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 **ORAL HEARING REQUESTED**

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 7(h), Plaintiffs the American Hospital Association, the Association of American Medical Colleges, Mercy Health Muskegon, Olympic Medical Center, and York Hospital respectfully request that this Court enter summary judgment in Plaintiffs' favor because, in promulgating the "Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs" Final Rule for Calendar Year 2019 (Final Rule), the Centers for Medicare & Medicaid Services (CMS) far exceeded the scope of the powers delegated to the agency by Congress.

CMS's conduct is *ultra vires* for two central reasons. *First*, the Medicare statute mandates that changes to payments for covered hospital outpatients services that target only specific items or services must be budget neutral. 42 U.S.C. § 1395l(t)(9)(B). And yet the Final

Rule purports to do precisely what Congress expressly prohibited: CMS seeks to reduce total payments for covered hospital outpatient services by hundreds of millions of dollars per year by targeting a select group of services (*i.e.*, clinic visit services at excepted off-campus provider-based departments) for *non-budget-neutral* payment adjustments. CMS cannot exercise its limited authority in a manner so flagrantly inconsistent with the Medicare statute.

Second, in the Medicare statute, Congress has laid out a clear distinction between "excepted" off-campus provider-based departments, which meet specified grandfathering requirements, and "non-excepted" off-campus provider-based departments, which do not. The statute makes clear that services provided at excepted and non-excepted off-campus provider-based departments should be paid pursuant to different payment systems. 42 U.S.C. § 1395l(t)(21)(C). And yet the Final Rule effectively abolishes any distinction between excepted and non-excepted entities by subjecting them both to the same payment system and rate. That violates the clear intent of Congress and therefore is *ultra vires*.

For these reasons, and those set forth more fully in the accompanying Memorandum in Support, which is incorporated herein by reference, this Court should grant Plaintiffs' motion for summary judgment. Pursuant to Local Rule 7(f), Plaintiffs further request an oral hearing on this motion, given the importance of this issues and the complexity of the underlying regulatory scheme. A proposed order accompanies this motion.

Respectfully submitted,

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Dated: February 1, 2019

CERTIFICATE OF SERVICE

I certify that on February 1, 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

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

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

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INTRODUCTION

Administrative agencies may act only within the constraints of the legislative authority delegated to them by Congress. And where Congress has specifically constrained an agency's authority, agencies may not take action in excess of their statutory power. These are basic tenets of administrative law. The Centers for Medicare & Medicaid Services (CMS) has run afoul of these core principles by cutting certain Medicare payments in clear violation of statutory limits on the agency's power.

On November 21, CMS published in the Federal Register a Final Rule making changes to Medicare payment rates for outpatient services for Calendar Year (CY) 2019. As relevant here, the Final Rule reduces the payment rates for certain clinic-visit services provided at hospital outpatient practice locations known as "off-campus provider-based departments" (off-campus PBDs). Off-campus PBDs are practice locations of a hospital that are not located in immediate proximity to the main building of their affiliated hospital, but are nonetheless so closely integrated with and controlled by the main hospital as to be considered a part of the hospital.

In 2015, Congress amended the Medicare statute to provide that outpatient services furnished at off-campus PBDs would be subject to a separate payment system than the one governing hospitals. However, Congress recognized that this change would unsettle the expectations of off-campus PBDs that were already billing under the hospital payment system. So Congress struck a compromise: Qualifying off-campus PBDs that were already billing under the hospital payment system (so-called "excepted PBDs") would be excepted from the new payment system. But going forward, Congress required that *newly* created or acquired off-campus PBDs (so-called "non-excepted PBDs") be paid under a different payment system, resulting in lower payment rates to those hospitals.

CMS apparently thinks otherwise. In the Final Rule, CMS announced its decision to reduce overall Medicare payments for hospital outpatient services. The agency accomplished this goal *not* by making across-the-board cuts to all payment rates for outpatient services—the only mechanism the Medicare statute contemplates for non-budget-neutral payment cuts for outpatient services—but instead by making selective cuts to the payment rates for particular services. Specifically, CMS cut the payment rate for clinic visit services provided by *excepted* PBDs so that they are now equal to the (lower) payment rate for *non-excepted* PBDs.

The payment reductions contemplated by the Final Rule contravene the clear statutory safeguards Congress crafted to constrain CMS's authority. In short: They are *ultra vires*.

CMS has exceeded the boundaries of its delegated authority in two major ways. First, the Final Rule is unlawful because it is not budget neutral. Congress has established a clear structure for CMS to make annual changes to payments for covered hospital outpatient services under Medicare. 42 U.S.C. § 1395l(t)(9)(A). Changes to payments that target only specific items or services must be budget neutral. *Id.* § 1395l(t)(9)(B). And yet the Final Rule purports to do precisely what Congress expressly prohibited: CMS seeks to reduce total payments for covered hospital outpatient services by hundreds of millions of dollars per year by targeting a select group of services (*i.e.*, clinic visit services at excepted PBDs) for *non-budget-neutral* payment adjustments. CMS cannot exercise its limited authority in a manner so flagrantly inconsistent with the Medicare statute.

Second, by subjecting excepted and non-excepted PBDs to the exact same payment system and payment rate, the Final Rule abolishes the statutory distinction between those two entities. Congress intentionally created two classes of off-campus PBDs: excepted and non-excepted ones, with the clear expectation that they would be paid differently for performing

outpatient services. Indeed, the only logical purpose for creating the two categories of entities was to grandfather excepted PBDs into the higher payment system applicable to hospitals. CMS's attempt to override the statutory distinction between these two types of entities violates the clear intent of Congress and therefore is *ultra vires*.x

FACTUAL BACKGROUND

Statutory Framework

Title XVIII of the Social Security Act establishes a program of health insurance for the aged and disabled, commonly known as the Medicare Act. 42 U.S.C. § 1395 *et seq*. The Medicare Act comprises four parts. Part B covers, among other things, hospital outpatient department services (OPD services), which are services that are provided to patients on an outpatient basis. OPD services include emergency or observation services; services furnished in an outpatient setting (*e.g.*, physician visits, same-day surgery); laboratory tests billed by the hospital for outpatients; medical supplies (*e.g.*, splints and casts); preventive and screening services; and certain drugs and biologicals.

Medicare payments for OPD services are generally made under the Outpatient Prospective Payment System (OPPS), governed by 42 U.S.C. § 1395l(t). Congress specified the framework under which CMS was required to establish the OPPS in Subsections (t)(2)(A) through (H). Congress also authorized CMS to review and revise, on an annual basis, the "groups, the relative payment weights, and the wage and other adjustments" related to covered OPD services "to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* § 1395l(t)(9)(A).

The Medicare statute sets clear limits on these annual adjustments. Those limits include the one at issue here: any such adjustments must be budget-neutral. Specifically, Congress

mandated: "[T]he adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made." 42 U.S.C. § 1395l(t)(9)(A). That is a mouthful, but its meaning is plain: Any adjustments under Subsection (t)(9)(A) must be budget neutral, and CMS may not reduce the total amount of Medicare Part B spending by selectively slashing the payment rates for specific types of services.

If CMS wishes to make *non*-budget-neutral cuts to payments under the OPPS, the statute provides a separate mechanism for the agency to do so, with clear limits on both when and how that non-budget-neutral authority could be exercised. First, the statute 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). Only after the agency develops that method, another statutory provision authorizes CMS to make non-budget-neutral changes to address the unnecessary increases in volume—but even then only through an across-the-board adjustment to all items or services paid under the OPPS.

Specifically, Subsection (t)(9)(C) provides that if CMS determines under Subsection (t)(2)(F) that the "volume of services … [has] increased beyond amounts established through those methodologies," CMS "may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." *Id.* § 1395l(t)(9)(C). The conversion factor, which is updated annually, is a uniform amount that is used in the formula to calculate payment rates for *all* services or items paid under the OPPS. *Id.* § 1395l(t)(3)(C), (D). In other words, an adjustment to the conversion factor can shrink (or grow) the entire OPPS by a percentage-factor, but it cannot reduce the relative rate of payment for a particular set of services or items.

The upshot of Congress's chosen statutory structure is clear: If CMS wants to reduce outlays under OPPS, it must cut payments across the board, for all OPPS services and items, by lowering the conversion factor. In other words, if CMS wants to reduce the size of the pie, each slice can be made slightly smaller. If CMS instead wants to reduce payment for specific services (*i.e.*, to slice the pie differently), it must do so in a budget-neutral manner, by increasing payments for other services so that the pie remains the same size. But CMS *cannot* do both at the same time. In this way, the statute's structure prevents CMS from engaging in cost-control measures that will have a disproportionate impact on only some service providers and beneficiaries.

Off-Campus Provider-Based Departments

At issue in this lawsuit are Medicare payments for certain clinic-visit services provided by off-campus PBDs. As previously noted, off-campus PBDs are practice locations of a hospital that are not in immediate proximity to the main building of their affiliated hospital, but are nonetheless so closely integrated with and controlled by that hospital as to be considered a part of the hospital. *See* 42 C.F.R. § 413.65(e). An off-campus PBD may serve a range of critical healthcare functions and take various forms, including a stand-alone oncology clinic, an urgent care clinic, or a physician practice providing necessary specialty services (*e.g.*, cardiology, pulmonology, neurology, and urology).

Off-campus PBDs provide several unique advantages to patients and allow hospitals to better serve their communities. In some cases, there may be operational reasons for using an off-campus PBD. For example, a hospital might want to place an off-campus PBD in a location that is convenient to an under-served patient population. In other cases, a hospital may lack the space on its main campus to expand, and an off-campus PBD is opened as a matter of necessity. In

rural and other traditionally underserved areas of the country, allowing hospitals to expand their capabilities through off-campus PBDs often means that patients have access to care that they otherwise would not. *See generally* Declaration of Joanna Hiatt Kim (AHA Decl.) ¶ 10.

By law, off-campus PBDs must be integrated with their main hospitals and are subject to the same regulatory requirements as the hospital—unlike independent clinics or physician offices. *See* 42 C.F.R. § 413.65 (describing detailed regulatory requirements for off-campus facilities). As a result, off-campus PBDs typically have higher costs relative to a physician office. There are many reasons for this: The patient population that depends on the care provided at off-campus PBDs tends to be sicker and poorer than the patient population that visits independent physician offices.[1] In addition, CMS regulations require that off-campus PBDs comply with the same Medicare Conditions of Participation governing their affiliated hospital. These requirements are more demanding than those for physician offices and clinics.[2] Moreover, off-campus PBDs serve a greater number of functions than do standalone physician offices, providing advantages in the care for patients.

Section 603 of the Bipartisan Budget Act of 2015

Until November 2015, clinic-visit services at all off-campus PBDs were paid under the OPPS, at the relatively higher payment rates paid to hospitals (as compared to the rates for their physician-office counterparts). 83 Fed. Reg. 59,004–05 (Nov. 21, 2018). The total volume of outpatient services furnished at off-campus PBDs nationwide has been increasing for years, since at least 2010. *Id.* at 59,005–007. Much of that increase in volume has been necessary and

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[1] *See* Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices (KNG Health Consulting LLC, 2018), *available at* https://bit.ly/2Ed4Iaf.

[2] *See generally* Hospital Outpatient Department (HOPD) Costs Higher Than Physician Offices Due to Additional Capabilities, Regulations (AHA, 2014), *available at* https://bit.ly/2DnkFtb.

appropriate. The Medicare-eligible population as a whole has increased during that same time period, imposing greater demands for OPD services. *See* Medicare Board of Trustees, *2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* 181 (2018) (increase of approximately 9.5 million Medicare Part B enrollees from 2010 to 2017 alone).[3] In addition, medical technology has advanced in parallel with these demographic changes, enabling more and more services to be provided on an outpatient (rather than an inpatient) basis. *See* Ken Abrams, Andreea Balan-Cohen & Priyanshi Durbha, *Growth in Outpatient Care*, Deloitte (Aug. 15, 2018).[4]

In addition, however, one of the many factors contributing to the increase in volume of outpatient services furnished at off-campus PBDs was the acquisition of standalone physician offices by some hospitals, and the subsequent integration of those physician offices into hospital operations. *See* 83 Fed. Reg. 59,005–007. That phenomenon had the effect of shifting some services that otherwise would have been provided in the physician office setting to the off-campus PBD setting. 83 Fed. Reg. 59,008. CMS has long taken the view that Medicare costs could be lowered if outpatient services performed by off-campus PBDs were instead furnished in the generally less-expensive setting of a physician's office. *See id.* The agency has contended that off-campus PBDs should therefore be treated the same as physician offices and paid under the Medicare Physician Fee Schedule (PFS) rather than the OPPS. *See id.* In response, commenters pointed out that off-campus PBDs typically have higher costs than physician offices (in some cases even exceeding the Medicare payment rate for such services) and that off-campus PBDs are often able to provide services that are not available in physician offices. Critics of CMS's position also noted that paying off-campus PBDs at the lower rates paid to physician

[3] *Available at* https://go.cms.gov/2JottiO.
[4] *Available at* https://bit.ly/2nOkG05.

offices would upset the reasonable expectations of hospitals that acquired or built off-campus PBDs, and conformed those hospital-affiliated departments with rigorous and detailed regulatory requirements, with the understanding that they would be paid under the OPPS.[5]

Congress sought to address these competing concerns when it enacted Section 603 of the Bipartisan Budget Act of 2015. Pub. L. No 114-74 § 603, 129 Stat. 584, 598. Its solution was to create two classes of off-campus PBDs. Qualifying off-campus PBDs that were billing as hospital departments under the OPPS when the Act became law on November 2, 2015 (referred to as "excepted PBDs") would continue to be paid under the OPPS. *See* 42 U.S.C. §§ 1395l(t)(1)(B)(V), (t)(21) & (t)(21)(B)(ii). But going forward, Congress required that *newly* created or acquired off-campus PBDs (referred to as "non-excepted PBDs") be paid under the "applicable payment system" in order to eliminate the possibility that a payment differential would motivate a hospital's decision to open a new off-campus PBD. *Id.* § 1395l(t)(21)(C); *see also id.* § 1395l(t)(21)(B)(iii)–(vi) (codifying additional exceptions, such as allowing off-campus PBDs that were mid-build when Section 603 was enacted to continue to be paid under the OPPS).

CMS has since interpreted the statutory phrase "applicable payment system" to mean that non-excepted PBDs should be paid under the Medicare Physician Fee Schedule. 81 Fed. Reg. 79,562, 79,659 (Nov. 14, 2016). The Physician Fee Schedule has lower payment rates relative to OPPS because it is intended to reflect the costs for furnishing items or services in a physician

[5] *Cf.* Letter from the Honorable Rob Portman, Senator, United States Senate, et al. to Seema Verma, Administrator, Centers for Medicare & Medicaid Services (Sept. 28, 2018) ("In passing Section 603, Congress was clear in its intention to grandfather existing facilities, so that only new off-campus sites would have payments reduced."), *available at* https://bit.ly/2R9yOle.

office as opposed to in a hospital.[6] Thus, the payment rates for excepted PBDs (under the OPPS) are generally higher than non-excepted PBDs (under the Physician Fee Schedule). 83 Fed. Reg. 59,008.

In practice, CMS does not actually abide by the statutory requirement to pay non-excepted PBDs under a separate payment system from OPPS. Rather, CMS continues to pay such non-excepted PBDs under the OPPS but applies a "PFS Relativity Adjustor," which CMS says is intended 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.

The Final Rule

Against this backdrop, on July 31, CMS issued a Proposed Rule proposing changes to the OPPS for Calendar Year 2019, titled "Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs." As relevant here, CMS proposed that the payment rate for certain clinic-visit services provided at *excepted* PBDs be reduced to render it equal to the payment rate for services provided at *non*-excepted PBDs (referred to as the Clinic Visit Policy). 83 Fed. Reg. 37,046, 37,142 (July 31, 2018). Specifically, the Proposed Rule provided that the payment rate for clinic services furnished by excepted off-campus PBDs in CY 2019 "would now be equivalent to the payment rate for" services provided by non-excepted off-campus PBDs. *Id.* CMS estimated that this change would result in a decrease in overall payments to hospitals under the OPPS by $760 million in CY 2019 *alone*. *Id.* at 37,143. But CMS maintained that it had the authority to make this

[6] *See* 83 Fed. Reg. 59,006–008 (citing MedPAC, Report to the Congress: Medicare Payment Policy (Mar. 2018), *available at* https://bit.ly/2FNItVG).

equalizing adjustment in a non-budget-neutral fashion—that is, without an off-setting increase in payment rates for other OPPS services. *Id.* at 37,142.

Almost 3,000 commenters submitted comments in response to the Proposed Rule, including Plaintiffs AHA and AAMC. Among other things, Plaintiffs pointed out that CMS lacks the statutory authority to adjust payment rates in a non-budget-neutral manner under 42 U.S.C. § 1395l(t)(9)(B). Plaintiffs also explained that the Proposed Rule ran afoul of Congress's statutory mandate that CMS treat excepted and non-excepted off-campus PBDs differently.

The Final Rule was published in the Federal Register on November 21. 83 Fed. Reg. 58,818. Like the Proposed Rule, the Final Rule adjusts the payment rate for services provided by excepted PBDs so that it is "equal to" the payment rate for services provided by non-excepted PBDs. *Id.* at 58,822, 59,013. CMS also confirmed its decision to implement the adjustment in a non-budget neutral fashion, targeting only a select group of services. *Id.* at 59,014. However, CMS announced that it would be phasing in the payment reduction over a two-year period; in the first year, CY 2019, the estimated reductions in payments to hospitals would be approximately $380 million. *Id.* Around the same time it announced the Final Rule, CMS issued a press release stressing that the Final Rule would result in "lower costs" and "an estimated amount of $380 million" in "savings for the Medicare program" overall.[7]

Absent Judicial Relief, Plaintiffs Will Suffer Concrete and Imminent Harm

The Final Rule became effective on January 1, 2019. The Plaintiff-Hospitals and the Plaintiffs AHA's and AAMC's members have already begun to feel the effects of CMS's patently *ultra vires* conduct. Many hospitals rely heavily on the structure of Medicare payments

[7] Press Release, *CMS Finalizes Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System changes for 2019 (CMS-1695-FC)*, CMS.Gov (Nov. 2, 2018), *available at* https://go.cms.gov/2CW9jw6.

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.) ¶¶ 4, 9–14; Declaration of Kristi K. Nagengast (Mercy Decl.) ¶ 8; Declaration of Jud Knox (York Decl.) ¶¶ 4, 7. By reducing the payment rate for covered services provided at excepted 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; AAMC Decl. ¶ 6; Olympic Decl. ¶¶ 9–14; Mercy Decl. ¶¶ 7–9. By CMS's own estimate, this amount will total approximately $380 million in CY 2019 alone. 83 Fed. Reg. 59,014. This payment reduction is particularly troubling for hospitals already operating at low or negative margins. AHA Decl. ¶ 10; Olympic Decl. ¶¶ 8–14; Mercy Decl. ¶ 8.

For all of these reasons, affected hospitals and the vulnerable patients and communities they serve face concrete and imminent harms—both economic and noneconomic—if CMS's Final rule is allowed to stand.

ARGUMENT

It is a fundamental principle of administrative law that federal agencies may not act unless authorized to do so by Congress. "Under our system of government, Congress makes laws and the President, acting at times through agencies . . . 'faithfully execute[s]' them." *Utility Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2445 (2014) (*citing* U.S. Const., art. II, § 3). In keeping with this constitutional principle, federal agencies may promulgate rules only to the extent authorized to do so by Congress. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."); *Lyng v. Payne*, 476 U.S. 926,

937 (1986) ("an agency's power is no greater than that delegated to it by Congress"). Federal agencies similarly lack the authority to override Congress's clear commands. *See Utility Air*, 134 S. Ct. at 2445 ("An agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.").

When a federal agency acts in blatant excess of its statutory authority, that action is *ultra vires* and should be vacated. *See, e.g.*, *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1168 (D.C. Cir. 2003) (agency action is *ultra vires* when it "exceed[s] the agency's delegated authority under the statute."); *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988) (agency violation of "clear and mandatory" statutory provision is *ultra vires*). *See also Leedom v. Kyne*, 358 U.S. 184, 188 (1958) (recognizing a cause of action where plaintiff is not merely seeking "review" of agency decision made within its jurisdiction but rather "to strike down" agency action "made in excess of its delegated powers and contrary to a specific prohibition" in the statute). CMS's conduct here easily meets this standard.

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

First and foremost, the Final Rule is *ultra vires* because the Clinic Visit Policy is not budget neutral, in plain violation of the statute. As a result, the Final Rule transgresses "the core administrative-law principle" that an agency lacks the authority to override Congress's commands. *See Utility Air*, 134 S. Ct. at 2446.

The Medicare statute makes clear that 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 incentive for CMS to employ draconian cost-control measures that target only certain service providers.

And yet the Final Rule announces cuts to the payment rates for specific services without creating any off-setting increases to other payment rates. By CMS's own admission, the Clinic Visit Policy set forth in the Final Rule would reduce total hospital payments by $380 million in CY 2019, with no offsetting increases in payments for other services. 83 Fed. Reg. at 59,014. But by reducing payment rates for selected services in a non-budget-neutral fashion, CMS flatly ignores "clear statutory terms to suit its own sense of how the statute should operate." *Utility Air*, 134 S. Ct. at 2446. It also reflects "an attempted exercise of power that had been specifically withheld." *Leedom v. Kyne*, 358 U.S. at 189. The Final Rule is therefore *ultra vires*.

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 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) (emphasis 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).[8] 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). *See Philip Morris USA Inc. v. United States Food & Drug Admin.*, 202 F. Supp. 3d 31,

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

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 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 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)."). CMS thus has acknowledged that changes to payment rates resulting from Subsection (t)(2)(F) must occur pursuant to an across-the-board change in the conversion factor. That is telling.

Contrary to CMS's present assertion, then, Subsection (t)(2)(F) does not confer authority to modify payment rates for specific items or services in response to unnecessary increases in the volume of OPD services. Rather, as noted above, if the methodology developed by CMS under Subsection (t)(2)(F) shows that there are unnecessary increases in the volume of OPD services, Congress has said in Subsection (t)(9)(C) that CMS's recourse is to modify the conversion factor and effectuate an across-the-board reduction in payment rates under the OPPS. And to state the obvious, in crafting the Clinic Visit Policy, CMS has not adjusted the conversion factor,[9] nor has it cut payment rates across-the-board. Instead, it has cut the payment rates for a targeted subset of services. In short, Subsection (t)(2)(F) is of no use to CMS in justifying the Final Rule.

II. THE FINAL RULE EXCEEDS CMS'S AUTHORITY BECAUSE IT ERASES THE STATUTORY DISTINCTION BETWEEN EXCEPTED AND NON-EXCEPTED 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 PBDs, in violation of Congress's statutory command. Specifically, the Final Rule provides that the payment rate for services furnished at excepted PBDs will be adjusted so that it would be "equal to" the payment rate for services provided at non-excepted PBDs. 83 Fed. Reg. 59,013.

[9] In fact, CMS has separately adjusted the conversion factor elsewhere in the Final Rule. *See* 83 Fed. Reg. 58,861.

But the Medicare statute requires CMS to pay excepted and non-excepted 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 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.[10] CMS itself has effectively acknowledged as much by requiring non-excepted 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 PBDs is meaningless and can

[10] While not dispositive of Congress's intent when crafting Section 603 in 2015, it is nonetheless notable that when Congress amended Section 603 through the 21 Century Cures Act 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).

simply be ignored. *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 PBDs the same, it would have drawn no statutory distinction between these entities at all. And yet it did.

By decreeing that excepted and non-excepted entities will not only be billed under the same payment system but now also be subject to the same payment *rate*, CMS has entirely abolished the statutory separateness put in place by the statute, performing an end-run around the congressional mandate. The agency lacks the authority to nullify the Medicare statute in this manner. Agencies are "bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes." *Colorado River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 466 F.3d 134, 139–140 (D.C. Cir. 2006).

CMS purports to justify its Clinic Visit Policy with a resort to policy arguments. The agency explains: "To the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another." 83 Fed. Reg. 59,008; *see also id.* at 58,823, 59,011. That may or may not be true as a matter of medical practice and regulatory policy—but it is not the solution that Congress chose. The Medicare Act reflects Congress's deliberate decision to treat excepted and non-excepted PBDs differently, and to grandfather excepted PBDs so that they would continue to receive payment at hospital rates rather than physician office rates. CMS does not have the authority to do away with that statutory distinction merely because it disagrees with Congress. Policy preferences do not "give the agency carte blanche to ignore the statute"

whenever the agency decides statutory "requirements aren't worth the trouble." *Waterkeeper All. v. EPA*, 853 F.3d 527, 535 (D.C. Cir. 2017).

To the contrary. When Congress dictates policy, agencies must follow that mandate. *See Utility Air.*, 134 S. Ct. at 2446 ("[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate."); *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 91 (2002) ("Regardless of how serious the problem an administrative agency seeks to address, . . . it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law.") (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000)). Whatever advantages CMS may believe inure to a different approach, it lacks the power to override its statutory mandate when Congress has already set the agency's course.

Because Congress established a clear division between excepted and non-excepted off-campus PBDs, CMS's attempt to override that statutory distinction by paying both entities the same rate is *ultra vires*.

CONCLUSION

The Clinic Visit Policy set forth in the Final Rule is *ultra vires* because CMS has exceeded the statutory authority delegated to the agency by Congress. This Court should grant Plaintiffs' Motion for Summary Judgment, 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 February 1, 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
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