IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, 800 Tenth Street, N.W., Suite 400 Washington, D.C. 20001, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, 655 K Street, N.W., Suite 100 Washington, D.C. 20001, MERCY HEALTH MUSKEGON, 1500 E. Sherman Boulevard Muskegon, MI 49444, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2, d/b/a OLYMPIC MEDICAL CENTER, 939 Caroline Street Port Angeles, WA 98362, YORK HOSPITAL, 3 Loving Kindness Way York, ME 03909, *Plaintiffs*, v. ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W. Washington, D.C. 20201, *Defendant*.	Civil Action No. 1:18-cv-2841

FIRST AMENDED COMPLAINT

Plaintiffs the American Hospital Association, Association of American Medical Colleges, Mercy Health Muskegon, Clallam County Public Hospital District No. 2, d/b/a Olympic Medical Center, and York Hospital bring this First Amended Complaint against Defendant Alex M. Azar II, in his official capacity as Secretary of Health and Human Services (HHS), and allege as follows:

PRELIMINARY STATEMENT

1. This is an action to challenge certain aspects of a final rule issued by the Centers for Medicare & Medicaid Services (CMS), an agency within HHS, published in the Federal Register on November 21. *See* Centers for Medicare & Medicaid Services, *Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, Dep't of Health and Human Servs., 83 Fed. Reg. 58,818 (Nov. 21, 2018) (Final Rule). The Final Rule, in relevant part, makes serious reductions to Medicare payment rates for certain clinic visit services provided at specified off-campus hospital provider-based departments (off-campus PBDs), commencing on January 1, 2019. 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.

2. In the Medicare statute, Congress has laid out a clear distinction between "excepted" off-campus PBDs, which meet specified grandfathering requirements, and "non-excepted" off-campus PBDs, which do not. The statute makes clear that services provided at excepted and non-excepted off-campus PBDs 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*.

3. Congress also 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 payment that target only specific items or services must be budget neutral. 42 U.S.C. § 1395l(t)(9)(B). And yet in an unprecedented assertion of the agency's authority, the Final Rule purports to do precisely what Congress has expressly prohibited: CMS seeks to reduce total payments for covered hospital outpatient services for calendar year (CY) 2019 by hundreds of millions of dollars by targeting a select group of services for non-budget-neutral payment adjustments. CMS cannot exercise its limited authority in a manner so flagrantly inconsistent with the Medicare statute. That, too, is textbook *ultra vires* action.

4. This Court should reject CMS's attempts to replace Congress's unequivocal directives with the agency's own policy preferences. CMS may not contravene clear congressional mandates merely because the agency wishes to make cuts to Medicare spending.

PARTIES

5. Plaintiff the American Hospital Association (AHA) is a national, not-for-profit organization headquartered in Washington, D.C. The AHA represents and serves nearly 5,000 hospitals, health care systems, and networks, plus 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, systems, and other related organizations that are accountable to the community and committed to health improvement. The AHA provides extensive education for health care leaders and is a source of valuable information and data on health care issues and trends. It also

ensures that members' perspectives and needs are heard and addressed in national health-policy development, legislative and regulatory debates, and judicial matters. The AHA has a principal place of business located at 800 Tenth Street, N.W., Suite 400, Washington, D.C. 20001.

6. Plaintiff Association of American Medical Colleges (AAMC) is a national, not-for-profit association based in Washington, D.C. The AAMC represents and serves all 152 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 83,000 medical students, and 110,000 resident physicians. The AAMC works to improve the nation's health by strengthening the quality of medical education and training, enhancing the search for biomedical knowledge, advancing health services research, and integrating education and research into the provision of effective health care. In addition, it is one of the AAMC's core missions to advocate on behalf of its members and patients in connection with national health-policy matters. The AAMC has a principal place of business located at 655 K Street, N.W., Suite 100, Washington, D.C. 20001.

7. Plaintiff Mercy Health Muskegon is a Catholic nonprofit hospital that serves the greater Muskegon, Michigan area and surrounding communities. Mercy Health Muskegon operates 27 off-campus PBDs, 25 of which are excepted PBDs. These include a sleep center, a comprehensive breast high risk clinic, specialty clinics (including neurosurgery, cardiology, geriatrics, and gastroenterology), and a number of primary care facilities capable of providing x-ray, laboratory, and pharmacy services in the same building. Mercy Health Muskegon furnishes outpatient services at these excepted off-campus PBDs and will suffer immediate and concrete harm from the outpatient service payment reductions set forth in the Final Rule. Mercy Health

Muskegon has its principal place of business at 1500 E. Sherman Boulevard, Muskegon, Michigan 49444.

8. Plaintiff Clallam County Public Hospital District No. 2, d/b/a Olympic Medical Center (Olympic Medical) is a comprehensive health care provider serving the North Olympic Peninsula with a network of facilities in Clallam County, Washington. Olympic Medical is a large rural hospital and health care center designated as a Sole Community Hospital and Rural Referral Center, and which operates as a safety-net hospital, employing over 100 physicians and advanced practice clinicians. Of Olympic Medical's patients, 83% rely on Government-paid insurance and 58.3% rely on Medicare. Olympic Medical furnishes outpatient services at eight excepted off-campus PBDs, including a specialty physician clinic offering cardiology, gastroenterology, pulmonary medicine, neurology, urology and women's health, a sleep center, a primary care clinic, a coagulation clinic, a walk-in clinic, a cancer center providing medical oncology services and radiation oncology services in Sequim, which is 17 miles from the main hospital campus, and a primary care clinic in Port Angeles which is approximately one mile from the hospital. Olympic Medical will suffer immediate and concrete harm from the outpatient service payment reductions set forth in the Final Rule. Olympic Medical has its principal place of business at 939 Caroline Street, Port Angeles, Washington 98362.

9. Plaintiff York Hospital (York) is a small community hospital located in York, Maine and serving the surrounding area. York is licensed for 79 beds, and currently has only 50 beds in operation. Founded in 1906, York is dedicated to giving back to its community: among other things, it provides support programs and services to schools, civic organizations, and non-profit groups, runs an opiate treatment facility, and offers transportation and food to patients

unable to afford them. Of York's patients, almost 54% rely on Medicare. York furnishes outpatient services at 12 excepted off-campus PBDs, including three oncology clinics and specialty clinics offering psychiatry, cardiovascular care, and gynecology care. York will suffer immediate and concrete harm from the outpatient service payment reductions set forth in the Final Rule. York has its principal place of business at 3 Loving Kindness Way, York, Maine 03909.

10. Defendant Alex M. Azar II, is the Secretary of HHS and is responsible for the conduct and policies of HHS, including those relating to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. The Secretary maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201, and is sued in his official capacity only.

JURISDICTION AND VENUE

11. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 28 U.S.C. § 1361, in that this is an action to compel officers of the United States to perform their duty; and 28 U.S.C. §§ 2201–2202, in that there exists an actual justiciable controversy as to which Plaintiffs require a declaration of their rights by this Court and injunctive relief to prohibit the Defendants from violating laws and regulations.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (e) because this is a civil action in which the Defendant is an officer of the United States acting in his official

capacity and maintains his office and conducts business in this judicial district. Moreover, a substantial part of the events giving rise to the claims occurred within this judicial district.

13. Plaintiffs have standing to bring this lawsuit because the Plaintiff-Hospitals and the AHA's and AAMC's members are suffering and face imminent actual injury as a result of CMS's *ultra vires* decision to reduce the payment rates for targeted services furnished at members' off-campus PBDs. This lawsuit seeks to vindicate interests that are germane to the AHA's and AAMC's purposes because a critical mission of both entities is to protect their members' interests in connection with policy changes initiated by CMS. The AHA's and AAMC's members use the Medicare payments at issue in this lawsuit to provide critical health care services and will suffer a concrete and imminent injury absent judicial relief.

14. This lawsuit is ripe for judicial review. Because Plaintiffs are alleging *only* that CMS is acting well beyond the agency's statutorily granted powers, this Court has the authority to review Plaintiffs' claims, and to do so now. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 114 (D.C. Cir. 2004); *American Hospital Ass'n v. Azar*, D.E. 25, No. 18-2084-RC (D.D.C. Dec. 27, 2018).

15. After the Final Rule became effective on January 1, 2019, the Plaintiff-Hospitals presented claims to their Medicare Administrative Contractors (MACs). The Plaintiff-Hospitals also specifically requested that they be paid pursuant to the higher hospital payment rates because the clinic visit policy set forth in the Final Rule is unlawful for the reasons specified herein. Nonetheless, the Plaintiff-Hospitals are being paid at the lower rates governed by the Final Rule, rather than the rates required by the Medicare Act. Statutory requirements relating to exhaustion are not applicable in the context of a non-statutory *ultra vires* challenge. In any

event, further administrative appeal or review of the Plaintiff-Hospitals' claims would be futile, both because CMS administrative adjudicators are bound by the Final Rule, and because CMS has refused to change its position in response to these very same legal arguments.

FACTUAL BACKGROUND

Statutory Framework

16. Title XVIII of the Social Security Act establishes a program of health insurance for the aged and disabled, commonly known as Medicare. 42 U.S.C. §§ 1395 *et seq*. The Plaintiff-Hospitals and many of Plaintiffs AHA's and AAMC's members qualify as providers of hospital services under Title XVIII, commonly known as the Medicare Act.

17. Part B of the Medicare Act 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 clinic (*e.g*., physician visits, same-day surgery), laboratory tests billed by the hospital, medical supplies (*e.g*., splints and casts), preventive and screening services, and certain drugs and biologicals.

18. Payments for OPD services are generally made under the Medicare Outpatient Prospective Payment System (OPPS) created pursuant to 42 U.S.C. § 1395l(t). The Medicare statute authorized CMS to establish the OPPS pursuant to requirements spelled out in 42 U.S.C. § 1395l(t)(2)(A) through (H).

19. The Medicare statute authorizes CMS, on an annual basis, to review and revise the "groups, the relative payment weights, and the wage and other adjustments . . . 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." 42 U.S.C. § 1395l(t)(9)(A).

20. But the Medicare statute sets clear limits on these annual adjustments, including the critical requirement that any such adjustments be budget neutral. Specifically, Congress mandated: "the 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). This is a mouthful, but its meaning is plain: Any adjustments under Subsection (t)(9)(A) must be budget neutral, and CMS may not reduce Medicare Part B spending by selectively slashing the payment rates for specific types of services.

21. When Congress confers authority on CMS to make non-budget neutral changes, it has said so expressly. *See, e.g.*, 42 U.S.C. § 1395l(t)(7)(I). Indeed, 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. 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). Once the agency identifies that method, another statutory provision authorizes the agency to make non-budget-neutral adjustments to address those unnecessary increases in volume – but only through across-the-board adjustments 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 is a uniform amount that is used in the formula to calculate payment rates for *all* services or items paid under the OPPS. In other words, a conversion factor adjustment 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.

22. The implications for CMS are clear: If CMS wants to make cuts to payment rates in order to control unnecessary increases in the volume of hospital services, it must do so across-the-board, to all services and items under the OPPS, by using the conversion factor. If CMS instead wants to make adjustments to payment rates for specific services, it must do so in a budget-neutral manner. And for good reason: The statute's structure and directives prevent the agency from engaging in cost-control measures by making draconian payment reductions targeting only specific services.

Off-Campus Provider-Based Departments

23. At issue in this lawsuit are Medicare payments for certain clinic visit services provided at off-campus PBDs. As previously noted, off-campus PBDs are practice locations of a hospital that are not in immediate proximity to the main hospital building, but are nonetheless so closely integrated with the hospital as to be considered a part of the hospital. *See* 42 C.F.R. § 413.65(e). An off-campus PBD could include a stand-alone oncology clinic, an urgent care clinic, or an office providing necessary specialty services (*e.g.*, cardiology, pulmonology, neurology, and urology). Off-campus PBDs vary significantly in function and purpose. In some cases, a hospital may lack the space on its main campus to expand, and a practice location is located off-campus as a matter of necessity. In other cases, there may be operational reasons for having a practice location off-campus. For example, a hospital might want to place an off-campus PBD in a location that is convenient to the patient population it serves. Notably, in Clallam County, where Olympic Medical Center is located, the community of Sequim (located

17 miles from the hospital) has no hospital of its own, and there are no emergency care services of any kind. The vital clinic services Olympic Medical Center offers the 28,000 residents provide essential primary, specialty and walk-in clinic services to a patient population in desperate need of those services.

24. Off-campus PBDs must be closely integrated with their main hospitals and are subject to regulatory requirements as a part of the hospital—unlike independent clinics or physician offices. *See* 42 C.F.R. § 413.65(a). As a result, off-campus PBDs often have higher costs relative to a physician office. There are many reasons for this: The patient population that visits off-campus PBDs tends to be sicker and poorer than the patient population that visits independent physician offices. *See* Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices (KNG Health Consulting LLC, 2018). In addition, off-campus PBDs are often intended to serve more functions than standalone physician offices. For example, an off-campus PBD may be an emergency department operating on nights and weekends with a team of specialist doctors and nurses on staff. In addition, CMS requires off-campus PBDs to satisfy the Medicare Conditions of Participation applicable to their main hospital, which are more demanding than the requirements imposed on physician offices or clinics. *See* Hospital Outpatient Department (HOPD) Costs Higher than Physician Offices Due to Additional Capabilities, Regulations https://www.aha.org/system/files/2018-09/info-hopd.pdf.

Section 603 of the Bipartisan Budget Act of 2015

25. 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 their physician office counterparts). 83 Fed. Reg. 59,004–005.

26. The total volume of outpatient services furnished at off-campus PBDs nationwide has been increasing for years. *Id.* at 59,005–007. That increase has been necessary and appropriate. The Medicare-eligible population as a whole has increased during that same period. In addition, as medical technology has evolved, more and more services are able to be furnished on an outpatient (rather than an inpatient) basis.

27. Among the many factors contributing to the increase in volume of outpatient services furnished at off-campus PBDs is the acquisition of stand-alone physician offices by some hospitals and integration of the physician offices into hospital operations. CMS took the view that Medicare costs could be lowered if these same outpatient services were furnished in a less-expensive physician office setting. 83 Fed. Reg. 59,008–009. The off-campus PBDs could—the agency argued—be effectively de-integrated from their main hospital and operated independently, and therefore paid under the Medicare physician fee schedule rather than the OPPS. In response, commenters pointed out that off-campus PBDs have higher costs than physician offices (in some cases, exceeding even the current payment rate for such services) and that off-campus PBDs are often able to provide services that are not available in physician offices. Commenters also noted that paying off-campus PBDs at the lower rates paid to physicians would upset the reasonable expectations of hospitals that acquired or built off-campus PBDs with the understanding that they would be paid under the OPPS.

28. Congress sought to balance 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. Congress's solution was to create two classes of off-campus PBDs. Qualifying off-campus PBDs that were billing as a hospital department under the OPPS when the statute took effect on

November 2, 2015 (so-called "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 (so-called "non-excepted PBDs") be paid under the "applicable payment system" in order to eliminate the possibility that a payment differential could be a factor in 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 for off-campus PBDs that were mid-build when Section 603 was enacted, which allowed those mid-build PBDs to continue to be paid under the OPPS).

29. CMS has interpreted the statutory phrase "applicable payment system" to mean that non-excepted PBDs should be paid under the Medicare Physician Fee Schedule (PFS). 81 Fed. Reg. 79,562, 179,659 (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 office (as opposed to in a hospital). Thus, the payment rates for excepted PBDs (under the OPPS) are generally higher than non-excepted PBDs (under the Physician Fee Schedule).

30. 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).

31. Common sense and the statutory structure make clear that in requiring that excepted and non-excepted PBDs be subject to different payment systems, Congress intended that they would receive different rates of payment. Congress's choice to grandfather some off-campus PBDs to permit them to continue billing under the OPPS, and thus be subject to different payment rates from other off-campus PBDs, cannot have been anything but deliberate.

The Final Rule

32. On July 31, 2018, CMS published a Proposed Rule proposing changes to the OPPS for CY 2019. As relevant here, the Proposed Rule proposed changes to the payment rate for certain clinic visit services provided at *excepted* PBDs in order to render it equal to the payment rate for services provided at *non*-excepted PBDs (the Clinic Visit Policy). Specifically, the Proposed Rule stated that the payment rate for clinic services provided by excepted PBDs in CY 2019 "would now be equivalent to the payment rate for" services provided by non-excepted PBDs. 83 Fed. Reg. 37,046, 37,142 (July 31, 2018). CMS proposed to make this adjustment in a non-budget-neutral fashion. *Id*. In other words, the payment rate reductions proposed by CMS would *not* be offset by increases in other payment rates under the OPPS to ensure that the overall payments to hospitals would remain the same. CMS estimated that this change would result in reductions in payments to hospitals of $760 million in CY 2019 alone. *Id*. at 37,143.

33. Almost 3,000 commenters submitted comments in response to the Proposed Rule, including the AHA, the AAMC, and the Plaintiff-Hospitals or their associated health systems, either directly or through an association. Among other things, Plaintiffs pointed out that CMS was statutorily prohibited from making adjustments to 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 PBDs differently under 42 U.S.C. § 1395l(t)(21).

34. On November 2, CMS posted the Final Rule on its website. 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. 83 Fed. Reg. 58,822, 59,013. CMS explained its decision succinctly: "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." *Id.* at 59,008. CMS also confirmed its decision to implement the adjustment in a non-budget-neutral fashion. *Id.* at 59,014. However, CMS announced that it would be phasing in the payment reduction over a two-year period, such that the estimated reductions in payments to hospitals in CY 2019 would be approximately $380 million. *Id*.

35. The Final Rule became effective on January 1, 2019.

The Final Rule Exceeds CMS's Authority Under the Medicare Act

36. In promulgating the Final Rule, CMS has acted in clear violation of its statutory authority. This is so for at least two separate reasons: (i) the Clinic Visit Policy violates the Medicare statute's mandate of budget neutrality; and (ii) the Clinic Visit Policy violates the statutory mandate that excepted and non-excepted PBDs must be treated differently.

Budget Neutrality:

37. First and foremost, the Final Rule is *ultra vires* because the Clinic Visit Policy is not budget neutral, in plain violation of the statute. 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, and $760 million in CY 2020, with no offsetting increases in payments for other services. 83 Fed. Reg. 59,014. Indeed, that was one of the *justifications* given by CMS for its proposed adjustments. *Id.*

38. But a critical element of the statute's structure is that changes in the payments for individual OPD services be made "in a budget neutral manner." 42 U.S.C. § 1395l(t)(9)(B). That is, if CMS wishes to reduce the amount of Medicare payments going to one type of service, it must increase the payments for other items or services in equal amount. *Id.*

39. While the Medicare statute allows for reductions to the total amount of Medicare payments in appropriate, limited circumstances under Subsection (t)(9)(C) through changes to the conversion factor, there is *no* statutory mechanism allowing CMS to reduce the total amount of Medicare payments by targeting only selected services. By requiring budget neutrality for payment reductions targeting specific services, the statute recognizes – and puts a check on – any incentive for CMS to employ draconian cost-control measures.

40. To get around 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 from the agency's separate statutory authorization to "develop a method for controlling unnecessary increases in the volume of covered OPD services." *Id.* § 1395l(t)(2)(F). CMS grounds 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.

41. 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 services. 42 U.S.C. § 1395l(t)(2)(F). Another statutory provision governs how that method may be *used* in actual volume-control efforts.

42. Specifically, Subsection (t)(9)(C) addresses what CMS should do if it wants to make adjustments 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 applies broadly to affect the payments for all covered services and cannot be used to change the relative payment rates between and among individual services.

43. Contrary to CMS's 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 the clinic visit policy portion of the Final Rule CMS has not adjusted the update to the conversion factor. Instead, it has only decreased the payments for a certain subset of services. In short, Subsection (t)(2)(F) is of little use to CMS in justifying the Final Rule.

44. In explaining its statutory authority in the Final Rule, CMS attempted to bolster its reliance on Subsection (t)(2)(F) by arguing that it had, in prior proposed rules, purported to invoke Subsection (t)(2)(F) to justify selective cuts to payment rates. 83 Fed. Reg. at 59,004–005. Not so. In fact, CMS has never actually implemented *anything* using Subsection (t)(2)(F).

45. In 1998, CMS proposed invoking Subsection (t)(2)(F) when establishing the OPPS, but that proposal – which involved modifications to *the conversion factor*—was indefinitely delayed for "further study" in another CMS action in 2000. 65 Fed. Reg. 18,434, 18,502–503 (April 7, 2000). Indeed, CMS said that "possible legislative modification" would be necessary before it could use its authority under Subsection (t)(2)(F) to adopt alternative options, which would have implemented non-conversion factor adjustments. And in 2001, both CMS and the Medicare Payment Advisory Commission (MedPAC) implicitly acknowledged that the options turned on selecting the proper contemplated methodology for triggering updates *to the conversion factor*. 66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2001). Thus, in every prior instance that the agency considered invoking Subsection (t)(2)(F), CMS implicitly (and correctly) acknowledged that any corresponding non-budget neutral changes to payment rates must occur pursuant to a change in the conversion factor. CMS's present assertion of sweeping authority to target only specific types of services under Subsection (t)(2)(F) in the Final Rule is unprecedented—and unlawful.

46. In any event, CMS has never made an adequate factual finding—as it must to lawfully invoke whatever authority it has under Subsection (t)(2)(F)—that any increase in the volume of covered OPD services is "unnecessary." Instead, the agency merely asserted in circular fashion that the increases in volume of covered outpatient services *must* have been

"unnecessary" simply because they occurred. 83 Fed. Reg. 59,006–008. To bolster this self-serving conclusion, CMS purports to rely upon recommendations and estimates made by MedPAC, an agency established *by Congress* to make recommendations *to Congress* regarding payment policy. *See* 42 U.S.C. § 1395b-6. And Congress has already spoken about the appropriate path forward here.

47. For the foregoing reasons, the Clinic Visit Policy is *ultra vires* because it is not budget neutral, as required by the plain language of the statute.

Statutory Distinction Between Excepted and Non-Excepted PBDs.

48. In addition, the Final Rule is *ultra vires* because it sets the same rate of payment 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 provided 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.

49. But the Medicare statute reflects Congress's intent to treat excepted and non-excepted PBDs differently. The statute creates two distinct categories of off-campus PBDs: excepted entities, which satisfy certain grandfathering requirements and may continue billing under the OPPS, and non-excepted entities, which do not and must instead be paid under an alternative payment system. *See* 42 U.S.C. § 1395l(t)(21). Congress's clear intent in creating that distinction was to create 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).

50. Congress necessarily understood and clearly intended that these separate payment systems would entail separate payment rates. And Congress intentionally grandfathered qualifying off-campus PBDs that were already in existence at the time the different payment system for non-excepted PBDs was put in place in order to ensure that the excepted PBDs would still be paid under the OPPS. *See* 42 U.S.C. § 1395(t)(21)(B) (cross-referencing 42 C.F.R. § 413.65(a)(2)).

51. By decreeing that excepted and non-excepted entities will now be subject to the same payment rate, CMS has effectively abolished that statutory separateness, performing an end-run around the congressional mandate. But the agency lacks authority to nullify the Medicare statute in such manner.

52. The Clinic Visit Policy set forth in the Final Rule is *ultra vires* for this reason as well.

Plaintiffs Will Suffer Concrete and Imminent Harm Absent Judicial Intervention

53. The Plaintiff-Hospitals and Plaintiffs AHA's and AAMC's member 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.

54. As CMS itself notes, the challenged policy will result in a total reduction in payments for outpatient services of approximately $380 million in CY 2019. 83 Fed. Reg. 59,014.

55. The Plaintiff-Hospitals and Plaintiffs AHA's and AAMC's members operate excepted PBDs that are statutorily entitled to be paid differently from non-excepted PBDs. The Final Rule reduces the payment rate for covered services performed at the excepted PBDs. If the Final Rule is left in place, Plaintiff-Hospitals and Plaintiffs AHA's and AAMC's members face the prospect of serious payment reductions for affected services, and may have to make difficult decisions about whether to reduce services in response to the lowered payment rate.

56. This is particularly troubling for hospitals already operating at low or negative margins.

57. Plaintiffs 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.

COUNT I
(*Ultra Vires* Agency Action)

58. Plaintiffs re-allege and incorporate by reference the allegations made in the foregoing numbered paragraphs of the Complaint.

59. This Court has the inherent power to review alleged *ultra vires* agency action when an agency patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute. *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*).

60. The Clinic Visit Policy is *ultra vires* because it is not budget neutral. Annual adjustments to payment rates for ODPs must be budget neutral. 42 U.S.C. § 1395l(t)(9)(B). But by CMS's own admission, the Clinic Visit Policy would result in a net reduction in total outpatient-services payments of more than $380 million for CY 2019. 83 Fed. Reg. 59,014. Rather than providing for offsetting increases in payments for other services or adjusting the generally applicable conversion factor—as required by statutory safeguards enacted to curb the agency's discretion—CMS chose to slash the payment rate for a particular set of services and thereby reduce total expenditures. That is clearly in excess of the agency's statutory authority.

61. The Clinic Visit Policy also is *ultra vires* because it effectively eliminates the statutorily mandated distinction between excepted and non-excepted PBDs. 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 outpatient services. The Final Rule, premised on CMS's contrary policy preferences, effectively erases that distinction by providing that outpatient services provided at excepted and non-excepted PBMs be subject to the exact same payment rate.

62. For these and other reasons, CMS has simply ignored Congress's instructions contained in the Medicare Act. The agency's wholly unauthorized adoption of the Clinic Visit Policy is *ultra vires* and cannot stand.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that the Final Rule exceeds CMS's statutory authority under the Medicare Act, 42 US.C. § 1395l, and is

unenforceable to the extent it does so;

B. Preliminary and permanent injunctive relief (i) vacating and barring Defendants from enforcing the *ultra vires* changes made to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Payment System for Calendar Year 2019; (ii) requiring CMS to conform its payment policies and conduct to the requirements of the Medicare Act; and (iii) ordering that Defendants provide immediate payment of any amounts improperly withheld as a result of the unauthorized conduct described above to Plaintiff-Hospitals and all affected members of the AHA and AAMC.

C. An order awarding Plaintiffs their costs, expenses, and attorneys' fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

D. Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Catherine E. Stetson

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