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.

Civil Action No. _____

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.

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 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, for Medicare hospital outpatient services in calendar year (CY) 2020. *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., 84 Fed. Reg. 61,142 (Nov. 12, 2019) (2020 Final Rule).

2. The 2020 Final Rule, in relevant part, continues in effect (and indeed, increases) certain payment cuts made in CY 2019 that this Court already declared unlawful and vacated in a September 17, 2019 decision. *See* Order, *American Hospital Ass'n v. Azar*, No. 18-2841, ECF No. 32 (RMC) (Sept. 17, 2019) (granting summary judgment against CMS and vacating "the Secretary's Method to Control for Unnecessary Increases in the Volume of Outpatient Services" in the 2019 Final Rule). Following the Court's decision, CMS moved to modify the Court's order and/or to stay its effect. After "careful consideration of the parties' briefs," the Court denied that motion and determined that "vacatur was appropriate and that a stay was not." *See* Orders, *Am. Hosp. Ass'n v. Azar*, No. 18-2841, ECF No. 39 (RMC) (Oct. 21, 2019), and ECF No. 50 (RMC) (Dec. 16, 2019).

3. Nonetheless, CMS pressed ahead with the same unlawful payment cuts for CY 2020. Like the 2019 Final Rule, the 2020 Final Rule implements reductions to Medicare

payment rates for certain clinic visit services provided at specified off-campus hospital 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.

4. The 2020 Final Rule is *ultra vires* for the same reasons as the 2019 Final Rule. 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 payment that target only specific items or services must be budget neutral. 42 U.S.C. § 1395l(t)(9)(B). And yet the 2020 Final Rule purports to do precisely what Congress has expressly prohibited: reduce total payments for covered hospital outpatient services for CY 2020 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 is textbook *ultra vires* action—as this Court has already held.

5. The 2020 Final Rule is unlawful for other reasons as well. 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 2020 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*.

6. CMS may not contravene clear congressional mandates merely because the agency wishes to make cuts to Medicare spending. And the agency's conduct in issuing the 2020 Final Rule is all the more stark because this Court has already rejected CMS's identical attempt to replace Congress's unequivocal directives with the agency's own policy preferences. The 2020 Final Rule is no less an impermissible flex of regulatory authority than the 2019 Final Rule, and should meet the same fate.

PARTIES

7. 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.

8. 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 154 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 173,000 faculty members, 89,000 medical students, and 129,000 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.

9. 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 2020 Final Rule. Mercy Health Muskegon has its principal place of business at 1500 E. Sherman Boulevard, Muskegon, Michigan 49444.

10. 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, 83.4% rely on Government-paid insurance and 59.2% 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 2020 Final Rule. Olympic Medical has its principal place of business at 939 Caroline Street, Port Angeles, Washington 98362.

11. 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 2020 Final Rule. York has its principal place of business at 3 Loving Kindness Way, York, Maine 03909.

12. 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

13. 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.

14. 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.

15. 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.

16. This lawsuit is ripe for judicial review. Because Plaintiffs are alleging that CMS is acting 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).

17. After the 2020 Final Rule became effective on January 1, 2020, several of the Plaintiff-Hospitals submitted claims to their Medicare Administrative Contractors (MACs). Those Plaintiff-Hospitals specifically requested that they be paid pursuant to the higher hospital payment rates because the clinic visit policy set forth in the 2020 Final Rule is unlawful, for the same reasons explained in this Court's prior order. 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 2020 Final Rule, and because CMS has refused to change its position in response to these same legal arguments.

FACTUAL BACKGROUND

Statutory Framework

18. 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.

19. 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.

20. 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).

21. 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).

22. 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.

23. As this Court has explained: "Every year, CMS must review the groups, relative payment weights, and wage and other adjustments for each Ambulatory Payment Classification to account for changes in medical practice or technology, new services, new cost data, and other relevant information and factors." *American Hosp. Ass'n v. Azar*, Civil Action Number 1:18-cv-2841, ECF No. 31 (*AHA I*) at 3, citing 42 U.S.C. § 1395l(t)(9)(A). "This annual review is conducted with an important caveat: any adjustment to the groups, relative payment weights, or adjustments must be budget neutral, meaning that it cannot cause a change in CMS' estimated

expenditures for OPD services for the year." *Id.*, citing 42 § 1395l(t)(9)(B) and 42 U.S.C. § 1395l(t)(9)(D)-(E) (requiring initial wage, outlier, and other adjustments also be budget neutral). "Thus, decreases or increases in spending caused by one adjustment must be offset with increases or decreases in spending by another." *Id.*

24. 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. Specifically, 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.

25. As this Court has noted, "because the same conversion factor applies equally to all Ambulatory Payment Classifications [(APCs)], adjustments to the conversion factor cannot be used to change the fee schedule for specific APCs." *AHA I* at 4. "In other words, changes to the conversion factor affect total spending and not spending on specific services." *Id.*

26. 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

27. 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).

28. As a result, "[m]any medical services that were once only offered in an inpatient hospital setting can now be provided by hospital outpatient departments whereby the patient does not spend the night. Medicare traditionally welcomed these cheaper alternatives to inpatient care and, to meet the growing demand for these services, some hospitals have established off-campus [PBDs]." *AHA I* at 4–5.

29. 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 an off-campus PBD is created 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.

30. 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.

31. As this Court has noted, "[a]lthough not physically proximate to their affiliated hospital's main campus, off-campus [PBDs] are so closely integrated into the same system that they are considered part of the hospital itself. This allows off-campus [PBDs] to offer more comprehensive services to their patients but also subjects off-campus provider-based departments to the same regulatory requirements as the main hospital." *AHA I* at 5, citing 42 C.F.R. § 413.65 (describing regulatory requirements for off-campus provider-based departments). "Because they are part of the same system and face the same regulatory requirements and regulatory costs as hospitals, off-campus provider-based departments have generally been paid at the same rates hospitals are paid for OPD services." *Id.*

32. This makes good economic sense. 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

33. 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.

34. 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. *AHA I* at 5, citing 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), available at https://go.cms.gov/2m5ZCok. In addition, as medical technology has evolved, more and more services are able to be furnished on an outpatient (rather than an inpatient) basis. *Id.* at 6, citing Ken Abrams, Andreea Balan-Cohen & Priyanshi Durbha, Growth in Outpatient Care, Deloitte (Aug. 15, 2018), available at https://bit.ly/2nOkG05.

35. 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.

36. 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).

37. 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, 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 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).

38. 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).

39. 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 2019 Final Rule

40. On July 31, 2018, CMS published a Proposed Rule proposing changes to the OPPS for CY 2019. As relevant here, the 2019 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 2019 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.

41. Almost 3,000 commenters submitted comments in response to the 2019 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 2019 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).

42. In November 2018, CMS published the 2019 Final Rule. 83 Fed. Reg. 58,818 (Nov. 21, 2018). Like the 2019 Proposed Rule, the 2019 Final Rule adjusted 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*.

43. The above-named Plaintiffs filed suit challenging the 2019 Final Rule, and this Court granted summary judgment to Plaintiffs and against CMS on September 17, 2019, holding that "CMS exceeded its statutory authority when it cut the payment rate for clinic services at off-campus provider-based clinics" and vacating the 2019 Final Rule in relevant part. Memo. Op., *American Hospital Ass'n v. Azar*, No. 18-2841 (RMC) (D.D.C.), ECF No. 31 at 2. The Government filed a notice of appeal to the D.C. Circuit on December 12, 2019.

The 2020 Final Rule

44. In August 2019, while Plaintiff's lawsuit challenging the 2019 Final Rule was still pending, CMS issued its proposed OPPS rule for CY 2020. 84 Fed. Reg. 39,398 (Aug. 9, 2019). In half a page of substantive reasoning cross-referencing the basis given in the 2019 Final Rule, the agency announced that "CY 2020 will be the second year of the 2-year transition of this [Clinic Visit] policy." 84 Fed. Reg. 39,512–513.

45. In November 2019, after this Court vacated the 2019 Final Rule in relevant part, CMS published the 2020 Final Rule. Rather than retreat from its *ultra vires* assertion of power in the Clinic Visit Policy, CMS chose to double down by completing the two-year phase-in contemplated by the 2019 Final Rule. Nowhere in the 2020 Final Rule does CMS try to assert any other lawful basis for its Clinic Visit Policy. Instead, in response to comments complaining 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. at 61,142.

46. The 2020 Final Rule became effective on January 1, 2020.

The 2020 Final Rule Exceeds CMS's Authority Under the Medicare Act

47. In promulgating the 2020 Final Rule, CMS has once again 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:

48. First and foremost, the 2020 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 2020 Final Rule would reduce total hospital payments $800 million in CY 2020 with no offsetting increases in payments for other services. 84 Fed. Reg. 61,369. Indeed, that was one of the *justifications* given by CMS for its proposed adjustments. *Id.*

49. 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.*

50. 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.

51. 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.

52. 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.

53. 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.

54. 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 2020 Final Rule.

55. As this Court has noted, "[t]here is no reason to think that Congress with one hand granted CMS the authority to upend such a 'basic principle' of the Outpatient Prospective Payment System while working with the other to preserve it." *AHA I* at 24. In addition, "CMS' interpretation would also swallow paragraph (t)(9)(C) in its entirety: why would the agency go through the annual hassle of updating the conversion factor if it could use paragraph (t)(2)(F) to decrease or increase payment rates for disfavored or favored services whenever desired?" *AHA I* at 24, n. 9.

56. In explaining its statutory authority for implementing the Clinic Visit Policy, 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).

57. 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 2020 Final Rule is unprecedented—and unlawful.

58. 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 to the appropriate path forward here.

59. 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.

60. As this Court noted in finding the 2019 Final Rule unlawful: "[T]he 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. The Court finds that the Final Rule is ultra vires." *AHA I* at 26.

Statutory Distinction Between Excepted and Non-Excepted PBDs.

61. 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 Clinic Visit Policy 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.

62. 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).

63. 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)).

64. 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.

65. The Clinic Visit Policy set forth in the 2020 Final Rule is *ultra vires* for this reason as well.

Plaintiffs Will Suffer Concrete and Imminent Harm Absent Judicial Intervention

66. 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.

67. As CMS itself notes, the challenged policy will result in a total reduction in payments for outpatient services of approximately $800 million in CY 2020. 84 Fed. Reg. 61,369.

68. 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 2020 Final Rule reduces the payment rate for covered services performed at the excepted PBDs. If the 2020 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.

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

70. Plaintiffs and the vulnerable patients and communities they serve face concrete and imminent harms—both economic and noneconomic—if CMS's 2020 Final Rule is allowed to stand.

COUNT I
(*Ultra Vires* Agency Action)

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

72. 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*).

73. This Court also the same power to declare agency action unlawful, *ultra vires*, and beyond the scope of the agency's authority under the Administrative Procedure Act (APA).

74. 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 $800 million for CY 2020. 84 Fed. Reg. 61,369. 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.

75. 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.

76. 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 2020 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 2020; (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
Catherine E. Stetson (D.C. Bar No. 453221)
Susan M. Cook (D.C. Bar No. 462978)
Kyle M. Druding (D.C. Bar No. 1044631)
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, D.C. 20004
Phone: (202) 637-5491
Fax: (202) 637-5910
cate.stetson@hoganlovells.com

Counsel for 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

Dated: January 13, 2020

CIVIL COVER SHEET

JS-44 (Rev. 6/17 DC)

I. (a) PLAINTIFFS
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

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF 11001
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
Alex M. Azar II, in his official capacity as Secretary of Health and Human Services

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004 Tel: (202) 637-5491

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT
(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A.** ***Antitrust***
- ☐ 410 Antitrust

○ **B.** ***Personal Injury/ Malpractice***
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

◉ **C.** ***Administrative Agency Review***
- ☒ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D.** ***Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E.** ***General Civil (Other)*** **OR** ○ **F.** ***Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ G. *Habeas Corpus/ 2255* ☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	○ H. *Employment Discrimination* ☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	○ I. *FOIA/Privacy Act* ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ J. *Student Loan* ☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ K. *Labor/ERISA (non-employment)* ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ L. *Other Civil Rights (non-employment)* ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	○ M. *Contract* ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ N. *Three-Judge Court* ☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

Plaintiffs sue to remedy ultra vires conduct of the Centers for Medicare & Medicaid Services

VII. REQUESTED IN COMPLAINT CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint YES ☐ NO ☒

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☒ NO ☐ If yes, please complete related case form

DATE: 1/13/2020 **SIGNATURE OF ATTORNEY OF RECORD** [signature]

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

CLERK'S OFFICE

CO-932
Rev. 4/96

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOTICE OF DESIGNATION OF RELATED CIVIL CASES PENDING
IN THIS OR ANY OTHER UNITED STATES COURT

Civil Action No. _____
(To be supplied by the Clerk)

NOTICE TO PARTIES:

Pursuant to Rule 40.5(b)(2), you are required to prepare and submit this form at the time of filing any civil action which is related to any pending cases or which involves the same parties and relates to the same subject matter of any dismissed related cases. This form must be prepared in sufficient quantity to provide one copy for the Clerk=s records, one copy for the Judge to whom the cases is assigned and one copy for each defendant, so that you must prepare 3 copies for a one defendant case, 4 copies for a two defendant case, etc.

NOTICE TO DEFENDANT:

Rule 40.5(b)(2) of this Court requires that you serve upon the plaintiff and file with your first responsive pleading or motion any objection you have to the related case designation.

NOTICE TO ALL COUNSEL

Rule 40.5(b)(3) of this Court requires that as soon as an attorney for a party becomes aware of the existence of a related case or cases, such attorney shall immediately notify, in writing, the Judges on whose calendars the cases appear and shall serve such notice on counsel for all other parties.

The plaintiff , defendant or counsel must complete the following:

I. RELATIONSHIP OF NEW CASE TO PENDING RELATED CASE(S).

A new case is deemed related to a case pending in this or another U.S. Court if the new case: [Check appropriate box(e=s) below.]

- ☐ (a) relates to common property
- ☐ (b) involves common issues of fact
- ☒ (c) grows out of the same event or transaction
- ☐ (d) involves the validity or infringement of the same patent
- ☐ (e) is filed by the same pro se litigant

2. RELATIONSHIP OF NEW CASE TO DISMISSED RELATED CASE(ES)

A new case is deemed related to a case dismissed, with or without prejudice, in this or any other U.S. Court, if the new case involves the same parties and same subject matter.

Check box if new case is related to a dismissed case: ☐

3. NAME THE UNITED STATES COURT IN WHICH THE RELATED CASE IS FILED (IF OTHER THAN THIS COURT):

_____

4. CAPTION AND CASE NUMBER OF RELATED CASE(E=S). IF MORE ROOM IS NEED PLEASE USE OTHER SIDE.

American Hospital Association et al. v. Alex M. Azar II C.A. No. 18-2841

January 13, 2020
DATE

Signature of Plaintiff /Defendant (or counsel)

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

The American Hospital Association, et al.

Plaintiff(s)

v.

Alex M. Azar II, in his official capacity as Secretary of Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or mo

ANGELA D. CAESAR, CLERK OF COURT

Date: 01/13/2020

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

The American Hospital Association, et al.

Plaintiff(s)

v.

Alex M. Azar II, in his official capacity as Secretary of Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* William P. Barr
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-001

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 01/13/2020

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

The American Hospital Association, et al.

Plaintiff(s)

v.

Alex M. Azar II, in his official capacity as Secretary of Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Jessie K. Liu
United States Attorney for the District of Columbia
United States Attorney's Office
555 4th Street, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Catherine E. Stetson
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: 01/13/2020

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc: