UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY 4000 Cambridge Street Kansas City, KS 66160	)	
BARNES-JEWISH HOSPITAL One Barnes-Jewish Hospital Plaza Saint Louis, MO 63110	)	
BARNES-JEWISH WEST COUNTY HOSPITAL 12634 Olive Boulevard Saint Louis, MO 63141	)	Civil Action No. 1:20-cv-75
BLUE RIDGE HEALTHCARE SYSTEM, INC. d/b/a CHS Blue Ridge 2201 S Sterling Street Morganton, NC 28655	)	
CARILION MEDICAL CENTER 1906 Belleview Avenue Roanoke, VA 24014	)	
CENTRAL VERMONT MEDICAL CENTER, INC. 130 Fisher Road Berlin, VT 05602	)	
COLUMBUS REGIONAL HEALTHCARE SYSTEM INC. 500 Jefferson Street Whiteville, NC 28472	)	
EAST BATON ROUGE MEDICAL CENTER, LLC. d/b/a OCHSNER MEDICAL CENTER - BATON ROUGE 17000 Medical Center Drive Baton Rouge, LA 70816	)	
FLORIDA HEALTH SCIENCES CENTER INC dba Tampa General Hospital One Tampa General Circle Tampa, Florida 33606	)	
HACKENSACK MERIDIAN HEALTH d/b/a Jersey Shore University Medical Center	)	

343 Thornall Street)
Edison, NJ, 08837)
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HACKENSACK MERIDIAN HEALTH)
d/b/a Bayshore Medical Center)
343 Thornall Street)
Edison, NJ, 08837)
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HACKENSACK MERIDIAN HEALTH)
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MISSOURI BAPTIST MEDICAL CENTER)
3015 North Ballas Road)
Saint Louis, MO 63131)
)
MONTEFIORE HEALTH SYSTEM, INC.)
d/b/a Montefiore Medical Center)
555 South Broadway)
Tarrytown, New York 10591)
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MONTEFIORE HEALTH SYSTEM, INC.)
d/b/a St. Luke's Cornwall Hospital)
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Tarrytown, New York 10591)
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PIEDMONT NEWNAN HOSPITAL, INC.)
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Newnan, GA 30265)
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PROGRESS WEST HEALTHCARE CENTER)
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2 Progress Point Parkway)
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HOSPITAL AUTHORITY)
d/b/a Atrium Health University City)
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)
THE CHARLOTTE-MECKLENBURG)
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THE MEDICAL CENTER, INC.,)
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OF CENTRAL GEORGIA, INC.)
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THE RECTOR AND VISITORS OF THE)
UNIVERSITY OF VIRGINIA)
d/b/a University of Virginia Medical Center)
1215 Lee Street)
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)
UNIVERSITY OF VERMONT MEDICAL CENTER)
111 Colchester Avenue)
Burlington, VT 05401)

VANDERBILT UNIVERSITY MEDICAL CENTER)
1211 Medical Center Drive)
Nashville, TN 37232)
)
Plaintiffs,)
)
v.)
)
)
ALEX M. AZAR II, in his official capacity)
as Secretary of Health & Human Services)
United States Department of)
Health & Human Services,)
200 Independence Avenue, S.W.)
Washington, D.C. 20201)
)
Defendant.)
)

AMENDED COMPLAINT

Plaintiffs, thirty-eight hospitals that participate in the Medicare program, bring this complaint against Defendant Alex M. Azar II, in his official capacity as Secretary of Health and Heath Human Services ("Secretary"), and allege as follows:

INTRODUCTION

1. Plaintiffs find themselves in a familiar position, once again asking the Court to restore the statutorily-required payment rates for certain outpatient services performed at off-campus provider-based departments. The Secretary initially went astray when he attempted, in his rulemaking setting payment rates under Medicare's Outpatient Prospective Payment System ("OPPS") for calendar year 2019, to cut the rates for evaluation and management ("E/M") services performed at excepted off-campus provider-based departments. This Court has held that the Secretary's action was *ultra vires*, and vacated the portion of the 2019 OPPS rule that announced that payment cut. Despite this Court's ruling, the Secretary has boldly attempted to reinstate the same policy in his 2020 rulemaking. 84 Fed. Reg. 61,142 (Nov. 12, 2019) ("2020 Final Rule"). The payment cut in the 2020 rule is unlawful for precisely the same reasons that the payment cut in the 2019 rule was. Plaintiffs accordingly ask this Court to award the same relief with respect to the 2020 Final Rule that it has for the 2019 rule.

2. In Section 603 of the Bipartisan Budget Act of 2015 ("BBA 2015"), Congress amended the Social Security Act so that the Medicare program now pays the same rates for medical services regardless of whether they are provided in a physician's office or in a hospital department that is located away from or "off" the main campus of the hospital. At the same time, Congress excepted from this amendment all off-campus hospital outpatient departments that were providing services *before* the enactment of Section 603. Pursuant to the line drawn by Congress, those pre-

existing departments would continue to be paid for their services at the higher hospital rates that pre-dated Section 603. This case involves the Secretary's disregard, both in the 2019 OPPS rule and now in the 2020 OPPS rule, for this line that Congress has drawn.

3. Many hospitals, including Plaintiffs, operate off-campus hospital departments which the Medicare program commonly refers to as "provider-based departments" ("PBDs"). Medicare defines an off-campus PBD as a facility not located on a hospital's main campus but operated by and integrated with the main hospital to such a degree that services furnished there are considered furnished by the hospital itself. *See generally* 42 C.F.R. § 413.65. Many hospitals locate off-campus PBDs throughout the community so that they are closer to and more convenient for patients to visit for care as compared to traveling to the hospital's main campus. Off-campus PBDs provide outpatient hospital services, which are those services that do not require a patient to stay overnight in a hospital bed, sometimes referred to as ambulatory or same-day services. *See e.g.*, Medicare Benefit Policy Manual, CMS Pub. 100-02, Ch. 6 § 20.2 (defining "outpatient"). Evaluation and management services, or E/M services, are a common outpatient service. E/M services involve the assessment and treatment of a patient by a physician. *See* Medicare Learning Network, *Evaluation and Management Services*, ICN 006764 available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf (overviewing E/M services). Off-campus PBDs that offer E/M and other services help improve quality and access to hospital-level care, particularly for underserved communities that may not otherwise have access to these services at other nonhospital sites such as independent physician offices.

4. In general, medical services provided in hospital outpatient departments are more resource-intensive—and therefore more costly—than those furnished in an independent

physician's office. *See* 73 Fed. Reg. 66,187, 66,191 (Nov. 7, 2008) (recognizing the "high facility overhead expenses that are associated with the delivery of services unique to an outpatient hospital or a department of an outpatient hospital . . ."). Hospitals are required to provide a wider range of services and meet much stricter regulatory requirements than freestanding physician offices. For example, hospitals must offer 24-hour nursing care, maintain discharge planning protocols, and meet various health and safety requirements. 42 U.S.C. § 1395x(e)(3)-(9). Hospitals must maintain a formal "institutional plan and budget" that "provide[s] for capital expenditures for at least a 3-year period" and is subject to State review. 42 C.F.R. § 482.12(d). Hospitals must also maintain a pharmacy overseen by a licensed pharmacist, as well as ensure security for prescription drugs. *Id.* at § 482.25. Hospitals must maintain or have available diagnostic radiologic and laboratory services, as well as food and dietetic services. *Id.* at § 482.26–28. Hospitals must ensure that they have emergency sources of electricity, water and gas, and that the physical plant meets all applicable building and fire code standards. *Id.* at § 482.41. None of these conditions for participating in Medicare and other Federal healthcare programs apply to an independent physician's office.

5. Because these statutory and regulatory requirements create additional operating and capital expenditures that other healthcare entities do not incur, Medicare pays hospitals more for services, including outpatient services, than it pays for comparable services provided by an independent physician office. *See* 83 Fed. Reg. at 59,008 (comparing Medicare payment for a certain clinic visit furnished under the Medicare Outpatient Prospective Payment System ("OPPS") and under the Medicare Physician Fee Schedule ("MPFS")). The higher payment rates for hospitals, however, raised concerns as to whether some hospitals have been motivated to purchase independent physician offices and convert them into hospital departments to capture the

higher payment rates without incurring the corresponding increase in costs to provide comparable services. *See, e.g.*, 83 Fed. Reg. 37,046, 37,148 (July 31, 2018). The Medicare Payment Advisory Commission ("MedPAC"), a body established by statute to make recommendations to Congress regarding healthcare policy, has recommended that Congress consider legislation to address this possibility, such as eliminating the payment difference between all hospital outpatient departments and physician offices. 83 Fed. Reg. 58,818, 59,006–07 (Nov. 21, 2018) (citing 2012 and 2014 reports).

6. Congress recognized that it was not necessary to adopt such broad proposals into law to address this concern. Instead, Congress enacted Section 603 of the BBA 2015, which creates clear, specific and narrowly-tailored rules governing how the Medicare program will pay for medical services provided at off-campus PBDs. Pub. L. No. 114-74 § 603, 129 Stat. 584, 598. Rather than lower rates for all off-campus PBDs, for example, Congress determined that only those off-campus PBDs that began operations on or after November 2, 2015 would be paid according to a different, lower-paying rate system. These off-campus PBDs are often called "nonexcepted" PBDs because they are not excepted by the payment changes Congress made in Section 603. 42 U.S.C. § 1395*l*(t)(21)(C). In contrast, Congress determined that off-campus PBDs that were operating before November 2, 2015 would continue to receive higher rates determined under the hospital OPPS. These off-campus PBDs are referred to as "excepted" or "grandfathered" PBDs because Congress excepted them from the changes in Section 603. As for the rates paid to new, nonexcepted PBDs, Congress authorized the Secretary to determine which reimbursement system to use to calculate payments for those off-campus PBDs. *See* 42 U.S.C. § 1395*l*(t)(21)(C) (identifying that payment be made for nonexcepted PBDs under an "applicable payment system").

7. The Secretary ultimately chose to calculate payment rates for nonexcepted PBDs using the MPFS, the same methodology he uses to set payment rates for independent physician practices. *See* 81 Fed. Reg. 79,562, 79,570 (Nov. 14, 2016). At that time, he acknowledged that Congress intended to preserve the ability of excepted off-campus PBDs to continue to receive those higher rates so that they could serve their communities effectively without any disruptions in care. *Id.* at 79,704 ("we believe that section 603 applies to off-campus PBDs as they existed at the time the law was enacted. That is, we believe that the statutory language provides for payment to continue under the OPPS for such departments as defined by the regulations at § 413.65 as they existed at the time of enactment of [Section 603]").

8. Despite this clear directive from Congress, on November 21, 2018, the Secretary issued a rule setting OPPS payment rates for 2019 that significantly reduced the amount paid for E/M services performed at excepted off-campus provider-based departments. The Secretary announced that he would pay for these services only at the lower Physician Fee Schedule rate. 83 Fed. Reg. 58,818 (Nov. 21, 2018) ("2019 Final Rule"). The payment cut took effect on January 1, 2019 and was scheduled to phase in over a two-year period. In other words, notwithstanding Congress's decision that excepted off-campus PBDs were exempt from Section 603's payment changes and would continue to be reimbursed at OPPS rates, the Secretary blatantly disregarded a specific and unambiguous statutory directive, acted well beyond his authority and nullified that statutory exemption.

9. The Secretary's actions are no garden variety error of law; they are *ultra vires*. He has left no doubt that he is substituting his will for Congress's. In the Final Rule, the Secretary expressed his opinion that Section 603 only "address[ed] *some* of [his] concerns related to shifts in settings of care and overutilization of services in the hospital outpatient setting." *Id.* at 59,012

(emphasis added). He criticized Congress's decision to allow many "hospital off-campus departments [to] continue to receive full OPPS payment," referring to those off-campus PBDs Congress specifically exempted from Section 603's payment rate changes. *Id.*

10. The Secretary cited 42 U.S.C. § 1395*l*(t)(2)(F)—a provision enacted nearly 20 years before Section 603—as authority that allows him to override Congress's mandate. But Section (t)(2)(F) allows for no such thing. It authorizes the Secretary to "develop a method for controlling unnecessary increases" in the volume of hospital outpatient department services, but it does not authorize the Secretary to set payment rates contrary to those established by statute, nor does it allow the Secretary to override Congress's more recent and specific statutory mandate in Section 603 to continue to pay excepted off-campus PBDs at hospital OPPS rates. No provision of law—not Section (t)(2)(F) or any other—permits the Secretary to ignore a clearly expressed mandate of Congress simply because the Secretary disagrees with Congress's legislative choices. And even in circumstances where the Secretary is permitted to tinker with OPPS payment rates, the statute permits him to do so only in a budget neutral fashion, that is, by adopting offsetting payment increases for the remainder of outpatient services paid under OPPS. 42 U.S.C. § 1395*l*(t)(2)(D)-(E), (t)(9)(B). Despite this statutory limit on his authority, the Secretary did not offset his payment cut to excepted off-campus PBDs by increasing funding to the providers of those services elsewhere.

11. The Plaintiff hospitals here filed a complaint in this Court that challenged the Secretary's 2019 Final Rule. Plaintiffs contended that the Secretary acted outside the scope of his authority by disregarding Congress's decision, in enacting Section 603, to preserve OPPS payment rates for excepted off-campus PBDs. Plaintiffs also contended that the Secretary had unlawfully

circumvented the requirement in the OPPS statute that payment adjustments be conducted in a budget-neutral manner.

12. This Court held, in a decision addressing several consolidated actions that each had challenged the 2019 payment cuts, that the Secretary exceeded his statutory authority in the 2019 OPPS rule when he reduced the payment rates for E/M services performed at excepted off-campus provider-based departments. *Am. Hosp. Ass'n v. Azar ("AHA I")*, No. CV 18-2841, 2019 WL 4451984, at *1 (D.D.C. Sept. 17, 2019), *appeal docketed*, No. 19-5352 (D.C. Cir. Dec. 12, 2019). This Court held that the Secretary had unlawfully invoked his so-called "methods" authority under 42 U.S.C. § 1395*l*(t)(2)(F) in an attempt to circumvent the OPPS statute's budget neutrality requirements. *Id.* at *12. Accordingly, the Court vacated the relevant portions of the 2019 Final Rule. *Id.*

13. The Secretary is undeterred by this Court's ruling. He is now attempting to implement the same unlawful rate cuts in his 2020 Final Rule. As noted above, the Secretary's (now-vacated) payment cut in the 2019 Final Rule had announced a two-year phase in of the rate cut for E/M services. The Secretary now attempts to continue "the second year of the two-year transition in CY 2020," relying on precisely the same legal theories that this Court has already rejected. 84 Fed. Reg. 61,142, 61,365 (Nov. 12, 2019). The Secretary makes only a passing reference to this Court's vacatur of the 2019 payment cut, stating flatly, he does "not believe it is appropriate at this time to make a change to the second year of the two-year phase-in of the [vacated] clinic visit policy. The government has appeal rights, and is still evaluating the rulings and considering, at the time of this writing, whether to appeal from the final judgment." *Id.* at 61,368. In short, the Secretary has put forth no new rationale or information to rescue his 2020 Final Rule from the same fate as its prior-year counterpart.

14. Just as this court held with respect to the 2019 Final Rule, the Secretary's payment cut in the 2020 rule is *ultra vires* and so too should be vacated. Section (t)(9)(B) requires the Secretary to "budget neutralize" any changes he makes in the amounts paid for specific outpatient department items or services. 42 U.S.C. § 1395*l*(t)(9)(B) (Section 1833(t)(9)(B) of the Social Security Act). The Secretary attempts to avoid the budget-neutrality rule by declaring his payment cut to be a "method" under 42 U.S.C. § 1395*l*(t)(2)(F), but he made precisely the same attempt in the 2019 rule, and that attempt has already been resoundingly rejected by this Court. Section (t)(2)(F) authorizes the Secretary to "develop a method for controlling unnecessary increases" in the volume of hospital outpatient department services, but it *does not*, as the Court held, authorize the Secretary to set payment rates for particular services contrary to those established by statute. Any increases (or decreases) in payment rates must be offset by a corresponding reduction (or increase) in the rates for other services so that aggregate payments for outpatient department services remains the same. The Secretary has admitted that the rate cut for E/M services would reduce Medicare payments for hospital outpatient department services by $640 million in 2020. *See* 84 Fed. Reg. at 61,369. However, rather than offset that payment cut by increasing funding to the providers of those services elsewhere, the Secretary intends to retain this amount in direct defiance of Congress's instructions. Just as was true regarding the 2019 Final Rule, neither Section (t)(2)(F)—nor any other provision of law—permits the Secretary to ignore a clearly expressed mandate regarding budget neutrality.

15. What is more, the Secretary's 2020 Final Rule suffers from the same additional defect as did the 2019 rule: the Secretary has blatantly disregarded the will of Congress that was expressed in the enactment of Section 603. The Secretary has no authority to disregard Congress's specific statutory mandate in Section 603 to continue to pay excepted off-campus PBDs at hospital

OPPS rates. The Secretary's unlawful rate cut directly contravenes clear congressional directives and will impose significant harm on affected off-campus hospital outpatient departments and the patients they serve. Accordingly, this Court should also declare the Secretary's 2020 Final Rule *ultra vires* on these grounds, and enjoin the agency from implementing any payment methodology other than OPPS rates for all E/M services provided by excepted off-campus PBDs.

16. This Court has recognized that the 2020 Final Rule is unlawful for the same reason that the 2019 Final Rule was. This Court considered a motion that asked the Court to enforce its judgment in the previous action by enjoining the Secretary from implementing the 2020 payment cut. This Court concluded that it lacked jurisdiction to do so in the absence of a claim for Medicare payment submitted to the agency by a provider under the 2020 payment rule. This Court understood, however, that, jurisdictional issues aside, the 2020 rule is patently unlawful. This Court stated, "CMS set 2020 OPPS reimbursement rates using the same reasoning the Court found *ultra vires* when CMS set the 2019 OPPS reimbursement rates." *Am. Hosp. Ass'n v. Azar*, No. CV 18-2841 (RMC), 2019 WL 6841719, at *4 (D.D.C. Dec. 16, 2019). The Secretary "clearly disregarded the substance of the Court's decision in *AHA I* when it relied on the same *ultra vires* reasoning to justify its 2020 reimbursement rates" and the Secretary "has now intentionally placed [himself] in a position to suffer those same alleged harms [of a purported logistical challenge he faces in recalculating OPPS rates], which calls its argument into serious question and appears to set the agency above the law." *Id.*

17. This Court now possess jurisdiction to address the 2020 Final Rule. No claims for Medicare payment under the 2020 Final Rule had been presented to the Court at the time that it considered the motion to enforce. The 2020 Final Rule has now become effective, and Plaintiffs have submitted their claims to the agency for payment for E/M clinical services, seeking payment

at the full OPPS rate to which they are entitled under the OPPS statue, absent the Secretary's unlawful payment cut.

PARTIES

18. Plaintiffs operate excepted off-campus PBDs that participate in the Medicare program. and are affected by the unlawful rate cut in E/M services that became effective January 1, 2020.

19. The plaintiffs in this action are:

- UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, Medicare Provider No. 17-0040;
- BARNES-JEWISH HOSPITAL, Medicare Provider No. 26-0032;
- BARNES-JEWISH WEST COUNTY HOSPITAL, Medicare Provider No. 26-0162;
- BLUE RIDGE HEALTHCARE SYSTEM, INC. d/b/a CHS Blue Ridge, Medicare Provider No. 34-0075;
- CARILION MEDICAL CENTER, Medicare Provider No. 49-0024;
- CENTRAL VERMONT MEDICAL CENTER, INC., Medicare Provider No. 47-0001;
- COLUMBUS REGIONAL HEALTHCARE SYSTEM, INC., Medicare Provider No. 34-0068;
- EAST BATON ROUGE MEDICAL CENTER, LLC d/b/a OCHSNER MEDICAL CENTER - BATON ROUGE, Medicare Provider No. 19-0202;
- FLORIDA HEALTH SCIENCES CENTER INC d/b/a Tampa General Hospital, Medicare Provider No. 10-0128;
- HACKENSACK MERIDIAN HEALTH, d/b/a Jersey Shore University Medical Center, Medicare Provider No. 31-0073;
- HACKENSACK MERIDIAN HEALTH, d/b/a Bayshore Medical Center, Medicare Provider No. 31-0112;

- HACKENSACK MERIDIAN HEALTH, d/b/a Riverview Medical Center, Medicare Provider No. 31-0034;
- MISSOURI BAPTIST MEDICAL CENTER, Medicare Provider No. 26-0108;
- MONTEFIORE HEALTH SYSTEM, INC. d/b/a Montefiore Medical Center, Medicare Provider No. 33-0059;
- MONTEFIORE HEALTH SYSTEM, INC. d/b/a St. Luke's Cornwall Hospital, Medicare Provider No. 33-0264;
- MONTEFIORE HEALTH SYSTEM, INC. d/b/a White Plains Hospital, Medicare Provider No. 33-0304;
- NORTHWEST MEDICAL CENTER, Medicare Provider No. 04-0022;
- OCHSNER CLINIC FOUNDATION d/b/a OCHSNER MEDICAL CENTER, Medicare Provider No. 19-0036;
- OSF HEALTHCARE SYSTEM d/b/a Saint Anthony Medical Center, Medicare Provider No. 14-0233;
- OSF HEALTHCARE SYSTEM d/b/a Saint Anthony's Health Center, Medicare Provider No. 14-0052;
- OSF HEALTHCARE SYSTEM, d/b/a Saint Francis Medical Center, Medicare Provider No. 14-0067;
- OSF HEALTHCARE SYSTEM d/b/a St. Joseph Medical Center, Medicare Provider No. 14-0162;
- PIEDMONT NEWNAN HOSPITAL, INC., Medicare Provider No. 11-0229;
- PROGRESS WEST HEALTHCARE CENTER, d/b/a Progress West Hospital, Medicare Provider Number 26-0219;
- RUSH UNIVERSITY MEDICAL CENTER, Medicare Provider No. 14-0119;
- SARASOTA MEMORIAL HOSPITAL, Medicare Provider No. 10-0087;
- STANFORD HEALTH CARE, Medicare Provider No. 05-0441;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Lincoln, Medicare Provider No. 34-0145;

- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Pineville, Medicare Provider No. 34-0098;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Union, Medicare Provider No. 34-0130;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health University City, Medicare Provider No. 34-0166;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Carolinas HealthCare System NorthEast, Medicare Provider No. 34-0001;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Carolinas Medical Center, Medicare Provider No. 34-0113;
- THE MEDICAL CENTER, INC., d/b/a Piedmont Columbus Regional Midtown, Medicare Provider No. 11-0064;
- THE MEDICAL CENTER OF CENTRAL GEORGIA, INC., Medicare Provider No. 11-0107;
- THE RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA d/b/a University of Virginia Medical Center, Medicare Provider No. 49-0009;
- UNIVERSITY OF VERMONT MEDICAL CENTER, INC., Medicare Provider No. 47-0003; and
- VANDERBILT UNIVERSITY MEDICAL CENTER, Medicare Provider Number 44-0039.

20. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services, which administers the Medicare program established under title XVIII of the Social Security Act. Defendant Azar is sued in his official capacity only. The Centers for Medicare & Medicaid Services ("CMS") is the federal agency to which the Secretary has delegated administrative authority over the Medicare and Medicaid programs, including issues relating to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. References to the Secretary herein are meant to refer

to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires.

JURISDICTION AND VENUE

21. This Court has subject-matter jurisdiction pursuant to 42 U.S.C. § 405(g). Due to the Secretary's Final Rule, each of the Plaintiffs has been paid an amount for E/M services provided at excepted off-campus PBDs at the MPFS rate rather than the hospital department OPPS rate that is required by Section 603. As discussed above, Plaintiffs have presented claims to the Secretary in the form of a concrete request for additional Medicare reimbursement that challenges the Secretary's authority to pay excepted off-campus PBDs at rates contrary to Section 603. Further administrative appeal and review of Plaintiffs' claims is futile because the Secretary's administrative adjudicators are bound by the Secretary's Final Rule, and the Secretary has already determined that he will not revise the Final Rule leaving Plaintiffs with no recourse other than federal court review.

22. Alternatively, this Court has subject-matter jurisdiction under 42 U.S.C. § 1331 because Plaintiffs' claims arise under the laws of the United States.

23. Venue is proper in this district under 28 U.S.C. § 1391 because Defendant resides in the District of Columbia and a substantial part of the events giving rise to this action occurred in this district.

24. An actual controversy exists between the parties under 28 U.S.C. § 2201, and this Court has authority to grant the requested declaratory and injunctive relief under 28 U.S.C. §§ 2201 & 2202 and 5 U.S.C. §§ 705 & 706.

STATEMENT OF FACTS

A. Statutory and Regulatory Framework

25. Medicare is a federal health insurance program for eligible disabled individuals and senior citizens. 42 U.S.C. §§ 1395 *et seq*. Plaintiffs provide hospital services to Medicare beneficiaries that qualify for reimbursement through Medicare.

26. Medicare provider-based status is a decades-old mechanism that hospitals nationwide use to furnish outpatient hospital services to their patients, particularly at locations beyond a hospital's main campus and closer to where patients live. CMS has acknowledged that the concept has been active "[s]ince the beginning of the Medicare program," as large hospital facilities "have functioned as a single entity while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main provider for Medicare purposes." 67 Fed. Reg. 49982, 50,078 (Aug. 1, 2002). Specifically, hospitals' transformation into "integrated delivery systems" has led many of them to "acquire control of nonprovider treatment settings, such as physician offices." 65 Fed. Reg. 18,434, 18,504 (April 7, 2000).

27. The requirements for provider-based status are set out at 42 C.F.R. § 413.65. The regulation generally requires that an off-campus hospital department operate on the main hospital's license; that its clinical services and staff are supervised by and integrated with those of the main provider; that the hospital retain ultimate managerial and administrative control over the department; that the department is held out to the public as part of the main provider; and that the department's income and expenses are accounted together with those of the main hospital. If a hospital can demonstrate that it meets these requirements, then the department "is clearly and unequivocally an integral part of a [hospital] provider." 65 Fed. Reg. at 18,506.

28. Payment for medical services provided by *all* off-campus PBDs prior to November 2015 were reimbursed under the OPPS, whereas services rendered at physician offices were reimbursed at lower rates set by the MPFS. As the Secretary himself has recognized, off-campus

PBDs have higher costs than physician offices and offer "enhanced" services; therefore, the difference in pay rates was warranted.

29. Because of the important and unique role played by PBDs, the volume of services provided at off-campus PBDs has increased over the years. 83 Fed. Reg. at 59,005–07. This trend reflects developments in medical technology that have increased treatment options that were previously unavailable on an outpatient basis and that have allowed PBDs to offer increased access to hospital care to many outlying communities. *See, e.g.*, OIG Rep. No. OEI-04-97-00090 at 27 (Aug. 2000) ("We . . . believe that provider-based entities can improve access to care. In fact, many provider-based entities provide services that are enhanced relative to free-standing entities and that are virtually identical to those provided in the main portion of the hospitals.").

30. MedPAC has documented the increases in hospital outpatient services and the practice of hospitals purchasing physician offices—also referred to as "vertical integration." MedPAC has recommended to Congress that it reform the payment differences for services provided in hospital outpatient departments and physicians' offices, including a 2012 report in which MedPAC recommended that Congress eliminate payment differences in rates for E/M services. *See* Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, Ch. 3 at 71 (March 2012). In 2014, MedPAC expanded the list of services it recommended Congress target for payment rate equalization. *See* Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, Ch. 3 at 83 (March 2014).

31. Many hospitals opposed MedPAC's proposals as extreme and having failed to consider the negative effects such rate reductions would have on hospitals' ability to provide safety-net services for vulnerable populations. If adopted, MedPAC's proposals would "result in the closure of some [PBDs] and the reduction of services in others, greatly affecting the vulnerable

populations—especially those with complex medical problems—that receive care there, and limiting the ability to train the next generation of health professionals in these outpatient settings." Letter from Atul Grover, Chief Pub. Policy Officer, Association of American Medical Colleges, to The Honorable John Barrasso et al., (Jan. 13, 2012) https://www.aamc.org/download/271334/data/aamccommentletteronproposedhopdcuts.pdf.

32. Amid this ongoing debate, Congress enacted Section 603 of the BBA 2015. Contrary to MedPAC's recommendations, Congress *did not* equalize the payment rates between all PBDs and physician offices for E/M services or any others. Instead, Congress addressed the financial incentives that were generating *new* off-campus PBDs by equalizing the payment rates for all newly created off-campus PBDs with those paid to physician offices. In the same enactment, Congress preserved the ability of *existing* off-campus PBDs to continue treating patients under the OPPS reimbursement framework by excepting them from the changes in Section 603.

33. Congress left no room for doubt when it directed the Secretary to continue to pay excepted off-campus PBDs at OPPS rates. The Medicare statute requires the Secretary to develop an outpatient prospective payment system—OPPS—to pay for "covered OPD [outpatient department] services." 42 U.S.C. § 1395l(t)(1)(A). When it enacted Section 603, Congress amended Section (t)(1)(A) to exclude from the definition of "covered OPD services" those "applicable items and services" provided by "an off-campus outpatient department of a provider." 42 U.S.C. § 1395l(t)(1)(B)(v). The impact of Section 603 on an "off-campus outpatient department" is clear: all of the "items and services" it furnishes are no longer "covered OPD services" paid under OPPS. Instead, they must be paid under an "applicable payment system" that is not OPPS.

34. Section 603 is just as clear that if OPD services are furnished by a department that is *not* "an off-campus outpatient department of a provider," then Section 1833(t)(1)(A) and OPPS rates still apply. And Section 603 excludes from the definition of "off-campus outpatient department of a provider" a "department of a provider . . . that was billing under [subsection (t)] with respect to covered OPD services furnished prior to" November 2, 2015. 42 U.S.C. § 1395*l*(t)(21)(B)(ii.). Therefore, Section 603 mandates that the Medicare program must continue to pay for *all* services furnished by excepted off-campus PBDs under OPPS.

B. 2020 Rulemaking

35. As described above, the Secretary issued a rule for OPPS payments for the 2019 calendar year that flouted Congress's instructions by cutting payment rates for E/M services performed at excepted off-campus provider-based departments, and by doing so without an offsetting budget-neutrality calculation. This Court held that the payment cut in the 2019 rule was unlawful, and vacated the relevant portion of that rule. On November 12, 2019, not a month after this Court entered its final judgment, the Secretary issued a final rule setting OPPS reimbursement rates for 2020 that again reduced payments to off-campus provider-based departments for the same OPD services on the same *ultra vires* basis. 84 Fed. Reg. 61,142; *see also* 84 Fed. Reg. 39,398 (Aug. 9, 2019). The 2020 Final Rule did not attempt to offer any legal analysis that differed from what was offered in the 2019 Final Rule. The Secretary admitted in the 2020 Final Rule that it was merely a continuation of the "policy[] adopted in 2019" and that the rate cuts implemented "the second year of the 2-year phase-in" started by the 2019 Final Rule. *Id.* at 61,365.

36. In the comment period following the release of the proposed rule, and after the Court issued its vacatur of the 2019 Final Rule, stakeholders urged the Secretary not to finalize the 2020 rate cuts for E/M services for excepted off-campus PBDs, and to instead restore the

statutorily-required payment rates for those services. Specifically, a number of hospitals, including Plaintiffs in this action, submitted comments that explained that the Secretary had exceeded his statutory authority in adopting this rate cut provision in the 2019 Final Rule and that the 2020 Final Rule suffered from the same legal flaws. The Secretary, however, dismissed the commenters' legal concerns out of hand and moved ahead with the 2020 rate cut. The Secretary has failed to engage meaningfully with commenters' concerns that the agency again lacks the authority to implement the rate cut in a non-budget-neutral manner. The Secretary, instead, simply repeated his mistakes.

C. Plaintiffs Are Suffering Substantial Harm

37. The rate cut, which lowers payment rates for clinic visits by 60 percent went into effect on January 1, 2020, thereby depriving critical funding to Plaintiffs that is necessary for these institutions to effectively serve their communities.

38. The Secretary has forecasted that the total reduction in payments to affected hospital providers will amount to $640 million. 84 Fed. Reg. at 61,369.

39. Even prior to this rate cut, Plaintiffs were under significant financial strain from steadily increasing costs in the healthcare marketplace and reimbursement cuts from the government and private insurers alike.

40. Hospital outpatient departments, including those formed and operated by Plaintiffs before enactment of Section 603, play an important role serving members of their communities who otherwise may face increased barriers to receiving timely care.

41. Plaintiffs, both at the time they created their affiliated outpatient departments and when Section 603 was enacted, reasonably expected they would continue to be reimbursed under the OPPS as they had been for many years and as mandated by Congress.

42. Hospitals across the industry documented their concerns to the Secretary during the comment period preceding the 2019 Final Rule. Sarasota Memorial Hospital ("SMH") noted that it "established PBDs to provide necessary services that are *not commonly provided by Part B physicians in our community*, such as radiology, bone density, mammography, ultrasound, nuclear medicine, CT scan, MRI, cardiopulmonary rehab, cardiac rehab, anti-coagulation, a COPD clinic, a heart failure clinic, and, most importantly, urgent care services. Urgent care, in particular, is one of SMH's most significant outpatient service lines because it fills a significant gap between physician offices that offer limited services during limited hours, and costly hospital emergency departments." Sarasota Memorial Hospital, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 24, 2018) (emphasis added). Urgent care and many specialty services are billed as E/M services. As a result, "CMS's proposals to reduce payments to excepted departments for E/M services will result in an annual estimated impact to SMH of $3.7 million" and would "dramatically erode[] SMH's ability to provide services to [its] growing and aging patient population and will instead have the likely effect of increasing more costly visits to the ED." *Id*.

43. Tampa General Hospital noted that it "operate[s] two offsite clinics which primarily serve the most vulnerable patient populations in the greater Tampa metropolitan area. The services provided, and patients seen, in these clinics are substantially different from those treated in [the] average physician's office[]. These patients are more medically complex and have a substantially higher proportion of social determinants of health—such as housing, transportation, literacy, and nutrition—which provide additional challenges and add to the complexity of care." Tampa General Hospital, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to

Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 24, 2018). Once again, many of the services furnished to these patients are classified as E/M visits, and "CMS' proposed reimbursement cut for these … facilities would have a disastrous impact" on the hospital's ability to continue treating these costly patients. *Id.*

44. University of Virginia Medical Center noted that the proposed payment rate reduction would be particularly devastating to academic medical centers that "operate centers of excellence … based in hospital settings and provide outstanding team-based, patient centered care" with additional benefits such as "translators and other social services" that independent physician offices generally do not offer. Office of the Chief Executive Office of the Medical Center, University of Virginia Health System, Comment Letter on CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sept. 21, 2018). Indeed, the hospital said, low-income and vulnerable patients turn to PBDs because they "face difficulty being seen in physician offices" at all. *Id.* The hospital noted that it already incurs "negative margins when we treat Medicare patients in [PBDs], and these cuts will hurt our ability to continue to provide the full range of quality safety net services that we currently offer. This is not a sustainable financial model for public institutions like UVA Medical Center who serve[] all citizens regardless of their ability to pay for care." *Id.*

45. The Secretary nonetheless again ignored these comments, and the law, and has adopted the rate reduction and Plaintiffs, and the patients they care for, face immediate harm and will continue to suffer these harms as long as the Secretary's unlawful Final Rule is allowed to remain in place.

46. Plaintiff hospitals have submitted claims for payment to the Medicare program for their excepted off-campus E/M services that were affected by the Final Rule. In those claims, Plaintiff hospitals have asserted that they are entitled to payment for these services at the statutorily-required OPPS rates.

FIRST CAUSE OF ACTION
(Administrative Procedure Act)

The Secretary Has Violated Congress's Clear And Unambiguous Directive That Excepted Off-Campus PBDs Are To Be Reimbursed Under The OPPS Methodology

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

48. Congress enacted a direct mandate under Section 603 of the BBA 2015 that excepted off-campus PBDs would continue to be paid at OPPS rates, and not at different, lower payment rates that the Secretary applies, at Congress's direction, to nonexcepted PBDs.

49. Congress left no gaps for the Secretary to fill as its command was clear and unequivocal that excepted off-campus PBDs were exempt from any such payment changes. This legislative action ensured that grandfathered off-campus PBDs in operation before the enactment of Section 603 would not be adversely affected by the changes in payment methodology that would apply to newly formed off-campus PBDs.

50. However, the Secretary's Final Rule disregards a specific and unambiguous statutory directive by denying OPPS rates for E/M services at off-campus PBDs, and instead reimbursing for these services at lower MPFS rates, the exact same methodology the Secretary has adopted for nonexcepted off-campus PBDs following enactment of Section 603. The Secretary's actions are *ultra vires*, and he has acted well beyond his statutory authority simply to pursue his preferred policy of cutting payment rates at excepted off-campus PBDs.

51. Contrary to his assertions in the Final Rule, Section 1395l(t)(2)(F) adopted in 1997 does not permit the Secretary to make an end run around Section 603 adopted in 2015. Section 603, which sets forth an unambiguous and "specific policy" to continue OPPS payment for excepted off-campus PBD services, is a "later federal statute" setting forth a "specific policy," and the Secretary's "construction of" (t)(2)(F)—the "earlier statute"—is impermissible because it conflicts with Congress's later-adopted specific policy.

52. Further, Section (t)(2)(F) and its vague references to adopting "methods" to control "volume" does not authorize the Secretary to deviate from Congress's command that the Secretary pay for medically necessary services at statutory prescribed rates. The fact that the Medicare statute sets forth different payment rates for the same service depending on where those services are provided does not make the services provided at the more expensive setting "unnecessary." The Secretary's reliance on section (t)(2)(F) to set aside those payment rates and pay at the least costly alternative exceeds his statutory authority.

53. For these and other reasons, the Secretary's rate cut for E/M visits at off-campus PBDs is unlawful.

SECOND CAUSE OF ACTION
(Administrative Procedure Act)

The Secretary Has Further Exceeded Its Statutory Authority By Not Making the Payment Cut In A Budget Neutral Manner That Congress Required For All Adjustments To Payment Rates For OPD Services

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

55. Even assuming the Secretary has authority to impose MPFS rates for E/M visits at excepted off-campus PBDs, which he clearly does not under Section 603 of the BBA 2015, the

Secretary acted unlawfully in the Final Rule by not implementing the rate cut in a "budget neutral" manner.

56. Section 1833(t)(9) of the Social Security Act requires that "adjustments" of this sort must be implemented in a budget-neutral manner.

57. The Secretary, however, in the Final Rule chose not to make any funding increases to offset the anticipated loss of $640 million in Medicare funding in 2020 to excepted off-campus PBDs resulting from this rate cut. Instead, directly contravening the budget neutrality requirements of Section 1833(t)(9), CMS will retain that money in its coffers.

58. In so doing, the Secretary has acted in an *ultra vires* manner well beyond his delegated authority.

59. For these and other reasons, the Secretary's rate cut for E/M visits at off-campus PBDs is unlawful.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request an Order:

a. Declaring that Section X.C of the 2020 Final Rule exceeds the Secretary's statutory authority in that CMS must reimburse Excepted Off-Campus PBDs under the OPPS methodology;

b. Declaring that Section X.C of the 2020 Final Rule exceeds the Secretary's statutory authority in that rate cuts for OPD services must be done in a budget neutral manner;

c. Vacating and setting aside Section X.C of the 2020 Final Rule;

d. Enjoining the Secretary from enforcing, applying, or implementing Section X.C of the 2020 Final Rule, and ordering that the Secretary provide prompt payment of any amounts improperly withheld as a result of the Final Rule;

e. Requiring the Secretary to pay legal fees and costs of suit incurred by the Plaintiffs; and

f. Providing such other just and proper relief as the Court may consider appropriate.

Respectfully submitted,

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