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)
)
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)
555 South Broadway)
Tarrytown, New York 10591)
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MONTEFIORE HEALTH SYSTEM, INC.)
d/b/a White Plains Hospital)
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Tarrytown, New York 10591)
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NORTHWEST MEDICAL CENTER)
6200 N. La Cholla Blvd.)
Tucson, AZ 85641)
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OCHSNER CLINIC FOUNDATION)
d/b/a OCHSNER MEDICAL CENTER)
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d/b/a OSF Heart of Mary Medical Center)
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Peoria, IL 61603)
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OSF HEALTHCARE SYSTEM)
d/b/a OSF Sacred Heart Medical Center)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
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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)
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d/b/a Saint Anthony Medical Center)
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d/b/a Saint James Hospital)
800 NE Glen Oak Avenue)
Peoria, IL 61603)
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OSF HEALTHCARE SYSTEM)
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Peoria, IL 61603)
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PIEDMONT ATHENS REGIONAL)
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1968 Peachtree Road, NW)
Atlanta, GA 30309)
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PIEDMONT MOUNTAINSIDE HOSPITAL, INC.)
1266 HWY 515 South)
Jasper, GA 30143)
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PIEDMONT NEWNAN HOSPITAL, INC.)
745 Poplar Road)
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THE CHARLOTTE-MECKLENBURG)
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d/b/a Atrium Health Kings Mountain)
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THE MEDICAL CENTER
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THE RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA
d/b/a University of Virginia Medical Center
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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.

AMENDED COMPLAINT

Plaintiffs, 44 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;
- 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*
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Date: February 15, 2019

Exhibit A

SARASOTA MEMORIAL
HEALTH CARE SYSTEM

September 24, 2016
Centers for Medicare & Medicaid Services

RE: CMS 1695-P, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule, July 31, 2018

To Whom It May Concern:

On behalf of the patients and staff of Sarasota Memorial Hospital (SMH), I appreciate the opportunity to comment on the provisions contained in the Centers for Medicare & Medicaid Services's (CMS) calendar year (CY) 2019 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule. 83 Fed. Reg. 37046 (July 31, 2018). SMH strongly opposes CMS's proposals to: (i) exclude from OPPS payment those services provided by an excepted off-campus provider-based department (PBD) that were not part of a "clinical family of services" that the PBD provided during a baseline period covering November 1, 2014 through November 1, 2015; and (ii) cap the OPPS reimbursement rate for evaluation and management (E/M) services provided by excepted off-campus PBDs to the amount of the newly blended rate for E/M services CMS recently proposed under the Medicare Physician Fee Schedule (MPFS). As a legal matter, these proposals are contrary to statutory authority, are not supported by substantial evidence, and are otherwise arbitrary and capricious. But much more importantly, these proposals, if adopted, would visit serious harm to safety net hospitals like SMH that are often the only source of care for underserved populations.

SMH is a public hospital owned by the Sarasota County Public Hospital District. As the only nonprofit hospital in Sarasota County, Florida, SMH provides a wide range of high-risk, high-cost safety net services, including obstetrics, neonatal intensive care, pediatric, and psychiatric services for patients of all ages. Recognizing that good care extends beyond the hospital campus, SMH has also established a network of outpatient facilities and provider-based urgent care centers located throughout the community that serves Sarasota's growing population and provides on-site radiology, laboratory, and pharmacy services that are not typically found in freestanding physician offices. In addition to improving the community's access to care, our off-campus PBDs help address the costs associated with serving as the county's sole provider of safety net services by offering a lower-cost alternative to the costly emergency room setting.

As stated in comments to CMS's proposals in the CY 2017 OPPS Proposed Rule, which are attached here as **Exhibit 1**, SMH strongly believes that CMS continues to mischaracterize the majority of off-campus PBDs as hospital acquisitions and conversions of freestanding physician practices that previously furnished services under the MPFS only to become hospital departments offering the same services but paid at the OPPS rate. The Sarasota County Public Hospital District includes a separate non-profit 501(c)(3) entity that employs 61 primary care physicians, 62 specialty care physicians and 39 non-physician practitioners, all of whom are enrolled in Medicare Part B and paid under the MPFS. None of these physicians' practices has been established as or converted to PBD status and paid under the OPPS. They remain physician offices and clinics reimbursed pursuant to the MPFS.

Rather, SMH 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

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limited hours, and costly hospital emergency departments. Many patients treated at SMH's urgent care departments are referrals from community physicians that do not offer sutures, incisions, draining procedures, EKGs, IVs, or foreign body removal. SMH's PBDs are constantly evolving to meet the medical needs of our growing – and aging – patient population. CMS's proposal to limit service line changes at excepted off-campus PBDs will handcuff our ability to offer resource-intensive services that Sarasota-area physician practices do not offer. Not only do physician offices not offer these services, they also do not operate at the extended hours that SMH's excepted PBDs operate.

SMH's urgent care departments are open twelve hours per day (8:00 a.m. to 8:00 p.m.), seven days a week, every day of the year except Thanksgiving Day and Christmas Day. During flu season, SMH extended its urgent care hours even further to 7:00 a.m. to 10:00 p.m. Most community physician offices are typically only open from 8:00 a.m. to 4:30 p.m. Monday through Friday. Most physician practices have large panels of established patients, making it difficult for even longstanding patients to make same-day appointments. The odds of getting an appointment for new patients or visitors are even lower. SMH established its urgent care departments as a direct response to these gaps in access as local physicians showed no desire to fill these needs. Not surprisingly, SMH treated 17,102 total out-of-state patients during the peak visiting season of January-March 2018, a four-fold spike over summer months (3,280 out-of-state patients from July-September 2017).

This dynamic is exactly why OPPS reimbursement is critical to our excepted PBDs. These departments offer a variety of specialized services for extended hours each day. By contrast, independent physician offices maximize their schedules by squeezing in as many short, relatively low-complex visits into a given day. They do not offer advanced specialized services because they can only treat so many patients in a short time period. The "availability cost" – i.e., the cost necessary to maintain long hours for specialized services that very few patients may utilize on any particular day or even a season – is too great for a physician office to bear. But the need for these services and hours is still present in the community, and SMH has filled that gap. Limiting OPPS reimbursement for any new specialized services that SMH's excepted PBDs may want offer in the future increases the likelihood that they will not be offered in these departments at all.

To make matters worse, SMH's service area is in the midst of an increasing physician shortage that will further limit patient access. As described in **Exhibit 2**, the greater Sarasota area projects an acute physician shortage by 2020 that will coincide with a significant increase in our Medicare-age population. The Sarasota area itself continues to expand as former ranch and agricultural properties are developed into new housing communities. As a public hospital

with an exceptional reputation for quality, SMH is the first provider many of these new residents seek out. This population will require additional services and, as a result, our facilities must have the flexibility to offer these services to them. SMH simply cannot build enough parking garages and facilities on its landlocked campus to accommodate this growth. These patients must continue to be treated in our urgent care and other excepted departments throughout the community.

And CMS must provide payment for services furnished at these locations at the rate full OPPS prescribed by Congress in order for safety net hospitals to ensure access to such services. It is simply not enough for CMS to blithely state that its proposals do not prevent patients from being treated in outpatient hospital settings. The agency simply ignores the effect that these proposals will have, on patients and the facilities they seek out for care, in favor of an unsubstantiated fear. CMS's belief that it needs to deploy additional tools to curb hospital acquisitions of physician practices – when it has provided no new information or data showing that such acquisitions continue apace – is simply inappropriate when the biggest trend in physician practice is a wave of retirements hitting just as the Medicare population is about to swell.

In addition, 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, as documented in **Exhibit 3**. Again, these services are not typical physician office services. SMH's excepted urgent care centers offer a wide array of services that physician offices simply do not provide, an often a complex E/M code is billed for such encounters. Reducing E/M payment rates for excepted departments dramatically erodes SMH's ability to provide services to this growing and aging patient population and will instead have the likely effect of increasing more costly visits to the ED. In fiscal year 9/30/18 to date, SMH treated 31,745 total patients who were either seasonal residents or out of state or foreign tourists; 1,511 were inpatient admissions with the remaining being outpatient visits. These patients do not have regular primary care physicians in the area and face two choices for care: our urgent care centers or hospital emergency rooms. Indeed, 84 percent of SMH's non-state patients are seen in either the ED or in our provider-based urgent care; of these encounters, 70 percent are seen in urgent care departments. Even with the significant shift in lower-acuity services that SMH has managed to shift out of the ED and into its urgent care departments, volumes and wait times in our ED remain high, especially during peak tourist and visiting seasons. Any change that would potentially shift even more volume back to the ED is untenable for patients seeking true emergency services.

For the reasons set forth below, SMH urges CMS to abandon its proposals on these issues. These proposals are the product of implausible readings of the relevant statutory authority, and are not supported by substantial evidence in CMS's rulemaking record. If adopted, each will result in significant harm to patients treated by safety net providers like SMH.

I. CMS's Proposal to Deny OPPS Reimbursement for "New" Clinical Services at Excepted PBDs Is Contrary to the Statute and Lacks any Reasoned Basis

The Supreme Court has made clear: "If the statutory language is plain, we must enforce it according to its terms." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015). As the D.C. Circuit noted in *Loving v. I.R.S.*, 742 F.3d 1013, 1016 (D.C. Cir. 2014), "[n]o matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, whether the agency has stayed within the bounds of its statutory authority." Consistent with these principles of statutory interpretation, the plain language of Section 603 of the Bipartisan Budget Act of 2015 (BBA15) does not permit CMS to adopt this proposal.

CMS concedes that "there is no congressional record available" for Section 603. 83 Fed. Reg. at 37148. But the agency cannot use the absence of legislative history to rewrite a statute to suit its policy goals when the plain language of that statute does not support it. CMS believes that Congress's intent in passing Section 603 was to limit the establishment of new off-campus PBDs, apparently concerned that hospitals had a repeated practice of acquiring freestanding physician clinics, "flipping" them to PBD status while offering no new services or otherwise distinguishing the clinics from their previous status, and simply pocketing the difference in OPPS reimbursement over the MPFS rate. *See, e.g.*, 83 Fed. Reg. at 37147. SMH strongly objects to this characterization because it is not supported in any statutory authority nor, in SMH's case, is it supported by fact. Moreover, it ignores repeated statements by CMS recognizing the important and unique role played by PBDs—something that Congress certainly would want to preserve, and did though enactment of Section 603, in a meaningful way. *See, e.g.*, OIG Rep. No. OEI-04-97-00090 at 27 (Aug. 2000) ("The provider-based program is a critical part of [CMS's] program that does increase beneficiary protections. We also 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."); 73 Fed. Reg. 66187, 66193 (Nov. 7, 2008) (recognizing that outpatient hospital payment rates are appropriately higher than payments to freestanding sites because of "the high facility overhead expenses that are associated with the delivery of services unique to an outpatient hospital or department of an outpatient hospital."). But even if one were to concede that CMS has accurately captured Congress's intent, and SMH does not, CMS has strayed well beyond the statute to essentially halt hospitals in their tracks from offering new clinical innovations and treatments. This was not Congress's intent as evidenced by the plain language of Section 603 itself.

Section 1833(t)(1)(A) of the Social Security Act requires CMS to pay for "covered OPD services" under the OPPS. When it enacted Section 603, Congress excluded 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). Congress then defined "applicable items and services" as all "items and services other than items and services furnished by a dedicated emergency department." *Id.* § 1395l(t)(21)(A). Thus, the impact of Section 1395l(t)(1)(B)(v) on an "off-campus outpatient department" is substantial and broad. Unless it is a dedicated ED, then literally all of the "items and services" the off-campus department furnishes must be paid under a reimbursement methodology other than the OPPS. The converse is also true; if OPD services are furnished by an outpatient department that is *not* "an off-campus outpatient department of a provider," then Section 1833(t)(1)(A) still applies, and the Secretary is required to pay for

those OPD services under the OPPS. *Id.* § 1395l(t)(1)(A) ("With respect to covered OPD services . . . the amount of payment . . . *shall be determined under a prospective payment system*. . . .") (emphasis added).

Congress, of course, excluded from the definition of "off-campus outpatient department of a provider" a department of a provider . . . that was billing under this subsection with respect to covered OPD services furnished prior to" November 2, 2015. 42 U.S.C. § 1395l(t)(21)(B)(ii.). Therefore, Congress clearly intended that the Medicare program continue to pay for services furnished by an excepted off-campus department under the OPPS.

CMS's proposal to limit OPPS payment for excepted off-campus departments to clinical families of services that were billed under the OPPS prior to November 2, 2015 rewrites the exception language in Section 1395l(t)(21)(B)(ii). There, Congress defined "off-campus outpatient department of a provider" and excluded from that definition "a department" that was billing for OPD services prior to November 2, 2015. In drafting this definition, Congress chose precise language to define which facilities would be included and excluded from Section 603's broad mandate—and therefore which would continue to receive OPPS reimbursement and which would not. The language Congress chose focused on "departments of providers", not the "items and services" billed by those departments. In other words, it is the "off-campus outpatient department" that is either excepted or not excepted. CMS's proposal ignores this language and rewrites Section 1395l(t)(21)(B)(ii) to read that a department that was billing for OPD services prior to November 2, 2015, "but only for those types of services billed by the department prior to that date." Section 1395l(t)(21)(B)(ii) includes no such qualifying language.

Moreover, Congress did include language that limited Section 603's reach to certain types of "items and services." In Section 1395l(t)(21)(A), Congress defined the "items and services" to which Section 603 is applicable to not included items and services furnished by a dedicated emergency department. If Congress wanted to limit OPPS payment to a subset of services furnished by an excepted off-campus outpatient department, it could have easily done so in the definition of "applicable items and services." Just as Congress excluded emergency department services from Section 603's reach, it could have also defined "applicable items and services" to not include services that were of the type furnished by an excepted off-campus department prior to the date of enactment of Section 603.[1]

[1] Congress originally considered limiting the "items and services" exception to a select group of codes representing a subset of verifiable emergency services (CPT Codes 99281-99285) but rejected that approach in favor of exempting all services provided by qualified emergency departments. *See* Bipartisan Budget Act of 2015, Discussion Draft, *available at* https://docs.house.gov/billsthisweek/20151026/BILLS-114hr-PIH-BUDGET.pdf at 36. This decision shows that Congress was fully aware of the possibility of making exemptions based on a category of services rather based on the status of the facility as an outpatient department of a provider. But, significantly,

CMS attempts to blur the distinction between "excepted departments" and "applicable items and services" by stating that Congress identified both "excepted departments" and "excepted items and services." This is false: Congress never used the phrase "excepted items and services." The only category of services that Congress identified in Section 603 are "applicable items and services" that no longer meet the existing statutory definition of "covered OPD services." If a facility is not an "off-campus outpatient department of a provider" then it does not furnish "applicable items and services;" it furnishes "covered OPD services" that remain OPPS-reimbursed. Nothing in Section 603 gives CMS the ability to further transform covered OPD services furnished at an excepted PBD into "applicable items and services" just because they happened to be furnished after to November 1, 2015.

CMS's proposed policy rewrites the statute, but by doing so, CMS exceeds its delegated authority as the agency cannot simply nullify the specific department-based exemption that was enacted by Congress under Section 1395l(t)(21)(B)(ii). *See Lamie v. United States Trustee*, 540 U.S. 526, 537 (2004) ("there is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted"). By broadly defining what items and services would be affected by Section 603, Congress also broadly defined those services that are not subject to Section 603.

Congress's incorporation of the Medicare provider-based regulation, 42 C.F.R. § 413.65, in effect at the time that Section 603 was enacted, supports the conclusion that Congress intentionally framed the reach of Section 603 in terms of "departments" and not the "items and services" furnished by those departments prior to enactment of Section 603. 42 C.F.R. § 413.65(a)(2) provides:

> Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term "department of a provider" does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC.

The first sentence of this regulatory definition makes clear that the term "department of a provider" refers to a "facility or organization" for the "purpose of furnishing healthcare services of the same type as those furnished by the main provider." Therefore, at the time Section 603 was enacted, a "department of a provider" could expand clinical services at

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Congress chose not to implement those narrower service-based exemptions under Section 1833(t)(21), including as applicable to excepted off-campus PBDs that previously billed under OPPS.

that facility and still be deemed as part of the "department of a provider" for legal and regulatory purposes (provided the clinical and financial integration requirements were met) so long as the department is providing services "of the same type" offered by the main provider. In fact, CMS has made clear that a change in services did not require notification or constitute a change in circumstances that might affect the facility's status as a "department of a provider." The regulation defines a "material change" that would require such a notification as "any material change in the relationship between [a main provider] and any provider-based facility or organization such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization." 42 C.F.R. § 413.65(c) (emphasis added).

That was the state of the law on the day that Congress adopted Section 603, and Congress expressly incorporated that interpretation into Section 603. 42 U.S.C. § 1395l(t)(21)(B). The only substantive change made by Section 603 was that those "off-campus" outpatient departments of providers that did not bill for OPPS services prior to November 2, 2015 cannot be paid for "applicable items and services" under the OPPS. There is no language in Section 603 that suggests that Congress intended to change this long-standing interpretation of Section 413.65(a)(2) such that a change in services would now render the PBD no longer a "department of a provider."

CMS ignores both this critical language and in Section 413.65 and its longstanding interpretation and instead focuses on the reference to "personnel and equipment needed to deliver the services at the facility" contained in the next sentence of the regulation. But that reference to personnel and equipment standing alone does not nullify the meaning of the first sentence which makes the determination of the department of a provider turn on whether it offers the "same type of services" as the main facility. The language cited by CMS merely stands for the straightforward and uncontroverted point that the personnel and equipment, as well as the specific physical facility, of the department must be integrated with and under the control of the main provider consistent with the terms of the provider-based regulation. CMS itself has previously recognized in adopting provider-based requirements that "the provider-based rules do not apply to specific services; rather these rules apply to facilities as a whole." 67 Fed. Reg. 49982, 50088 (Aug. 1, 2003). The plain language of Section 603 adheres to, and incorporates, that commonsense understanding of "department of a provider," and thus clearly entitles off-campus, excepted PBDs to continue receiving OPPS-based reimbursements for all services they provide, even those added following enactment of Section 603.

We urge CMS to reconsider its proposal as Congress deliberately legislated in a manner that sought to limit new PBDs from being able to qualify for OPPS reimbursements, but preserved the ability of existing PBDs that previously billed under that system to continue operating and receiving OPPS rates for **all** "applicable items and services." The plain language of the statute is clear and unambiguous on that point, and CMS must faithfully implement Congress's directive accordingly.

A. It Would Be Arbitrary and Capricious for CMS to Finalize the Proposed Services Based Restriction Based on the Existing Factual Record

In addition to the serious concerns noted above about CMS's statutory authority to impose any proposed services-based restriction on excepted PBDs, SMH does not believe that CMS's proposed policy is based on any meaningful evidence demonstrating the harm that CMS is attempting to address, and would in fact indiscriminately and arbitrarily punish many institutions such as SMH that are simply trying to deliver care in the most effective manner to their patients. As part of its obligations to act in a reasoned manner, CMS must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted). CMS's proposal fails to satisfy these basic tenets of administrative law.

First, CMS has impermissibly changed its position without offering any reasoned basis for doing so. When it previously declined to finalize a services based restriction, CMS explicitly noted the need to gather additional data and evaluate that data before imposing any lines of services restrictions. "[W]e intend to monitor service line growth and, if appropriate, may propose to adopt a limitation on the expansion of services or service lines in future rulemaking." 81 Fed. Reg. at 79707 (emphasis added); *see also* 82 Fed. Reg. at 59388 ("we stated that we would continue to monitor claims data for changes in billing patterns and utilization"). To help with these data collection efforts, CMS even created new modifiers, "PO" and "PN," that hospitals were required to report to assist CMS's "efforts to begin collecting data and monitoring billing patterns for off-campus PBDs." 83 Fed. Reg. at 37148. The Proposed Rule offers no analysis of how CMS's review of billing patterns show a continued trend of vertical consolidation that now requires additional restrictions on hospital outpatient services that the agency believed were not necessary only two years ago. CMS offers no explanation for this dramatic change in its approach.

An agency may not "depart from a prior policy sub silentio or simply disregard rules that are still on the books." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Instead, an agency must provide "a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy," especially where an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy." *Id.* at 515–16. CMS explicitly recognized just two years ago that other changes resulting from Section 603 potentially mitigated any perceived abuses of vertical integration between hospitals and physician practices solely for billing purposes, and that additional data would be helpful to determine whether any additional regulatory restrictions on lines of services were even warranted. *See* 81 Fed. Reg. at 79707 (noting that "relocation policy for excepted off-campus PBDs . . . will help ensure that off-campus PBDs excepted from application of Sections 1833(t)(1)(B)(v) and (t)(21) of the Act will not be able to circumvent applicability of payment under Section 1833(t)(21) of the Act.").

Those same considerations remain equally true today, and yet without providing any data or explanation as to why perceived abuses from vertical integration continue despite these earlier attempts at mitigation, CMS has decided to issue restrictions on lines of services even in the absence of the data that the agency previously deemed critical to its decisionmaking. That abrupt and unexplained change in the agency's thinking fails to comport with reasoned decisionmaking requirements under the APA. Indeed, as explained in **Exhibit 4**, the most recently available claims data that providers have the opportunity to analyze is for CY 2016 claims – claims for services furnished before CMS's implementation of Section 603 took place. The agency and the public simply have no way of knowing if a

proposal to limit service line expansion is "appropriate" when there is no data set to evaluate the effect of CMS's other limitations on relocations and changes in ownership.

Moreover, CMS cannot cure this deficiency by simply releasing the data – if any – that it has relied upon as an accompaniment to its final rule. *See Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1148 (D.C. Cir. 2013) (recognizing that the very purpose of rulemaking is "to ensure that affected parties have an opportunity to participate in and influence agency decision making . . ."). CMS must "identify and make available technical studies and data that it has employed" in developing its proposed rule. *Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982); *see also Time Warner Entm't Co. v. FCC*, 240 F.3d 1126, 1140 (D.C. Cir. 2001) ("[A]n agency cannot rest a rule on data that, in critical degree, is known only to the agency."). "The most critical factual material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation." *Owner–Operator Indep. Drivers v. FMCSA*, 494 F.3d 188, 199 (D.C. Cir. 2007). Therefore, in order to satisfy fundamental requirements under the APA, **before** the agency may issue a final rule, CMS must disclose any data in its possession post-dating the enactment of Section 603 that purportedly demonstrates the need for a line of services restriction and allow for public input on that data. *See Shands Jacksonville Medical Center v. Burwell*, 139 F. Supp. 3d 240, 265 (D.D.C. 2015) ("APA . . . require[s] the disclosure of assumptions critical to the agency's decision, in order to facilitate meaningful comment and allow a genuine interchange of views.").

Second, CMS fails to identify *any* evidence that supports the proposed services restrictions for excepted off-campus PBDs. Notably, when CMS originally proposed this policy in 2016, it expressed concerns that "if excepted off-campus PBDs could expand the types of services provided at the excepted off-campus PBDs and also be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs." 81 Fed. Reg. at 79706 (Nov. 14, 2016). These same concerns are apparently prompting CMS to re-propose this policy now. *See* 83 Fed. Reg. at 37148. But the only evidence referenced by CMS as documenting this wave of physician acquisitions predates the enactment of Section 603 and the stringent limitations directly imposed by Congress that are already preventing any new off-campus PBDs from receiving OPPS reimbursement for applicable items and services. *See, e.g., id.* (citing to a 2015 GAO report analyzing data from 2007 to 2013). Indeed, the annual MedPAC reports, the GAO report, and other commentary referenced by CMS in the current proposed rule all analyzed data from periods **before** the statutory controls imposed by Section 603 went into effect.

As noted above, CMS previously recognized that other limitations CMS adopted when it first implemented Section 603 would curb the perceived abuses that CMS described. *See* 81 Fed. Reg. at 79707. CMS does not explain why these restrictions, which it previously deemed sufficient just two years ago, are no longer adequate. Indeed, CMS offers no evidence in the current proposed rule that demonstrates that hospital acquisitions and conversions of independent physician practices have continued to increase substantially (or at all) in the aftermath of Section 603 and the policy changes already adopted by Congress and CMS. In the absence of such evidence, it would be arbitrary and capricious for CMS to proceed forward with this services restrictions without any evidence that there is an actual problem needing to be addressed. *See Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 56–57 (D.C. Cir. 2015) ("If an agency fails to examine

the relevant data ... it has failed to comply with the APA."); *see also American Radio Delay League v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008) ("It is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data"); *Sierra Club v. EPA*, 671 F.3d 955, 965–66 (9th Cir. 2012) (agency's decision was arbitrary and capricious where it failed to consider newer "data [that] told a different story than . . . earlier data" that agency had relied on and where agency failed to provide an adequate explanation for doing so).

Third, not only has CMS has failed to provide any evidence demonstrating the need for the proposed line of services restrictions, it has ignored the significant harms that will result from this policy. Many excepted, off-campus PBDs, including SMH's, will likely need to expand the range of services they provide in the future to meet the needs of their communities. CMS itself recognizes that "community needs may evolve over time," 81 Fed. Reg. at 79707, but dismisses the harms that will result from limiting the range of services provided by excepted off-campus PBDs. That is misguided. The healthcare marketplace is anything but static, and hospitals need the flexibility to respond to changes in technology and patient populations without having to deal with distortions caused by different payment structures depending on the care they provide. Indeed, excepted off-campus PBDs may be far better suited to expand the range of services they provide to efficiently meet the needs of patients, who in the absence of these services, may be left with no recourse other than to visit more expensive emergency rooms at a hospital's main facility. Moreover, excepted outpatient facilities help expand access to care, particularly to underserved communities that may have limited access to transportation or face other barriers to receiving timely medical treatment.

Given these critical services that many excepted off-campus PBDs can offer to patients as healthcare delivery mechanisms continue to evolve, it would be irrational for CMS to adopt an overbroad policy that simply discourages these outpatient facilities from changing their operations to meet changing needs. Indeed, even if there remains substantial growth in vertical integration of physician practices after the changes directly mandated by Section 603—which, as noted above, would be entirely unfounded and speculative on CMS's part—the agency should engage in more targeted measures that would not cause off-campus facilities to discontinue expanding their services altogether. Notably, CMS's change of ownership and location restrictions for excepted facilities just went into effect recently, so it is possible that those added restrictions will achieve CMS's regulatory goals without the need for draconian measures limiting new clinical services altogether. At the very least, CMS should further analyze whether existing measures which continue to be implemented will suffice to address perceived abuses. And if there remain significant concerns as borne out by the empirical data, CMS should consider less invasive solutions that would not indiscriminately punish hospitals like SMH that are merely trying to serve the needs of their communities.

Fourth, trying to identify "clinical families of service" and requiring hospitals (and CMS) to track these newly created categories and to bill appropriately under CMS's proposed dual-track system for OPPS-approved services and non-OPPS-approved services will be tremendously complex and burdensome. That is not simply the belief of SMH and other hospital providers; these very concerns were voiced by CMS two years ago in explaining why the agency decided against finalizing the line of services restrictions. CMS stated: "we agree with commenters, including MedPAC, that our proposed policy could be

operationally complex and could pose an administrative burden to hospitals, CMS, and our contractors to identify, track, and monitor billing for clinical services." 81 Fed. Reg. at 79707. Notwithstanding those concerns, CMS is essentially re-proposing the same policy, including with similar categories for clinical lines of services, but does not offer any explanation of why these administrative burdens and challenges would be any less onerous now. As noted, CMS must provide "a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy, *Fox*, 556 U.S. at 515—something the agency has entirely failed to do here with respect to the enormous regulatory burden that CMS itself has predicted will result under the proposed rule.

B. CMS Should Not Adopt A Line of Services Restrictions, Nor Any Other Alternative that Would Raise the Same Concerns Described Above

CMS specifically sought comments on other potential methodologies to limit off-campus excepted PBDs from offering new services. Specifically, CMS mentioned a proposal by MedPAC that would impose a hard cap for OPPS eligible services, and once that cap is reached, any additional services provided by excepted by PBDs would be paid for under MPFS. *See* 83 Fed. Reg. at 37149. That proposal suffers from the same flaws described above: namely, there is absolutely no authority for this policy under Section 603; there is no evidence in the record that demonstrates the need to limit additional services provided by excepted PBDs following the existing significant restrictions on outpatient facilities that have already been implemented or are underway; and this policy is overbroad and would deter excepted PBDs from meeting the changing healthcare needs of their communities.

In addition, CMS specifically invited comments on the appropriate baseline period it should use in imposing any line of services restrictions (*i.e.*, in determining OPPS eligible clinical families of services, whether the agency should look at the services provided by the excepted off-campus PBD one year before the enactment of Section 603 of the BBA or a different timeframe such as 3 or 6 months). Again, Section 603 categorically exempts outpatient departments which billed under the OPPS prior to the date of enactment of the statute. The law does not place any temporal limitation concerning which services would continue to qualify for payment under OPPS, whether these services were provided 1 day, 1 year, or 10 years before the adoption of Section 603. Therefore, any limitation on lines of service at excepted off-campus PBDs would exceed CMS's authority, and establishing an even more compressed baseline period (such as 3 months) would only further exacerbate the harms from CMS's unlawful policy.

II. CMS's Proposal to Cap the OPPS Reimbursement Rate Equal to the MPFS Rate Exceeds the Agency's Statutory Authority and Lacks Any Reasoned Basis

As noted above, Section 603 of the BBA made substantial changes to the reimbursement rates for non-excepted PBDs by subjecting these facilities to reimbursement under the MPFS. Notably, items and services provided by off-campus emergency departments and off-campus PBDs that previously billed under OPPS prior to November 2, 2015 were specifically exempted by Congress from those payment changes. Now, without any intervening change in law by Congress, CMS is seeking to cut the reimbursement rates of E/M services provided by these Section 603-**excepted** PBDs to the

equivalent MPFS rate, a change that directly contradicts the legislative framework codified by Congress. Indeed, this new MPFS payment would not merely apply to expanded lines of service, but also to existing E/M services that excepted PBDs were providing prior to the enactment of Section 603—in other words, services that even CMS acknowledges that Congress exempted from the reach of Section 603 and therefore are required to be reimbursed under OPPS. As discussed more fully below, this proposal exceeds CMS's statutory authority and otherwise lacks any reasoned basis.

A. CMS Lacks the Statutory Authority to Cap the Reimbursement Rate for E/M Services Provided by Excepted PBDs to the MPFS Rate

CMS is "proposing to use [its] authority under Section 1833(t)(2)(F) of the [Social Security] Act to 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 the clinic visit service . . . when provided at an off-campus PBD excepted from Section 1833(t)(21) of the Act." 83 Fed. Reg. at 37,142. But CMS lacks the authority to impose lower MPFS rates for these statutorily-excepted off-campus outpatient departments.

1. First, Section 1833(t)(2)(F) cannot possibly be read to confer upon CMS nearly unfettered authority to impose payment rates in the manner proposed by the agency. Section 1833(t)(1) requires CMS to establish an OPPS rate structure and apply those rates to covered outpatient department services. Section 1833(t)(2)(F) merely specifies that CMS, in establishing that prospective payment system for covered hospital outpatient services, "shall develop a method for controlling unnecessary increases in the volume of covered OPD services." Notably, that provision was enacted in 1997 and has not previously been interpreted or applied by CMS to afford the agency the authority to deny OPPS reimbursement altogether for medically necessary covered services provided by outpatient hospital facilities and instead subject them to an entirely different MPFS reimbursement scheme.

The D.C. Circuit's opinion in *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), is directly on point and, in fact, forecloses CMS's efforts to sidestep the statutorily-proscribed OPPS payment structure in reimbursing medically necessary services. In *Hays*, CMS had developed a "least costly alternative policy" and sought to apply this policy to impose a lower reimbursement rate for a covered prescription drug because that drug combined doses of two component drugs that were in the aggregate less expensive. In other words, CMS sought to reimburse the covered drug at a lower amount reflecting the "least costly and medically appropriate alternative" of the two component drugs. The court rejected CMS's approach, finding that the agency "only [had] a binary coverage decision, namely to reimburse at the full statutory rate or not at all." *Id.* at 1281. The agency, however, could not perform "an end-run around the statute" by imposing a different reimbursement rate for the prescription drug simply because there was a potentially cheaper alternative available. *Id.* at 1282. Indeed, the court reasoned that it was highly unlikely that "Congress, having minutely detailed the reimbursement rates for covered items and services, intended

that the Secretary could ignore these formulas whenever she determined that the *expense* of an item or service was not reasonable or necessary." *Id.* (emphasis in original). Similarly, having spelled out in statute the OPPS-based reimbursement methodology for hospital outpatient services, it is unthinkable that Congress intended to allow CMS to freely ignore this methodology altogether whenever there were "unnecessary increases in the volume of covered OPD services." As in *Hays*, to the extent that the services are medically necessary, the mere fact that they may be more expensive in a hospital outpatient setting does not provide license to CMS to ignore the statutory-based OPPS payment formula.

Moreover, CMS's reference to Section 1833(t)(2)(F) does not provide this authority as it would effectively strain any sensible reading of this provision as effectively nullifying the OPPS-based payment scheme for hospital outpatient services. Indeed, when Congress intends to revise the fundamental features of a regulatory regime, it does not "delegate a decision of . . . economic and political significance to an agency" in a "cryptic . . . fashion." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000). "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 also American Bar Association v. Federal Trade Commission*, 430 F.3d 457, 468 (D.C. Cir. 2005) (rejecting agency's literalist reading of statute regulating "financial institutions" as extending to law firms because the statutory scheme was an "exceptionally poor fit for regulating lawyers"). Given that the basic command of the Medicare statute is that medically necessary covered services must be reimbursed pursuant to the method that Congress prescribes, *see, e.g., Hays*, it is extremely unlikely that Congress also gave CMS the authority to set that command aside and impose an entirely separate and inapt payment scheme with the vague reference in Section 1833(t)(2)(F) allowing the Secretary to develop a "method" to control "unnecessary increases" in "volume." As was the case in *Hays*, courts have been clear that before they will conclude that Congress gave the Secretary the authority to set aside an otherwise clear command to pay a specified rate for items and services, Congress must say so in a straightforward manner.

2. Moreover, any lingering uncertainties about whether Section 1833(t)(2)(F) could be read to provide this specific authority to CMS have been specifically foreclosed by Congress when it subsequently enacted Sections 1833(t)(1)(B)(v) and (t)(21) as part of the BBA of 2015. As noted above, Section 1833(t)(1)(B)(v) specifically excluded from covered outpatient department services those "items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph)." In other words, Congress denied OPPS reimbursement for providers of these non-covered items and services, and thus, as CMS recognizes, "they already receive a MPFS-equivalent payment rate for the clinic visit." 83 Fed. Reg. at 37,142. But, at the same time, Congress specifically exempted certain outpatient departments, including those off-campus facilities that previously billed under OPPS prior to November 2, 2015, effectively ensuring that these facilities would continue receiving reimbursement under OPPS rather than under MPFS or some other payment scheme. *See* Section 1833(t)(21)(B)(ii); *see also* Section 1833(t)(21)(A)(providing items and

services provided by emergency departments are not subject to the restrictions of Section 1833(t)(1)(B)(v)).

CMS clearly does not have the authority to directly overturn Congress's specific legislative choices codified at Sections 1833(t)(1)(B)(v) and (t)(21), nor does the general and undefined statutory language referencing "volume" under Section 1833(t)(2)(F) enacted nearly **twenty** years ago indirectly confer upon CMS that authority. The Supreme Court in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000) (citations omitted) articulated principles of statutory interpretation that squarely apply here:

> At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. The classic judicial task of reconciling many laws enacted over time, and getting them to make sense in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute. This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. As we recognized recently in *United States v. Estate of Romani*, "a specific policy embodied in a later federal statute should control our construction of the earlier statute, even though it has not been expressly amended."

Here, the "later federal statute" setting forth a "specific policy"—*i.e.*, Section 603 of the BBA exempting certain off-campus outpatient departments from being subject to a non-OPPS reimbursement framework—"control[s]" the "construction of the earlier statute"—*i.e.*, Section 1833(t)(2)(F) and CMS's efforts to rely on that provision to impose MPFS rates on outpatient departments that are plainly exempted under Section 603. Thus, CMS is bound by the express terms of Section 603 and cannot rely on Section 1833(t)(2)(F) or any other similarly "broad" statute to remove the protections granted by Congress to exempt facilities that allow them to continue to receive OPPS reimbursement rates (including for E/M services).

3. CMS further proposes to implement these unlawful rate changes for excepted off-campus PBDs in a non-budget neutral manner, but that also exceeds CMS's statutory authority. Section 1833(t)(9) specifies that "adjustments," including as to the "relative payment weights" under the OPPS, must be done in a budget-neutral manner. That provision requiring budget neutrality clearly encompasses rate changes such as the substitution of MPFS rates for E/M services instead of the currently paid OPPS rates. CMS tries to circumvent that requirement by arguing that "method[s]" for controlling "volume" increases is not subject to the same budget neutrality restrictions. That reading is unduly narrow, however, and ignores that the "method" for restricting volume increases proposed by CMS is to directly lower rates for selected services, and those sorts of "adjustments" are subject to budget neutrality requirements. If CMS were correct in its reading, the agency could invoke Section 1833(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 Section 1833(t)(9). Given the express statutory command that "adjustments" be budget neutral, it is unlikely that Congress also implicitly gave CMS the authority to ignore that

command with the vague references found in Section 1833(t)(2)(F). In interpreting the statute at hand, CMS must "read[] the whole statutory text, considering the purpose and context of the statute." *See, e.g., Dolan v. USPS*, 546 U.S. 481, 486 (2006). It is an "essential function of the reviewing court . . . to guard against bureaucratic excesses by ensuring that administrative agencies remain within the bounds of their delegated authority." *Planned Parenthood Fed'n of Am., Inc. v. Heckler*, 712 F.2d 650, 655 (D.C. Cir. 1983). Consistent with these authorities, the clear import of the change being proposed by CMS is to adjust the rates paid to outpatient hospital departments for E/M services, and the overall statutory structure and framework make clear that those types of changes must be done in a budget-neutral manner. If anything, CMS's arguments that rate changes implemented through Section 1833(t)(2)(F) are somehow exempt from budget neutrality requirements, whereas rate changes implemented through CMS's other statutory authorities are not so exempted, just underscores that Section 1833(t)(2)(F) does not provide CMS this authority to adjust rates so broadly in the first instance.

B. It Would Be Arbitrary and Capricious for CMS to Finalize this Rate Reduction for E/M Services Provided by Outpatient PBDs

There are fundamental gaps in the existing factual record, as well as other deficiencies with CMS's proposed policy, that the agency must address before it may implement any proposed rates changes for E/M services provided by outpatient hospital departments.

First, as with the proposed lines of services restrictions, CMS cites to concerns about slowing down the purported unnecessary "shift of services from the physician office to the hospital outpatient department" as its rationale to apply the equivalent MPFS rates to outpatient PBDs. 83 Fed. Reg. at 37,142. But CMS explicitly recognizes that the changes made by Congress under Section 603 "address[ed at least] some of the concerns related to shifts in settings of care and overutilization in the hospital outpatient setting." *Id.* at 37,141. Importantly, none of the data cited by CMS highlighting this significant increase in the utilization of E/M services at outpatient PBDs post-dates the enactment of Section 603 of the BBA. In other words, CMS offers no evidence purporting to demonstrate that there remains any ongoing problem that has not already been adequately addressed through Section 603 and CMS's implementation of those provisions. Notably, CMS required hospitals to report claims data using new modifiers, "PO" and "PN," so that the agency would have a more accurate understanding of whether this shift in location of clinical services remains an ongoing area of concern. As with the proposed line of services restrictions, CMS should first review and analyze those pending data collections, and allow for public comment on those findings, before the agency takes any additional measures such as this proposed rate change. *See Dist. Hosp. Partners*, 786 F.3d at 56–57 ("If an agency fails to examine the relevant data ... it has failed to comply with the APA."); *see also American Radio Delay League*, 524 F.3d at 237 ("It is not consonant with the purpose of a rule-making proceeding to promulgate rules on the basis of inadequate data"); *Sierra Club*, 671 F.3d at 965–66 (agency's decision was arbitrary and capricious where it failed to consider newer "data [that] told a different story than . . . earlier data" that agency had relied on and where agency failed to provide an adequate explanation for doing so).

Second, on a related note, the proposed lines of services restrictions and capping of MPFS rates for E/M services both target what CMS perceives to be unnecessary shifts of services from physician offices to outpatient hospital departments. Yet, CMS offers no analysis of how these policies may potentially overlap—*i.e.*, would either of the proposals be sufficient standing alone to address potential unnecessary shifts in services that have not already addressed by the changes directly mandated under Section 603 of the BBA? Simply put, CMS needs to examine the available data to better understand how the marketplace is operating following the restrictions that have already been put in place and then analyze the potential impacts these additional proposed restrictions would have based on **current** market conditions—not the marketplace that existed before Section 603 was enacted.

Finally, it is critical that CMS examine and understand the prevailing state of affairs, because imposing unnecessary and severe restrictions on outpatient departments could impair beneficial technological advancements in the delivery of care and also diminish access to care to all patients. CMS itself states that it "recognize[s] the importance of not impeding developing or beneficiary access to new innovations." 83 Fed. Reg. at 37,143. Well, in order to facilitate those goals, CMS must ensure that any policies further regulating outpatient departments are supported by substantial and contemporaneous data and appropriately account for facilities such as SMH that are actively seeking to better serve their communities.

Conclusion

SMH appreciates the opportunity to offer these comments and sincerely urges CMS not to adopt these two proposals.

Sincerely,

William Woeltjen

William Woeltjen, CFO

List of Exhibits

Exhibit 1: SMH's Comments to the CY 2017 OPPS Proposed Rule (Sep. 2, 2016)

Exhibit 2: Navigant Physician Needs Assessment (Jan. 28, 2016)

Exhibit 3: SMH Financial Impact Analysis of E/M proposal

Exhibit 4: Claims Analysis of Service Line Proposal by FTI Consulting

Exhibit 5: Summary of SMH Out of State Patient Visits by Zip Code

Exhibits 5a – 5d: SMH Out of State Patient Visits by Quarter

Exhibit B

THE UNIVERSITY OF KANSAS HEALTH SYSTEM

February 8, 2019

WPS GHA - Kansas
Claims Department
P.O. Box 7576
Madison, WI 53707-7576

To Whom It May Concern:

The University of Kansas Hospital Authority, Medicare provider number 17-0040, hereby submits the enclosed claims for evaluation and management (E/M) services represented by code G0463 and claims modifier "PO" for services furnished by excepted off-campus provider-based departments.

These claims should be paid at the full OPPS rate that Congress directed CMS to apply to all services furnished by excepted off-campus departments. Instead, effective in CY 2019, CMS has reduced E/M payment rates for excepted provider-based departments to the same rate as non-excepted departments. This determination violates the clear language of Section 603 of the Bipartisan Budget Act of 2015. It is also unlawful because the rate reduction to excepted E/M services was not applied in a budget neutral manner as required by the Medicare statute.

The provider hereby requests that these claims be paid at the full OPPS rate for excepted departments consistent with Congress's directive. The total amount of E/M payment due at the nonexcepted rate is $770.35.

Sincerely,

Scott Pester
Vice President of Reimbursement

2330 Shawnee Mission Pkwy, Suite 200 Westwood, KS 66205 Phone (913) 945-5357 Fax (913) 588-0846 www.kumed.com

1 UNIVERSITY OF KANSAS HOSP
2650 SHAWNEE MISSION PKWY
WESTWOOD KS 662052003

2 UNIVERSITY OF KANSAS HOSP
PO BOX 955915
ST LOUIS MO 63195

3a PAT. CNTL # [redacted]
b. MED. REC. # [redacted]

4 TYPE OF BILL: 0131

5 FED. TAX NO. [redacted]

6 STATEMENT COVERS PERIOD FROM [redacted]19 THROUGH [redacted]19

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b [redacted]

9 PATIENT ADDRESS a [redacted]
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38 MEDICARE PART A AND B
PO BOX 7576
MADISON WI 537077576

39 VALUE CODES CODE	AMOUNT	40 VALUE CODES CODE	AMOUNT	41 VALUE CODES CODE	AMOUNT
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	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
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6	0301	LAB/CHEMISTRY	84443 PO	[redacted]19	1	218 00		
7	0301	LAB/CHEMISTRY	84550 PO	[redacted]19	1	90 00		
8	0305	LAB/HEMOTOLOGY	85025 PO	[redacted]19	1	143 00		
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B [redacted]		Y	Y		
C					

56 NPI 1649259656
57 OTHER PRV ID

58 INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
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C				

63 TREATMENT AUTHORIZATION CODES
64 DOCUMENT CONTROL NUMBER
65 EMPLOYER NAME

66 DX 0
67: C8318 | I4891 | I509 | R197 | Z7901 | C8310
68

69 ADMIT DX
70 PATIENT REASON DX C8318
71 PPS CODE
72 ECI
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74 PRINCIPAL PROCEDURE CODE DATE
a. OTHER PROCEDURE CODE DATE
b. OTHER PROCEDURE CODE DATE
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LAST MCCOWEN FIRST HERBERT
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LAST FIRST

80 REMARKS
81CC a B3 282N00000X
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UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee LIC3810506 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

1 UNIVERSITY OF KANSAS HOSP
2650 SHAWNEE MISSION PKWY
WESTWOOD KS 662052003

2 UNIVERSITY OF KANSAS HOSP
PO BOX 955915
ST LOUIS MO 63195

3a PAT. CNTL. # [redacted] 4 TYPE OF BILL 0131
b. MED. REC. # [redacted]
5 FED. TAX NO. [redacted] 6 STATEMENT COVERS PERIOD FROM [redacted]19 THROUGH [redacted]19 7

8 PATIENT NAME a [redacted]
b [redacted]
9 PATIENT ADDRESS a [redacted]
b [redacted] c [redacted] d [redacted] e US

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38 MEDICARE PART A AND B
PO BOX 7576
MADISON WI 537077576

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69 ADMIT DX	70 PATIENT REASON DX			71 PPS CODE	72 ECI				73
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c. OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE

80 REMARKS

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UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC LIC3810509 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

1 UNIVERSITY OF KANSAS HOSP
8919 PARALLEL PKWY
KANSAS CITY KS 661121655

2 UNIVERSITY OF KANSAS HOSP
PO BOX 955915
ST LOUIS MO 63195

3a PAT. CNTL # [redacted]
b. MED. REC. # [redacted]
4 TYPE OF BILL: 0131
5 FED. TAX NO. [redacted]
6 STATEMENT COVERS PERIOD FROM [redacted]19 THROUGH [redacted]19
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8 PATIENT NAME a [redacted]
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9 PATIENT ADDRESS a [redacted]
b [redacted]
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10 BIRTHDATE [redacted] 11 SEX [redacted]
12 ADMISSION DATE [redacted] 13 HR 14 TYPE 3 15 SRC 1
16 DHR
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38 MEDICARE PART A AND B
PO BOX 7576
MADISON WI 537077576

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58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
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63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME

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68 ADMIT DX | 69 PATIENT REASON DX C8589 | 70 PPS CODE | 71 | 72 ECI | 73

74 PRINCIPAL PROCEDURE CODE	DATE	a. OTHER PROCEDURE CODE	DATE	b. OTHER PROCEDURE CODE	DATE	75
c. OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE	

80 REMARKS

81CC a B3 282N00000X
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LAST		FIRST

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC LIC3810506 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PAR

1 UNIVERSITY OF KANSAS HOSP 2650 SHAWNEE MISSION PKWY WESTWOOD KS 662052003	2 UNIVERSITY OF KANSAS HOSP PO BOX 955915 ST LOUIS MO 63195	3a PAT CNTL # [redacted]	4 TYPE OF BILL 0131
		b. MED REC. # [redacted]	
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38 MEDICARE PART A AND B
PO BOX 7576
MADISON WI 537077576

	39 VALUE CODES CODE / AMOUNT	40 VALUE CODES CODE / AMOUNT	41 VALUE CODES CODE / AMOUNT
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58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
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69 ADMIT DX	70 PATIENT REASON DX	71 PPS CODE	72 ECI	73
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80 REMARKS

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UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC [illegible] THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

1 UNIVERSITY OF KANSAS HOSP
8919 PARALLEL PKWY
KANSAS CITY KS 661121655

2 UNIVERSITY OF KANSAS HOSP
PO BOX 955915
ST LOUIS MO 63195

3a PAT. CNTL # [redacted]
b. MED. REC. # [redacted]
4 TYPE OF BILL: 0131
5 FED. TAX NO. [redacted]
6 STATEMENT COVERS PERIOD: FROM [redacted]19 THROUGH [redacted]19
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8 PATIENT NAME: a [redacted] b [redacted]
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10 BIRTHDATE: [redacted]
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13 HR
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16 DHR
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38 MEDICARE PART A AND B
PO BOX 7576
MADISON WI 537077576

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42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
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0001 PAGE 1 OF 1 CREATION DATE 020819 TOTALS 12500 000

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53 ASG BEN: Y Y
54 PRIOR PAYMENTS
55 EST. AMOUNT DUE
56 NPI: 1649259656
57 OTHER PRV ID

58 INSURED'S NAME: [redacted]
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60 INSURED'S UNIQUE ID: [redacted]
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62 INSURANCE GROUP NO.: [redacted]

63 TREATMENT AUTHORIZATION CODES
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69 ADMIT DX:
70 PATIENT REASON DX: D649
71 PPS CODE
72 ECI
73
74 PRINCIPAL PROCEDURE CODE DATE
a. OTHER PROCEDURE CODE DATE
b. OTHER PROCEDURE CODE DATE
75
c. OTHER PROCEDURE CODE DATE
d. OTHER PROCEDURE CODE DATE
e. OTHER PROCEDURE CODE DATE

76 ATTENDING NPI 1154389260 QUAL
LAST HARRIS FIRST PENELOPE
77 OPERATING NPI QUAL
LAST FIRST
78 OTHER DN NPI 1801912605 QUAL
LAST COPENING FIRST TELL
79 OTHER NPI QUAL
LAST FIRST

80 REMARKS
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UB-04 CMS-1450 APPROVED OMB NO. 0938-0997
NUBC
THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

1 UNIVERSITY OF KANSAS HOSP 2650 SHAWNEE MISSION PKWY WESTWOOD KS 662052003	2 UNIVERSITY OF KANSAS HOSP PO BOX 955915 ST LOUIS MO 63195	3a PAT. CNTL # [redacted]	4 TYPE OF BILL 0131
		b. MED. REC. # [redacted]	
		5 FED. TAX NO. [redacted]	6 STATEMENT COVERS PERIOD FROM [redacted] 19 THROUGH [redacted] 19

8 PATIENT NAME	9 PATIENT ADDRESS	10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18 19 20 21 22 23 24 25 26 27 28 CONDITION CODES	29 ACCT STATE	30
a [redacted]	a [redacted]	[redacted]	[redacted]			3	1		01	09 30		
b [redacted]	b [redacted] c [redacted] d [redacted] e US											

31 CODE	31 DATE	32 CODE	32 DATE	33 CODE	33 DATE	34 CODE	34 DATE	35 CODE	35 OCCURRENCE SPAN FROM	35 THROUGH	36 CODE	36 OCCURRENCE SPAN FROM	36 THROUGH	37
18	[redacted]													

38 MEDICARE PART A AND B
PO BOX 7576
MADISON WI 537077576

	39 CODE	39 VALUE CODES AMOUNT	40 CODE	40 VALUE CODES AMOUNT	41 CODE	41 VALUE CODES AMOUNT
a	D4	02924376				
b						
c						
d						

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0300	LAB/GENERAL	36415 POQ1	[redacted] 19	1	41 00		
2	0301	LAB/CHEMISTRY	80053 POQ1	[redacted] 19	1	333 00		
3	0301	LAB/CHEMISTRY	82652 PO	[redacted] 19	1	411 00		
4	0305	LAB/HEMOTOLOGY	85025 POQ1	[redacted] 19	1	143 00		
5	0510	CLINIC	G0463 POQ1	[redacted] 19	1	132 00		
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0001 PAGE 1 OF 1 CREATION DATE 020819 TOTALS 106 00 000

50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASG BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	57
MEDICARE PART A AND B		Y	Y			1649259656	OTHER PRV ID
[redacted]		Y	Y				

58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
[redacted]	18	[redacted]		[redacted]
	01			

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME

66 DG DRG	67	67A	67B	67C	67D	67E	67F	67G	67H	67I	67J	67K	67L	67M	68
0	C221	Z006	R945	D696	E119	E8339	I10	Z98890							

69 ADMIT DX	70 PATIENT REASON DX	71 PPS CODE	72 ECI	73
	C221			

74 PRINCIPAL PROCEDURE CODE	DATE	a. OTHER PROCEDURE CODE	DATE	b. OTHER PROCEDURE CODE	DATE	75
c. OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE	

76 ATTENDING	NPI 1881136794	QUAL	
LAST JOUBERTROCKE		FIRST NICHOLA	
77 OPERATING	NPI	QUAL	
LAST		FIRST	
78 OTHER DN	NPI 1518953561	QUAL	
LAST KAHLER		FIRST MARK	
79 OTHER	NPI	QUAL	
LAST		FIRST	

80 REMARKS

81 CC	
a	B3 282N00000X
b	
c	
d	

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC [redacted] THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

1 UNIVERSITY OF KANSAS HOSP
4000 CAMBRIDGE ST
KANSAS CITY KS 661607202

2 UNIVERSITY OF KANSAS HOSP
PO BOX 955915
ST LOUIS MO 63195

3a PAT. CNTL # [redacted] | b. MED. REC. # [redacted] | 4 TYPE OF BILL 0131

5 FED. TAX NO. [redacted] | 6 STATEMENT COVERS PERIOD FROM [redacted]19 THROUGH [redacted]19 | 7

8 PATIENT NAME a [redacted] b [redacted]

9 PATIENT ADDRESS a [redacted] b [redacted] c [redacted] d [redacted] e US

10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18	19	20	21	22	23	24	25	26	27	28	29 ACDT STATE	30
[redacted]	[redacted]			3	2		01	09												

CONDITION CODES

31 CODE	31 OCCURRENCE DATE	32 CODE	32 OCCURRENCE DATE	33 CODE	33 OCCURRENCE DATE	34 CODE	34 OCCURRENCE DATE	35 CODE	35 OCCURRENCE SPAN FROM THROUGH	36 CODE	36 OCCURRENCE SPAN FROM THROUGH	37
a 18	[redacted]											
b												

38 MEDICARE PART A AND B
PO BOX 7576
MADISON WI 537077576

	39 VALUE CODES CODE	39 VALUE CODES AMOUNT	40 VALUE CODES CODE	40 VALUE CODES AMOUNT	41 VALUE CODES CODE	41 VALUE CODES AMOUNT
a						
b						
c						
d						

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1	0510	CLINIC	G0463	[redacted]19	1	11600		
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0001 PAGE 1 OF 1 CREATION DATE 020819 TOTALS 11600 000

50 PAYER NAME	51 HEALTH PLAN ID	52 REL INFO	53 ASG BEN	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	57 OTHER PRV ID
MEDICARE PART A AND B [redacted]		Y	Y			1649259656	
		Y	Y				

58 INSURED'S NAME	59 P.REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
[redacted]	18	[redacted]		[redacted]
	18			

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME

66 DX: C50511 Z170

67 0

68 ADMIT DX | 69 PATIENT REASON DX C50511 Z170 | 70 PRINCIPAL PROCEDURE CODE DATE | 71 PPS CODE | 72 ECI | 73

74 a. OTHER PROCEDURE CODE DATE | b. OTHER PROCEDURE CODE DATE | c. OTHER PROCEDURE CODE DATE | d. OTHER PROCEDURE CODE DATE | e. OTHER PROCEDURE CODE DATE | 75

76 ATTENDING	NPI 1982824546	QUAL
LAST MITCHELL		FIRST MELISSA
77 OPERATING	NPI	QUAL
LAST		FIRST
78 OTHER DN	NPI 1154534733	QUAL
LAST WAGNER		FIRST JAMIE
79 OTHER	NPI	QUAL
LAST		FIRST

80 REMARKS

81 CC a B3 282N00000X
b
c
d

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC LIC3310506 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

THE UNIVERSITY OF KANSAS HOSPITAL

KUMED

Fax Cover Sheet

WARNING: Do not read the attached FAX if it is not addressed to you!

Patient information or other types of sensitive information included in this facsimile is for the exclusive use of the named recipient. If you are not the designated recipient or a person authorized to deliver this document or if you have obtained it in error, be advised that any reading, distribution, use or duplication of it is expressly prohibited. If this transmission came to you by mistake, please notify the sender by phone immediately. The University of Kansas Hospital Authority is committed to protecting patient and/or other types of sensitive information.

Sending parties are expected to verify that the FAX number that this document is being sent to is correct and that the stated recipient is authorized to receive the enclosed information.

To:	Medicare Appeals	**From:**	[redacted]
Fax:	[redacted]	**Phone:**	[redacted]
Phone:		**Pages:**	8 8
Re:	Redetermination Requests	**Date:**	2/6/19

Urgent ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Confidential**

Comments:

THE UNIVERSITY OF KANSAS HEALTH SYSTEM

February 6, 2019

WPS GHA Part A J5 Kansas
Medicare Appeals
P.O. Box 7576
Madison, WI 53707-7576

To Whom It May Concern:

The University of Kansas Hospital Authority, Medicare provider number 17-0040, hereby appeals the attached payment determinations for evaluation and management (E/M) services represented by code G0463 and claims modifier "PO" for services furnished by excepted off-campus provider-based departments. (See enclosed Excel spreadsheet of claims information.)

These claims have been paid contrary to Congress's express direction that CMS pay excepted off-campus departments the full OPPS payment rate for all services. Instead, effective in CY 2019, CMS has reduced E/M payment rates for excepted provider-based departments to the same rate as non-excepted departments. This determination violates the clear language of Section 603 of the Bipartisan Budget Act of 2015. It is also unlawful because the rate reduction to excepted E/M services was not applied in a budget neutral manner as required by the Medicare statute.

The provider hereby requests that these claims be repaid at the full OPPS rate for excepted departments consistent with Congress's directive. The total amount of additional payment due is $165.05.

Sincerely,

Scott Pester
Vice President of Reimbursement

2330 Shawnee Mission Pkwy, Suite 200 Westwood, KS 66205 Phone (913) 945-5357 Fax (913) 588-0846 www.kumed.com

Request for Redetermination
2/6/2019

University of Kansas Hospital
4000 Cambridge St Kansas City, KS 66160
Telephone: 913-588-1227
NPI: 1649259656

Medicare Number	Beneficiary Last Name	Beneficiary First Name	Date of Service From	Date of Service To	Date of Initial Determination Notice
[redacted]	[redacted]	[redacted]	[redacted]2019	[redacted]2019	1/23/2019
[redacted]	[redacted]	[redacted]	[redacted]2019	[redacted]2019	1/25/2019
[redacted]	[redacted]	[redacted]	[redacted]2019	[redacted]2019	1/23/2019
[redacted]	[redacted]	[redacted]	[redacted]2019	[redacted]2019	1/29/2019
[redacted]	[redacted]	[redacted]	[redacted]2019	[redacted]2019	1/23/2019

WPS GHA
KANSAS FAX

(Please indicate which type of request you are submitting.)

☑ **REDETERMINATION REQUEST**

☐ **Appeal of Overpayment (please attach overpayment letter)**

☐ **REOPENING REQUEST**

To: Medicare Appeals Department
Fax Number: 608-223-7547
# of pages _____ (including cover sheet)

ALL REQUESTED INFORMATION ON THIS FAX FORM MUST BE COMPLETED. INCOMPLETE FORMS MAY BE RETURNED TO THE SENDER.

Provider Information

Date 02/06/2019

Contact Name [redacted]

Contact Phone Number [redacted]

Claim Information
Claim ICN* in question [redacted]

***ONE REQUEST FORM IS REQUIRED FOR EACH ICN. THE ICN IS LOCATED ON YOUR REMITTANCE NOTICE.**

IMPORTANT NOTE:

- THIS FAX FORM **ALONE** DOES NOT QUALIFY AS A VALID REDETERMINATION REQUEST OR REOPENING REQUEST.
- YOU **MUST** ATTACH A VALID REQUEST TO THIS FAX FORM.
- REDETERMINATION AND REOPENING REQUEST FORMS ARE LOCATED ON THE WPS GHA WEBSITE.
- ALL REQUESTS WILL BE PROCESSED IN ACCORDANCE WITH INTERNET ONLY MANUAL (IOM) 100-04 CHAPTER 29 AND 34.

WPS GHA
KANSAS FAX

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