UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY 4000 Cambridge Street Kansas City, KS 66160	)	
ANMED HEALTH SYSTEM d/b/a AnMed Health d/b/a AnMed Health Medical Center 800 N Fant St. Anderson, SC 29621	)	
ANMED HEALTH SYSTEM d/b/a Cannon Memorial Hospital, Inc. d/b/a AnMed Health Cannon 800 N Fant St. Anderson, SC 29621	)	Civil Action No. 19-CV-132
BLUE RIDGE HEALTHCARE SYSTEM, INC. d/b/a CHS Blue Ridge 2201 S Sterling St Morganton, NC 28655	)	
CARILION MEDICAL CENTER 1906 Belleview Avenue Roanoke, VA 24014	)	
COLUMBUS REGIONAL HEALTHCARE SYSTEM INC. 500 Jefferson Street Whiteville, NC 28472	)	
COPLEY MEMORIAL HOSPITAL, INC. d/b/a Rush Copley Medical Center 2000 Ogden Avenue Aurora, IL 60504	)	
EAST BATON ROUGE MEDICAL CENTER, LLC. d/b/a OCHSNER MEDICAL CENTER - BATON ROUGE 17000 Medical Center Drive Baton Rouge, LA 70816	)	
FAYETTE COMMUNITY HOSPITAL, INC. d/b/a Piedmont Fayette Hospital, Inc	)	

1255 Hwy 54 West)
Fayetteville, GA 30214)
)
FLORIDA HEALTH SCIENCES CENTER INC)
dba Tampa General Hospital)
One Tampa General Circle)
Tampa, Florida 33606)
)
LIMA MEMORIAL HEALTH SYSTEM)
1001 Bellefontaine Ave.)
Lima, OH 45804)
)
MERCY MEDICAL CENTER, INC.)
1320 Mercy Drive NW, Canton, OH 44708)
)
MONTEFIORE HEALTH SYSTEM, INC.)
d/b/a Montefiore Medical Center)
555 South Broadway)
Tarrytown, New York 10591)
)
MONTEFIORE HEALTH SYSTEM, INC.)
d/b/a St. Luke's Cornwall Hospital)
555 South Broadway)
Tarrytown, New York 10591)
)
MONTEFIORE HEALTH SYSTEM, INC.)
d/b/a White Plains Hospital)
555 South Broadway)
Tarrytown, New York 10591)
)
NORTHWEST MEDICAL CENTER)
6200 N. La Cholla Blvd.)
Tucson, AZ 85641)
)
OCHSNER CLINIC FOUNDATION)
d/b/a OCHSNER MEDICAL CENTER)
1516 Jefferson Highway New Orleans, LA 70121)
)
OSF HEALTHCARE SYSTEM)
d/b/a OSF Heart of Mary Medical Center)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
OSF HEALTHCARE SYSTEM)
d/b/a OSF Sacred Heart Medical Center)

800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
OSF HEALTHCARE SYSTEM)
d/b/a Ottawa Regional Hospital & Healthcare Center)
d/b/a OSF Saint Elizabeth Medical Center)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
OSF HEALTHCARE SYSTEM)
d/b/a Saint Anthony Medical Center)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
OSF HEALTHCARE SYSTEM)
d/b/a Saint Anthony's Health Center)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
OSF HEALTHCARE SYSTEM)
d/b/a Saint James Hospital)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
OSF HEALTHCARE SYSTEM)
d/b/a St. Joseph Medical Center)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
)
PIEDMONT ATHENS REGIONAL)
MEDICAL CENTER, INC.)
1199 Prince Avenue)
Athens, GA 30606)
)
PIEDMONT HOSPITAL, INC)
1968 Peachtree Road, NW)
Atlanta, GA 30309)
)
PIEDMONT MOUNTAINSIDE HOSPITAL, INC.)
1266 HWY 515 South)
Jasper, GA 30143)
)
PIEDMONT NEWNAN HOSPITAL, INC.)
745 Poplar Road)
Newnan, GA 30265)
)

RUSH OAK PARK HOSPITAL, INC.
1700 W Van Buren St., Ste 301
Chicago, IL 60612

RUSH UNIVERSITY MEDICAL CENTER
1700 W Van Buren St., Ste 301
Chicago, IL 60612

SARASOTA MEMORIAL HOSPITAL
1700 Tamiami Trail
Sarasota, FL 34239

SCOTLAND HEALTH CARE SYSTEM
d/b/a Scotland Regional
210 W. Cronly Street
Laurinburg, NC 28352

THE CHARLOTTE-MECKLENBURG
HOSPITAL AUTHORITY
d/b/a Atrium Health Anson
1111 Metropolitan Avenue Suite 600
Charlotte, NC 28204

THE CHARLOTTE-MECKLENBURG
HOSPITAL AUTHORITY
d/b/a Atrium Health Cleveland
1111 Metropolitan Avenue Suite 600
Charlotte, NC 28204

THE CHARLOTTE-MECKLENBURG
HOSPITAL AUTHORITY
d/b/a Atrium Health Kings Mountain
1111 Metropolitan Avenue Suite 600
Charlotte, NC 28204

THE CHARLOTTE-MECKLENBURG
HOSPITAL AUTHORITY
d/b/a Atrium Health Lincoln
1111 Metropolitan Avenue Suite 600
Charlotte, NC 28204

THE CHARLOTTE-MECKLENBURG
HOSPITAL AUTHORITY
d/b/a Atrium Health Pineville
1111 Metropolitan Avenue Suite 600
Charlotte, NC 28204

)
THE CHARLOTTE-MECKLENBURG)
HOSPITAL AUTHORITY)
d/b/a Atrium Health Union)
1111 Metropolitan Avenue Suite 600)
Charlotte, NC 28204)
)
THE CHARLOTTE-MECKLENBURG)
HOSPITAL AUTHORITY)
d/b/a Atrium Health University City)
1111 Metropolitan Avenue Suite 600)
Charlotte, NC 28204)
)
THE CHARLOTTE-MECKLENBURG)
HOSPITAL AUTHORITY)
d/b/a Carolinas HealthCare System NorthEast)
1111 Metropolitan Avenue Suite 600)
Charlotte, NC 28204)
)
THE CHARLOTTE-MECKLENBURG)
HOSPITAL AUTHORITY)
d/b/a Carolinas HealthCare System Stanly)
1111 Metropolitan Avenue Suite 600)
Charlotte, NC 28204)
)
THE CHARLOTTE-MECKLENBURG)
HOSPITAL AUTHORITY)
d/b/a Carolinas Medical Center)
1111 Metropolitan Avenue Suite 600)
Charlotte, NC 28204)
)
THE MEDICAL CENTER)
OF CENTRAL GEORGIA, INC.)
691 Cherry Street, Suite 700)
Macon GA 31201)
)
THE RECTOR AND VISITORS OF THE)
UNIVERSITY OF VIRGINIA)
d/b/a University of Virginia Medical Center)
1215 Lee Street)
Charlottesville, VA 22908)
)
UNIVERSITY HOSPITALS HEALTH SYSTEM, INC.)
d/b/a UH Cleveland Medical Center)
3605 Warrensville Center Road)
Shaker Heights, OH 44122-5203)

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.

[PROPOSED] SECOND AMENDED COMPLAINT

Plaintiffs, 46 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. 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. But the Secretary believes that Congress did not go far enough, and under a rule that went into effect January 1, 2019, the Secretary is now paying the lower, physician office rate to the very hospital departments that Congress protected from this change. The Secretary's rule is irrational, a patent misconstruction of the Social Security Act and a blatant attempt to circumvent the will of Congress clearly expressed in Section 603.

2. 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.

3. 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.

4. 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).

5. 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. § 1395l(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. § 1395l(t)(21)(C) (identifying that payment be made for nonexcepted PBDs under an "applicable payment system").

6. 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]").

7. However, on November 21, 2018, the Secretary reversed course and issued a final rule, effective January 1, 2019, that eliminates the higher, OPPS reimbursement rate for E/M services provided by excepted off-campus PBDs. The Secretary, instead, will only reimburse for E/M services at the lower, MPFS rate that nonexcepted off-campus PBDs receive. *See* Centers for Medicare & Medicaid Services, Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Dep't of Health and Human Servs., 83 Fed. Reg. 58,818 (Nov. 21, 2018) ("Final Rule"). 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 has blatantly disregarded a specific and unambiguous statutory directive, acted well beyond his authority and nullified that statutory exemption.

8. 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.*

9. The Secretary has cited 42 U.S.C. § 1395l(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.

10. The Secretary's Final Rule is also *ultra vires* because it violates 42 U.S.C. § 1395l(t)(9)(B) (Section 1833(t)(9)(B) of the Social Security Act). 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. 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 admits that the initial rate cut for E/M services in 2019 alone will reduce Medicare payments for hospital outpatient department services by $300 million—and even more in future years when the E/M rate cut is fully implemented. 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.

11. 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 declare the Secretary's Final Rule to be *ultra vires* and enjoin the agency from implementing any payment methodology other than OPPS rates for all E/M services provided by excepted off-campus PBDs.

PARTIES

12. 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, 2019.

13. The plaintiffs in this action are:

- UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, Medicare Provider No. 17-0040;
- ANMED HEALTH SYSTEM d/b/a AnMed Health d/b/a AnMed Health Medical Center, Medicare Provider No. 42-0027;
- ANMED HEALTH SYSTEM d/b/a Cannon Memorial Hospital, Inc. d/b/a AnMed Health Cannon, Medicare Provider No. 42-0011;
- BLUE RIDGE HEALTHCARE SYSTEM, INC. d/b/a CHS Blue Ridge, Medicare Provider No. 34-0075;
- CARILION MEDICAL CENTER, Medicare Provider No. 49-0024;
- COLUMBUS REGIONAL HEALTHCARE SYSTEM, INC., Medicare Provider No. 34-0068;
- COPLEY MEMORIAL HOSPITAL, INC. d/b/a Rush Copley Medical Center, Medicare Provider No. 14-0029;
- EAST BATON ROUGE MEDICAL CENTER, LLC d/b/a OCHSNER MEDICAL CENTER - BATON ROUGE, Medicare Provider No. 19-0202;
- FAYETTE COMMUNITY HOSPITAL, INC. d/b/a Piedmont Fayette Hospital, Inc, Medicare Provider No. 11-0215;

- FLORIDA HEALTH SCIENCES CENTER INC d/b/a Tampa General Hospital, Medicare Provider No. 10-0128;
- LIMA MEMORIAL HEALTH SYSTEM, Medicare Provider No. 36-0009;
- MERCY MEDICAL CENTER, INC., Medicare Provider No. 36-0070;
- 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;
- THE MEDICAL CENTER OF CENTRAL GEORGIA, INC., Medicare Provider No. 11-0107;
- 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 OSF Heart of Mary Medical Center, Medicare Provider No. 14-0113;
- OSF HEALTHCARE SYSTEM d/b/a OSF Sacred Heart Medical Center, Medicare Provider No. 14-0093;
- OSF HEALTHCARE SYSTEM d/b/a Ottawa Regional Hospital & Healthcare Center d/b/a OSF Saint Elizabeth Medical Center, Medicare Provider No. 14-0110;

- 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 James Hospital, Medicare Provider No. 14-0161;
- OSF HEALTHCARE SYSTEM d/b/a St. Joseph Medical Center, Medicare Provider No. 14-0162;
- PIEDMONT ATHENS REGIONAL MEDICAL CENTER, INC., Medicare Provider No. 11-0074;
- PIEDMONT HOSPITAL, INC, Medicare Provider No. 11-0083;
- PIEDMONT MOUNTAINSIDE HOSPITAL, INC., Medicare Provider No. 11-0225;
- PIEDMONT NEWNAN HOSPITAL, INC., Medicare Provider No. 11-0229;
- RUSH OAK PARK HOSPITAL, INC., Medicare Provider No. 14-0063;
- RUSH UNIVERSITY MEDICAL CENTER, Medicare Provider No. 14-0119;
- SARASOTA MEMORIAL HOSPITAL, Medicare Provider No. 10-0087;
- SCOTLAND HEALTH CARE SYSTEM d/b/a Scotland Regional, Medicare Provider No. 34-0008;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Anson, Medicare Provider No. 34-0084;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Cleveland, Medicare Provider No. 34-0021;

- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Atrium Health Kings Mountain, Medicare Provider No. 34-0037;
- 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 HealthCare System Stanly, Medicare Provider No. 34-0119;
- THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY d/b/a Carolinas Medical Center, Medicare Provider No. 34-0113;
- THE RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA d/b/a University of Virginia Medical Center, Medicare Provider No. 49-009;
- UNIVERSITY HOSPITALS HEALTH SYSTEM, INC. d/b/a UH Cleveland Medical Center, Medicare Provider No. 36-0137; and
- VANDERBILT UNIVERSITY MEDICAL CENTER, Medicare Provider Number 44-0039.

14. 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

15. 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 as required by Section 603. Each of the Plaintiffs has 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.

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

17. 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.

18. 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

19. 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.

20. 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).

21. 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.

22. 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.

23. 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.").

24. 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).

25. 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.

26. 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.

27. 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.

28. 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. § 1395l(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. Proposed Rule

29. Notwithstanding this clear, specific and unambiguous statutory directive, the Secretary on July 31, 2018 issued a proposed rule that would "apply an amount equal to the site-specific MPFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the MPFS payment rate) for [E/M] services . . . when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act." 83 Fed. Reg. at 37,142. In other words, contrary to Section 603, the Secretary proposed to cut the payment rate for E/M services provided

at excepted off-campus PBDs by applying the lower, MPFS rate reserved for such services provided at new off-campus PBDs that are subject to Section 603's changes.

30. The Secretary reasoned that this rate cut was necessary to equalize payment between excepted and nonexcepted facilities to address what he regarded as an unnecessary "shift of services from the physician office to the hospital outpatient department" caused by the difference in payment rates. *Id.* Fully aware that Congress had already addressed this issue three years earlier, the Secretary determined that Section 603 only "address[ed] some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting." *Id.* at 37,141. Unsatisfied with the fact that Congress rejected MedPAC's recommendation to equalize payment rates between *all* hospital outpatient departments and physicians' offices, the Secretary proposed a rule to override Congress's mandate to exempt pre-existing off-campus PBDs from Section 603.

31. Notably, the Secretary does not claim that he has the authority to reduce E/M rates pursuant to any authorization under Section 603. In the proposed rule, the Secretary instead identified Section 1833(t)(2)(F) of the Medicare statute as the authority that permits him to implement this rate cut. When it created the OPPS system in 1997, Congress required the Secretary to reimburse hospitals for "covered outpatient department services" using a precise formula set forth in statute to set prospective rates for these services. *See* 42 U.S.C. § 1395l(t)(3). Section (t)(2)(F), enacted at the same time, directs the Secretary to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services." The Secretary has, until now, never interpreted Section (t)(2)(F) as permitting him to selectively override the precise formula in Section 1833(t)(3) to create his own, preferred payment rate for a specific outpatient hospital department service.

32. Although Section (t)(2)(F) directs the Secretary to develop a "method" to "control unnecessary increases in the volume" of services, E/M services provided in excepted off-campus PBDs are not "unnecessary" merely because they are reimbursed at a higher rate. 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."

33. Even if Section (t)(2)(F) allowed the Secretary to set his own payment rates (and it does not), the Secretary has acted far in excess of any such authority by implementing a new payment rate without any data to support it. None of the evidence or data cited by the Secretary in the proposed rule showed any ongoing "shift of services from the physician office to the hospital outpatient department" setting that post-dates the enactment of Section 603. In fact, the annual MedPAC reports and other commentary referenced by the Secretary in the proposed rule analyzed data from periods *before* the statutory changes imposed by Section 603 went into effect and do not support the Secretary's decision. Any "shift of services" cannot possibly increase Medicare expenditures because any newly-acquired physician practice would still be paid under the MPFS as a nonexcepted PBD. Therefore, even if the Secretary had the authority to override Congress's decision in Section 603 (which he does not), he cited no evidence to support it.

34. The Secretary also proposed to make this payment cut in a non-budget-neutral manner, meaning that the decreased payments to nonexcepted off-campus PBDs would not be offset by positive adjustments to OPPS rates elsewhere to achieve the same overall funding to hospitals under Medicare. *See* 83 Fed. Reg. at 37,142. Again, the Secretary acted contrary to clear and controlling legislative directives, as Section 1833(t)(9) requires that changes to the group of covered OPD services and "adjustments," including the "relative payment weights" under OPPS,

must be implemented in a budget-neutral manner. *See* Section 1833(t)(9)(B). This provision encompasses rate changes such as the substitution of MPFS rates for E/M services instead of the statutorily-required OPPS rates for excepted off-campus PBDs.

35. Despite this clear language, the Secretary reasoned that exercises of his authority to develop "method[s]" for controlling "volume" increases are not subject to the same budget neutrality restrictions. This reasoning ignores the fact that his proposed "method" for restricting volume increases was to directly lower rates for one-type of service (E/M services), the very sort of "adjustment" that is plainly subject to budget neutrality requirements. Moreover, Section (t)(9)(F) authorizes the Secretary to "adjust the update to the conversion factor"—*i.e.*, budget neutralize—when implementing "the methodologies described in paragraph (2)(F)."

36. In 2019 alone, CMS estimated the impact of making this payment cut in a non-budget-neutral manner would result in $610 million less Medicare funding to hospitals.

C. Comments

37. During the comment period following the release of the proposed rule, thousands of stakeholders submitted written comments, many stating that the Secretary's proposed rate cut for E/M services provided at excepted off-campus PBDs violated clear statutory directives and was unsupported by evidence. In particular, the commenters stated:

a. Congress was unambiguous in the choice it made in Section 603: pre-existing off-campus PBDs would continue to be paid at OPPS rates while new off-campus PBDs would be paid lesser rates. Further, the general authority in Section (t)(2)(F), enacted nearly *twenty* years before Section 603, to adopt "methods" to control unnecessary volume increases does not override this explicit mandate. Under well-established principles of statutory construction, a "later federal statute" setting forth

a "specific policy"—*i.e.*, Section 603—"control[s]" any "construction of the earlier statute" that could arguably conflict with that later-adopted specific policy. Ex. A (Comment of Sarasota Memorial Hospital) (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000) (citations omitted)).

b. 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." *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) ("As written, the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all."). Section (t)(2)(F) and its vague references to adopting "methods" to control "volume" does not authorize the Secretary to deviate from this fundamental structure of the Medicare statute to pay for medically necessary services at statutory prescribed rates. To read (t)(2)(F) as the Secretary does would "permit an end-run around the statute" and violate the judicial cannon that "Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. American Trucking Association*, 531 U.S. 457, 468 (2001). *See* Ex. A (Comment of Sarasota Memorial Hospital).

c. The Secretary failed to make the requisite showing of "unnecessary" increases in medical services to trigger whatever actual authority the Secretary could properly exercise under (t)(2)(F). The Secretary merely theorized about the purported shift in location where E/M visits were taking place, not that the visits themselves were

in any way "unnecessary." Therefore, not only did the Secretary fundamentally misconstrue (t)(2)(F) to assume powers not delegated to him by Congress—*i.e.*, modifying statutorily-prescribed rates for services provided by excepted off-campus PBDs—the Secretary failed to fulfill the basic threshold requirements of (t)(2)(F). *See* Ex. A (Comment of Sarasota Memorial Hospital).

d. The Secretary's proposal to implement the rate cut for excepted off-campus PBDs in a non-budget neutral manner also exceeded the agency's authority. Section 1833(t)(9) requires adjustments to be implemented in a budget-neutral manner which includes rate changes such as the substitution of MPFS rates instead of OPPS rates paid E/M services at excepted off-campus PBDs. If permitted to implement this rate cut in a non-budget-neutral manner, the Secretary could invoke (t)(2)(F) to justify the application of every rate reduction for any OPPS service in a non-budget neutral manner and thereby circumvent the budget neutrality requirement in (t)(9) altogether. Given the express statutory command that "adjustments" must be budget neutral, it would defy well-established canons of statutory construction for the Secretary to ignore, yet again, a specific legislative command in favor of the Secretary overly expansive reading of (t)(2)(F). *See* Ex. A (Comment of Sarasota Memorial Hospital).

D. Final Rule

38. On November 21, 2018, the Secretary issued a Final Rule that, among other things, finalized the rate cut for excepted off-campus PBDs effective January 1, 2019. 83 Fed. Reg. 58,818. In other words, as of January 1, excepted off-campus PBDs no longer receive OPPS rates for E/M services, but rather are reimbursed based at MPFS rates. The only substantive change

made by the Secretary in the Final Rule was phasing-in full implementation of the rate cut over a two-year period, meaning that affected hospitals will receive $300 million less in Medicare funding in 2019 and $610 million less in 2020 when the rate cut is fully implemented.

39. The Secretary dismissed the commenters' legal challenges out of hand. As to the concern that the Secretary was overturning Congress's mandate to except pre-existing off-campus PBDs from Section 603, the Secretary reiterated his view that Congress had not gone far enough: the "action Congress took in 2015 to address certain off-campus PBDs helped stem the tide of these increases in the volume of OPD services," but many "off-campus PBDs continue to be paid the higher OPPS amount for these services." 83 Fed. Reg. at 59,012. The Secretary did not engage with these comments in any meaningful way and stated: "We do not believe that the section 603 amendments to section 1833(t) of the Act, which exclude applicable items and services furnished by nonexcepted off-campus PBDs from payments under the OPPS, preclude us from exercising our authority in section 1833(t)(2)(F) of the Act to develop a method for controlling unnecessary increases in the volume of covered outpatient department services under the OPPS." *Id.*

40. The Secretary also failed to engage meaningfully with commenters' concerns that the agency lacked the authority to implement the rate cut in a non-budget-neutral manner. With no analysis whatsoever, the Secretary simply repeated his position in the proposed rule that budget-neutrality was not required because he was invoking his authority under (t)(2)(F). *See id.* ("we maintain that the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act.").

E. Plaintiffs Are Suffering Substantial Harm

41. The rate cut, which lowers payment rates for clinic visits by 30 percent in 2019 (and an additional 30 percent in 2020) went into effect on January 1, 2019, thereby depriving critical funding to Plaintiffs that is necessary for these institutions to effectively serve their communities.

42. As the Secretary has forecasted, the total reduction in payments to affected hospital providers will be approximately $380 million in 2019, and $760 million in 2020. 83 Fed. Reg. at 59014.

43. 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.

44. 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.

45. 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. The Secretary's Final Rule implementing this rate cut for E/M services, which was only first proposed five months before the January 1, 2019 effective date, was a severe and unexpected financial hit to the operations of Plaintiffs that jeopardizes their ability to care for the medically vulnerable populations often treated in PBDs.

46. Plaintiffs raised these concerns to the Secretary during the comment period preceding the Final Rule. Plaintiff 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*.

47. Plaintiff 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.*

48. Plaintiff 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.*

49. The Secretary nonetheless 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.

50. The 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, asserting their view that the Final Rule is invalid. *See* Ex. B at 1–8. Additionally, Medicare has paid E/M claims

submitted by the Plaintiff hospitals at the lower MPFS rate set by the Secretary's Final Rule. *See id.* at 9–16. The Plaintiff hospitals have filed Requests for Redetermination that take an administrative appeal of Medicare's failure to pay them the statutorily-prescribed rate for their services. *Id.*

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

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

52. 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.

53. 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.

54. 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.

55. 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.

56. 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.

57. 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

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

59. 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.

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

61. The Secretary, however, in the Final Rule chose not to make any funding increases to offset the anticipated loss of $300 million in Medicare funding in 2019 to excepted off-campus PBDs (and even more in future years) 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.

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

63. 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 the Final Rule Exceeds the Secretary's statutory authority in that CMS must reimburse Excepted Off-Campus PBDs under the OPPS methodology;

b. Declaring that the 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 the Final Rule;

d. Enjoining the Secretary from enforcing, applying, or implementing the 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,

/s/ *Mark D. Polston*
Mark D. Polston (D.C. Bar No. 431233)
Christopher P. Kenny (D.C. Bar No. 991303)
Nikesh Jindal (D.C. Bar No. 492008)
Joel McElvain (D.C. Bar No. 448431)
KING & SPALDING LLP
1700 Pennsylvania Avenue, N.W.
Suite 200
Washington, D.C. 20006
202.626.5540 (phone)
202.626.3737 (fax)
MPolston@kslaw.com

Date: March 13, 2019