions about

whether to reduce services. *See, e.g.*, AHA Decl. ¶¶ 9-10; AAMC Decl. ¶ 6; Olympic Decl. ¶¶ 9–14; Mercy Decl. ¶¶ 7–9. By CMS's own estimate, this amount will now total approximately $800 million in CY 2020. 84 Fed. Reg. 61,369. This payment reduction is particularly troubling for hospitals already operating at low or negative margins. AHA Decl. ¶ 10; Olympic Decl. ¶¶ 8–14; Mercy Decl. ¶¶ 7–8.

ARGUMENT

This Court has already held that CMS's conduct here is unlawful.[2] As it noted in rejecting the identical payment cut for CY 2019: "The Court finds that the 'method' developed by CMS to cut costs is impermissible and violates its obligations under the statute. While the intention of CMS is clear, it would acquire unilateral authority to pick and choose what to pay for OPD services, which clearly was not Congress' intention." *See AHA I*, ECF No. 31 at 26. The 2020 Final Rule, which rests on the same legal footing, is fatally flawed for the same reasons.

I. THE FINAL RULE EXCEEDS CMS'S AUTHORITY BECAUSE THE CLINIC VISIT POLICY IS NOT BUDGET NEUTRAL.

First, the Final Rule is *ultra vires* because the Clinic Visit Policy is not budget neutral, in plain violation of the statute. If CMS wishes to make changes to the payment rate for individual OPD services, it must do so "in a budget neutral manner." 42 U.S.C. § 1395l(t)(9)(B). Conversely, if CMS wishes to reduce Medicare costs by cutting payment rates to address "unnecessary increases in the volume of services," it must do so across-the-board, to all covered services. *Id.* §§ 1395(t)(2)(F), 1395l(t)(9)(C). By requiring budget neutrality for payment reductions targeting only specific services, the statute recognizes—and puts a check on—any

[2] Given the unusual nature of this case, in which CMS relied in a new rulemaking on an already-rejected theory of its authority, Plaintiffs incorporate by reference the materials submitted in support of their challenge to the 2019 Final Rule. *See AHA I*, ECF Nos. 14, 22 & 23.

incentive for CMS to employ draconian cost-control measures that target only certain service providers.

In an effort to sidestep the statutory requirement that annual adjustments be budget neutral, CMS has claimed that its authority to adopt the Clinic Visit Policy flows *not* from the annual adjustment authority granted in Subsection (t)(9)(A), but instead from the agency's separate statutory authorization under Subsection (t)(2)(F) to develop a "method" for controlling unnecessary increases in the volume of services covered under the OPPS. *See* 83 Fed. Reg. 59,011. CMS purports to ground the Clinic Visit Policy in Subsection (t)(2)(F) for a strategic purpose: that provision, unlike the rest of Subsection (t), makes no express mention of budget neutrality. For good reason, though. Subsection (t)(2)(F) does not need to address budget neutrality because it does not actually authorize the agency to make any adjustments or changes to payment rates at all. Instead, it merely authorizes CMS to "*develop a method* for controlling unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395l(t)(2)(F) (emphasis added). Another statutory provision then governs how that method may be *used* in actual volume-control efforts.

Specifically, Subsection (t)(9)(C) addresses what CMS should do if it wants to cut payment rates based on a finding under Subsection (t)(2)(F) that there are unnecessary increases in the volume of services: "If the Secretary determines *under the methodologies described* in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately *adjust the update to the conversion factor* otherwise applicable in a subsequent year." *Id.* § 1395l(t)(9)(C) (emphases added). The conversion factor, which is updated annually by CMS, is "calculated by use of a complex formula that takes into account the overall state of the economy of the United

States, the number of Medicare beneficiaries, the amount of money spent in prior years, and changes in the regulations governing covered services." *See* D.J. Seidenwurm & J.H. Burleson, *The Medicare Conversion Factor*, 35 Am. J. Neuroradiology 242, 242–243 (2014).[3] The conversion factor applies broadly to affect payments for *all* covered services under the OPPS. 42 U.S.C. § 1395l(t)(2)(C) and (D). As such, it cannot be used to change the relative payment rates between and among individual services.

CMS's "far-fetched" understanding of its authority under Subsection (t)(2)(F) is possible only "through an unintuitive, creative reading" of the statutory framework that would require this Court to assume, contrary to the text and purpose of these provisions, that when Congress "expressly spelled out" how CMS could make selective cuts in Subsection (t)(9)(A), it nevertheless implied a directly contrary power by remaining "utterly silent" in Subsection (t)(2)(F). *Philip Morris USA Inc. v. United States Food & Drug Admin.*, 202 F. Supp. 3d 31, 52 (D.D.C. 2016). Had Congress meant to construct "a backdoor means" around the budget-neutrality limitation, however, one "would expect to see some affirmative indication" that it intended to do so. *Czyzewski v. Jevic Holding Corp.*, 137 S. Ct. 973, 984 (2017).

While the statute is clear on its face, it is nonetheless noteworthy that the legislative history supports its plain meaning. Subsection (t) was added to the statute by the Balanced Budget Act of 1997. The associated conference report explains that, under Subsection (t):

> The Secretary would be authorized to periodically review and revise the groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, medical technology, the addition of new services, new cost data, and other relevant information. Any adjustments made by the Secretary would be made in a budget neutral manner. *If the Secretary determined that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary would be*

[3] *Available at* https://bit.ly/2DFJhyp.

> *authorized to adjust the update to the conversion factor otherwise applicable in a subsequent year.*

Balanced Budget Act of 1997, H.R. Rep. No. 105-217, at 784 (Conf. Rep.) (emphasis added).

And of course, as this Court has noted, the agency's position also is inconsistent with the statutory scheme as a whole. "CMS cannot shoehorn a 'method' into the multi-faceted congressional payment scheme when Congress's clear directions lack any such reference." *AHA I*, ECF No. 31 at 20. In addition, CMS's expansive interpretation of the term "method" to allow the agency, at its sole discretion, to make virtually unlimited payment cuts that are both targeted and non-budget-neutral is similarly inconsistent with the "great detail" and "granularity" in Congress's "extraordinarily detailed scheme" governing relative payment weights across different covered services. *Id.* at 22–26.

Finally, lest there be any remaining doubt, CMS has effectively admitted the limitations of Subsection (t)(2)(F) in the past. For example, in 1998, CMS acknowledged that "possible legislative modification" would be necessary before it could use its authority under Subsection (t)(2)(F) to adopt measures that would implement adjustments other than those to the conversion factor. 63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998). Similarly, in 2001, CMS implicitly acknowledged that the agency's options for implementing adjustments based on a finding under Subsection (t)(2)(F) were limited to updates to the conversion factor. 66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2001) ("[S]ection 1833(t)(2)(F) requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient services, and section 1833(t)(9)(C) authorizes the Secretary to adjust the update to the conversion factor if the volume of services increased beyond the amount established under section 1833(t)(2)(F).").

Both admissions are telling, and undermine any claim to deference that the Government might make. *See, e.g.*, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

II. THE FINAL RULE ERASES THE STATUTORY DISTINCTION BETWEEN EXCEPTED AND NON-EXCEPTED OFF-CAMPUS PBDs.

The Final Rule also separately is *ultra vires* because it sets the same payment rate for clinic visit services provided at both excepted and non-excepted off-campus PBDs, in violation of Congress's statutory command. Specifically, the Final Rule provides that the payment rate for services furnished at excepted off-campus PBDs will be adjusted so that it would be equal to the payment rate for services provided at non-excepted off-campus PBDs. 84 Fed. Reg. 61,369.

But the Medicare statute requires CMS to pay excepted and non-excepted off-campus PBDs differently for clinic visit services. The statute creates two distinct categories of off-campus PBDs: excepted entities, which satisfy certain grandfathering requirements, and non-excepted entities. *See* 42 U.S.C. § 1395l(t)(21). Congress created that distinction in order to fashion a grandfather provision for excepted off-campus PBDs, allowing entities that had been billing before November 2015 to continue billing under the OPPS, while non-excepted entities would be subject to a different payment system (later determined by CMS to be the Medicare Physician Fee Schedule). *See id*. § 1395l(t)(21)(C); H.R. Rep. No. 114-604, at 10 (2016).

Congress necessarily understood and clearly intended that these separate payment *systems* would entail separate payment *rates*. Indeed, the only logical reason for mandating that the two classes of off-campus PBDs be subjected to different billing systems was to ensure that different payment rates would apply.[4] CMS itself has effectively acknowledged as much by

[4] It is notable that when Congress amended Section 603 in 2016, a Conference Report described the "practical effect" of Section 603 as follows: "new off-campus PBD HOPDs would be eligible for only physician fee schedule or ambulatory surgical center payment rates rather than the higher hospital outpatient payment rate." H.R. Rep. No. 114-604, at 10 (2016).

requiring non-excepted off-campus PBDs to continue to bill through the OPPS billing system (notwithstanding the plain language of the statute) and instead using a "PFS Relativity Adjustor," to approximate what the rate of payment "would have been" if the item or service were actually paid under the Physician Fee Schedule. *See generally* 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016); *see also* 83 Fed. Reg. 59,009.

Moreover, from a statutory interpretation standpoint, it would be implausible to suppose that the statutory distinction between excepted and non-excepted off-campus PBDs is meaningless. *See Independent Ins. Agents of America, Inc. v. Hawke*, 211 F.3d 638, 644 (D.C. Cir. 2000) ("all words in a statute are to be assigned meaning, and . . . nothing therein is to be construed as surplusage"). Put simply: Had Congress intended to allow CMS to treat excepted and non-excepted off-campus PBDs the same, it would have drawn no statutory distinction between these entities at all. And yet it did.

CONCLUSION

Like the Clinic Visit Policy set forth in the 2019 Final Rule, the Clinic Visit Policy set forth in the 2020 Final Rule is *ultra vires* because CMS has, again, exceeded its statutory authority. This Court should again grant summary judgment in favor of Plaintiffs, 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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