UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:19-cv-00132-RMC
ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services,	)	Oral Argument Requested
Defendant.	)	

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure and Local Rule 7(h), the Plaintiff Hospitals respectfully request that this Court enter summary judgment in their favor. The Secretary of Health and Human Services exceeded his statutory authorities by issuing a Final Rule, 83 Fed. Reg. 58,818 (Nov. 21, 2018), that purports to decrease the Medicare Part B payment rate for evaluation and management services that are performed at excepted off-campus hospital departments by 60 percent from the statutorily-prescribed rate. The Plaintiff Hospitals respectfully request that the Court declare the Final Rule to be invalid and that the Court instruct the Secretary to pay the Plaintiff Hospitals for the services that their off-campus hospital departments perform at the rates specified under the Medicare Outpatient Prospective Payment System.

Dated: February 15, 2019

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

As a result of advances in medical technology, many services that formerly needed to be provided in hospitals on an inpatient basis may now be provided to patients at outpatient facilities. As a result, many hospitals, including the Hospital Plaintiffs here, have established off-campus outpatient departments, so that their patients may receive the medical services they need at locations that are more convenient to them than the hospital's main campus. Although these facilities are located elsewhere, they are required under the Medicare program to meet the same licensure, safety, and regulatory requirements as the main hospital facility. Accordingly, the Medicare program treats these facilities as part of the same "provider" as the hospital, and they historically have been paid for their services at the rates that apply for hospitals.

These rates—as relevant here, the rates under the Medicare Outpatient Prospective Payment System, or OPPS—are higher than the rates that are paid for independent physician offices. This has led to concerns that the payment differential may give hospitals the incentive to buy independent offices and convert them to off-campus hospital departments. The Secretary of Health and Human Services shared these concerns, and repeatedly urged Congress to take action to address the issue, while at the same time acknowledging that he lacked the authority to equalize payment rates absent legislative action. Congress considered these competing concerns—*i.e.*, the higher overhead costs that off-campus hospital departments experience on the one hand, against the incentives to create new off-campus departments on the other—and took targeted action that balanced those concerns. In the Bipartisan Budget Act of 2015, Congress directed that a lower payment rate would apply for *new* off-campus hospital departments. At the same time, however, Congress preserved OPPS payment rates for *existing* off-campus hospital departments, in recognition of the substantial reliance interests that hospitals had incurred.

The Secretary is unhappy with the balance that Congress struck. He accordingly adopted a final rule that rewrites the legislative compromise to apply the new, lower payment rate for evaluation and management services, or E/M services, performed at *all* off-campus hospital departments, whether or not Congress had preserved OPPS payment rates for those facilities. When his payment cut is fully implemented, payment for these services will be cut by 60 percent from OPPS rates, resulting in an annual loss of payment to affected hospitals of more than $600 million. To justify his flouting of the Congressional command, the Secretary invoked, for the first time ever, a provision in the OPPS statute that authorizes him to develop a "method" to control "unnecessary increases" in the volume of total outpatient services across the Medicare program. But the Secretary's raw payment cut for one particular form of medical service that he disfavors could hardly be described as a systematic "method" for the administration of the OPPS system as a whole. What is more, the Secretary quite plainly overstepped his bounds in substituting his judgment for that of Congress as to whether E/M services performed at excepted outpatient hospital departments are "necessary." Only three years ago, Congress determined that these services are necessary, and its judgment must control here. *Hays v. Sebelius*, 589 F.3d 1279, 1282 (D.C. Cir. 2009). The Secretary's Final Rule flagrantly violates the statute that he is charged to administer, and is *ultra vires*.

Even if the Secretary had the authority to cut the payment rates for E/M services in the way that he did here—and he does not—he would have been required to adopt offsetting payment increases for other OPPS services, so as to ensure budget neutrality. Congress explicitly instructed the Secretary to follow budget neutrality in those instances where it gave the Secretary the authority to adjust payment rates for outpatient services. In an attempt to avoid this budget-neutrality requirement, the Secretary resorts to linguistic gymnastics, asserting that the rule does

not apply because he has chosen to characterize this payment cut as a "method" to control the volume of outpatient services rather than an "adjustment" to OPPS payment rates. But a payment cut is certainly the same thing as a payment "adjustment," no matter what words the Secretary chooses to use to describe that cut. The Secretary's disregard for the OPPS statute's budget-neutrality mandate was *ultra vires*. Because the Secretary doubly erred—he wrongly assumed he had the authority to ignore Congress's command, and he wrongly assumed he could do so without following budget neutrality—the Secretary's final rule is invalid. This Court accordingly should instruct the Secretary to follow Congress's directive and to pay the Plaintiff Hospitals at the rate specified under the OPPS system for the E/M services that they perform.

FACTUAL BACKGROUND

I. Overview of the OPPS Framework for Off-Campus Hospital Departments

Medicare is a federal health insurance program for eligible senior citizens and disabled individuals. 42 U.S.C. § 1395 *et seq*. Medicare Part A provides insurance coverage for inpatient hospital care, home health care, and hospice services. 42 U.S.C. § 1395c. Medicare Part B provides supplemental coverage for other types of care, including outpatient hospital care. 42 U.S.C. §§ 1395j, 1395k. Hospital outpatient services under Medicare Part B are largely paid for under OPPS, which Congress enacted in 1997 as Section 1833(t) of the Social Security Act. 42 U.S.C. § 1395*l*(t). Under OPPS, "payments for outpatient hospital care [are] made based on predetermined rates." *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). The statute charges the Secretary of Health and Human Services, acting through the Centers for Medicare & Medicaid Services ("CMS"), with the task of setting annual OPPS reimbursement rates prospectively, before a given year. 42 U.S.C. § 1395*l*(t)(1).

Many hospitals, including the Plaintiff Hospitals, operate off-campus hospital departments, which the Medicare program commonly refers to as "provider-based departments," or "PBDs." Medicare regulations define an off-campus PBD as a facility that is not located on a hospital's main campus, but which is 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. In particular, the regulations require 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 hospital; 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 hospital; and that the department's income and expenses are accounted together with those of the main hospital. *Id.* If a hospital can demonstrate that it meets these requirements, then the department "is clearly and unequivocally an integral and subordinate part of a [hospital] provider." 65 Fed. Reg. 18,434, 18,506 (April 7, 2000).

This system, in which the main campus of a hospital and its off-campus departments are considered to be part of a single "provider," affords hospitals the flexibility to find innovative ways to provide health care to the members of their communities and, in particular, to furnish outpatient hospital services at locations closer to where their patients live or work. CMS has acknowledged that the provider-based system 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. at 18,504.

Off-campus PBDs provide outpatient hospital services, sometimes referred to as ambulatory or same-day services, which are those services that do not require a patient to stay overnight in a hospital bed. *See e.g.*, Medicare Benefit Policy Manual, CMS Pub. 100-02, Ch. 6 § 20.2 (defining "outpatient"), *available at:* https://www.cms.gov/Regulations-and-Guidance /Guidance/Manuals/Downloads/bp102c06.pdf. 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 (Aug. 2017), *available at:* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf (overview of E/M services). Off-campus hospital departments that offer E/M services and other services help improve the quality of 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. *See* Ex. A at 1–2 (comment letter of Sarasota Memorial Health Care System); Ex. D ¶¶ 7–8 (Declaration of Daniel W. Peters, Senior Vice President, University of Kansas Hospital Authority).

CMS has recognized that the medical services that hospital outpatient departments provide 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) (noting 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. 42 C.F.R. § 482.25.
- Hospitals must maintain or have available diagnostic radiologic and laboratory services, as well as food and dietetic services. 42 C.F.R. § 482.26–28.
- Hospitals must ensure that they have emergency sources of electricity, water and gas, and that the physical plant meets heightened building and fire code standards. 42 C.F.R. § 482.41.

None of these conditions for participating in Medicare and other Federal healthcare programs apply to an independent physician's office.

Given these greater overhead costs, Medicare pays hospitals more for services, including outpatient services, than it pays for comparable services provided by an independent physician's office. Indeed, payment for medical services provided by *all* off-campus PBDs prior to November 2015 were reimbursed under OPPS, whereas services rendered at physician offices were reimbursed at lower rates set by the Medicare Physician Fee Schedule ("MPFS"). *See* 83 Fed. Reg. 58,818, 59,008 (Nov. 21, 2018) (comparing Medicare payment for a certain clinic visit furnished under OPPS and under MPFS).

II. Section 603 of the Bipartisan Budget Act of 2015

Due to the critical and unique role that PBDs play in providing health care services to their communities, the volume of services that are provided at off-campus PBDs has increased over the years. 83 Fed. Reg. at 59,005–07. This trend reflects new 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.*, Department of Health and Human Services, Office of Inspector General, *HCFA Management of Provider-Based Reimbursement to Hospitals*, OIG Rep. No. OEI-04-97-00090 at 27 (Aug. 2000), *available at:* https://oig.hhs.gov/oei/reports/oei-04-97-00090.pdf (comments by HHS in response to Inspector General report stating the agency's belief "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.").

Some stakeholders have questioned whether the payment differential between OPPS and MPFS rates has created an incentive for hospitals to purchase independent physician offices and convert them into off-campus hospital departments. *See, e.g.*, 83 Fed. Reg. 37,046, 37,148 (July 31, 2018). The Medicare Payment Advisory Commission ("MedPAC") has recommended to Congress that it eliminate payment differences for many services provided in hospital outpatient departments and physicians' offices, including E/M services. *See* Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy*, Ch. 3 at 71 (Mar. 2012), *available at:* http://www.medpac.gov/docs/default-source/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf. In 2014, MedPAC expanded the list of services it recommended that Congress target for payment rate equalization. *See* Medicare Payment Advisory Commission,

Report to Congress: Medicare Payment Policy, Ch. 3 at 83 (March 2014), *available at:* http://www.medpac.gov/docs/default-source/reports/mar14_entirereport.pdf. At the same time, MedPAC "encouraged CMS to seek legislative authority to set equal payment rates across settings for evaluation and management office visits and other select services," in recognition of the point that CMS lacked authority to address the issue absent Congressional action. 79 Fed. Reg. 66,770, 66,912 (Nov. 10, 2014).

MedPAC's recommendations were controversial. Many hospitals noted that MedPAC had failed to consider that its proposed rate reductions would severely hinder their ability to provide safety-net services for vulnerable populations. Hospitals accordingly informed Congress that MedPAC's proposals could "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, Ass'n of Am. Med. Colls., to The Hon. John Barrasso, et al. (Jan. 13, 2012), *available at:* https://www.aamc.org/download/271334/data/aamccommentletteronproposedhopdcuts.pdf.

Congress resolved this debate by enacting Section 603 of the Bipartisan Budget Act of 2015 ("BBA 2015"), which established clear governing rules for how the Medicare program will pay for medical services provided at off-campus PBDs. Pub. L. No. 114-74, § 603, 129 Stat. 584, 598 (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 other service. Instead, Congress carefully targeted its efforts on the financial incentives that it believed were causing hospitals to generate *new* off-campus PBDs. Accordingly, Congress directed that off-campus PBDs that began operations on or after November 2, 2015 would be paid according to a different,

lower-paying rate system to be selected by CMS.[1] 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.

Congress left no room for doubt when it directed the Secretary to continue to pay excepted off-campus PBDs at OPPS rates. The statute, as it was originally enacted in 1997, requires the Secretary to develop an outpatient prospective payment system—OPPS—to pay for "covered OPD [outpatient department] services." 42 U.S.C. § 1395*l*(t)(1)(A). When it enacted Section 603 eighteen years later, 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. § 1395*l*(t)(1)(B)(v). The impact of Section 603 on a new "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.

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 1395*l*(t)(1)(A) and OPPS rates still apply. And, for this purpose, Section 603 excludes from the definition of "off-campus outpatient department of a provider" a "department of a provider … that was billing under

[1] 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 had two ends in mind with Section 603: to deter hospitals from acquiring physician offices solely to convert them to hospital departments for higher payment rates, but also 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]").

[subsection (t)] with respect to covered OPD services furnished prior to November 2, 2015." 42 U.S.C. § 1395*l*(t)(21)(B)(ii). Section 603 does not pick and choose which outpatient services continue to receive OPPS payment. Instead, Section 603 mandates that the Medicare program must continue to pay for *all* services furnished by excepted off-campus PBDs, including E/M services, under OPPS.

CMS has acknowledged the effect of the statute. Shortly after Section 603 was enacted, CMS informed the Government Accountability Office ("GAO") that Congress had resolved the issue of payments for off-campus PBDs and that, as a result, "the agency does not have the statutory authority to equalize total payment rates between HOPDs and physician offices." GAO, *Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform*, at 16 (Dec. 2015), *available at:* https://www.gao.gov/assets/680/674347.pdf (hereinafter "2015 GAO Report"). *See also* 81 Fed. Reg. at 79,704 ("the statutory language provides for payment to continue under the OPPS for such departments … as they existed at the time of enactment of [Section 603]").

Congress revisited the issue of payments to off-campus hospital departments in 2016, and again underscored its intent that departments that had been operating the year before should continue to be paid at OPPS rates for the services that they perform. Congress was concerned that CMS had overly aggressively applied Section 603 to lower payment rates for off-campus hospital departments that were in the process of being built at the time Section 603 was enacted. In acknowledgement of the reliance interests of hospitals that had established these departments, Congress amended Section 1833(t) to specify that "mid-build" off-campus hospital departments would be excepted from the payment cuts and, accordingly, would be subject to OPPS payment rates in the same manner as already-operating off-campus hospital departments would be. 21st

Century Cures Act, Pub. L. No. 114-255 § 16001, 130 Stat. 1033, 1324 (2016) (amending 42 U.S.C. § 1395*l*(t)(21)(B)). In its amendments to the OPPS statute, Congress recognized that its prior year's enactment had "effectively grandfathered any off-campus PBD [hospital outpatient department] that was billing outpatient services before [the] date of enactment" of BBA 2015. H.R. Rep. No. 114-604, at 10 (June 7, 2016).

III. The Proposed Rule

Notwithstanding the clear Congressional mandate, and CMS's subsequent acknowledgement in the 2015 GAO report that it lacked statutory authority to revisit payment rates for off-campus hospital departments, the Secretary issued a proposed rule in 2018 that would "apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for [E/M] service[s] … 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, the Secretary proposed to adjust OPPS payment rates so as to apply the lower MPFS rate for all E/M services provided at any off-campus hospital departments, whether or not Congress had excepted that department from the payment cut enacted in Section 603.

The Secretary reasoned that this payment rate adjustment was needed 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 spoken on this issue only three years earlier, the Secretary opined that Section 603 had only "address[ed] some of [his] concerns related to shifts in settings of care and overutilization in the hospital outpatient setting." *Id.* at 37,141. Unsatisfied with the balance that Congress had struck, the Secretary proposed a rule to override Congress's decision to exempt pre-existing off-campus hospital departments from Section 603.

Notably, the Secretary did not claim that he had the authority to reduce E/M rates pursuant to any authorization under Section 603. Indeed, he has acknowledged that the statute "provides for payment to continue under the OPPS" for outpatient services performed by existing off-campus hospital departments. 81 Fed. Reg. at 79,704. He instead proposed to invoke Section 1833(t)(2)(F) of the Social Security Act, 42 U.S.C. § 1395*l*(t)(2)(F), as the authority for his proposed adjustment to OPPS payment rates. *See* 83 Fed. Reg. at 37,142. 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. § 1395*l*(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 had never previously interpreted Section (t)(2)(F) to permit him to selectively override the precise payment formula in Section (t)(3) to create his own, preferred payment rate for a specific outpatient hospital department service.

The Secretary also proposed to make this payment adjustment 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. 83 Fed. Reg. at 37,142. This proposal contravened Section 1833(t)(9) of the OPPS statute, which requires that changes to the group of covered OPD services and "adjustments," including to the "relative payment weights" under OPPS, must be implemented in a budget-neutral manner. *See* 42 U.S.C. § 1395*l*(t)(9)(B). In light of this provision, CMS had previously acknowledged in its comments to GAO in 2015 that it "lacks the authority to return the associated savings [from equalizing payments between PBDs and physician offices] to the Medicare program," meaning that any savings achieved from cuts in payment for particular

services must by statute be used to increase payments for other services. 2015 GAO Report at 16. Citing to Section 1833(t)(9), GAO agreed with the agency's views: "Because of this budget neutrality requirement, Medicare would not realize savings resulting from such revisions, in that foregone payments would not be returned to the Medicare program." *Id.* at 16 n.26.

Despite this clear language, and the government's previous (and correct) interpretation of Section 1833(t)(9), the Secretary in the proposed rule reversed course and argued that an exercise of his authority to develop a "method" for controlling unnecessary increases in the "volume" of OPPS services would not be subject to the same budget-neutrality restrictions. The Secretary reasoned that, by characterizing his cut in payment rates for E/M services as a "method" to control volume rather than as an "adjustment" in payment rates, he could avoid the budget-neutrality requirements of Section (t)(9)(B). *See* 83 Fed. Reg. at 37,142–43. For 2019 alone, the Secretary estimated the impact of making this payment cut in a non-budget-neutral manner would result in a $610 million decrease in Medicare funding for hospitals. *Id.* at 37,143.

IV. Comments to the Proposed Rule

During the comment period following the release of the proposed rule, thousands of stakeholders submitted written comments, many stating that the Secretary's proposed payment adjustment violated clear statutory directives and was unsupported by evidence. In particular, the Secretary was informed that:

- Congress was in no way ambiguous when it enacted Section 603: it instructed CMS that pre-existing off-campus PBDs should continue to be paid at OPPS rates, while also declaring that new off-campus PBDs would be paid at lesser rates. Congress's specific resolution of this issue in 2015 controlled over CMS' proposed invocation

of general authority in a statute enacted twenty years earlier to strike a different balance. *See* Ex. A (comment letter of Sarasota Memorial Hospital).

- Congress resolved the question of whether services performed at off-campus PBDs are "necessary" by striking the balance that it reached in Section 603; accordingly, CMS could not invoke its general authority under Section (t)(2)(F) to adopt a "method" to control "unnecessary increases" in the volume of services to second-guess Congress's judgment on that score. *See id.*
- Even if CMS had the authority under Section (t)(2)(F) to override Congress's will in this manner, the agency had nonetheless not identified any "unnecessary" increases in medical services. The agency instead had merely theorized about a purported shift in location where E/M visits were taking place, not that the visits themselves were in any way "unnecessary." *See id.*
- At all events, CMS lacked the authority to implement its proposed payment adjustment for excepted off-campus PBDs in a non-budget neutral manner. Section 1833(t)(9) requires payments adjustments to be budget-neutral, and CMS lacked the authority to evade that requirement simply by declaring a payment cut to be a "method" rather than an "adjustment." *See id.*

V. The Final Rule

The Secretary issued a Final Rule that, among other things, finalized his proposed rate cut for excepted off-campus hospital departments, effective January 1, 2019. 83 Fed. Reg. at 59,004. In other words, as of January 1, excepted off-campus hospital departments no longer receive OPPS rates for E/M services, but rather are reimbursed based at the lower MPFS rates. The only substantive change that the Secretary made in the Final Rule was to stagger the 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 annually in 2020 and future years, when the rate cut is fully implemented. *Id.* at 59,009, 59,014.

The Secretary dismissed the commenters' legal concerns 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. Congress's resolution of the issue in this manner accordingly had only "address[ed] some of [his] concerns." *Id.* The Secretary adhered to his view that he had the power to override the Congressionally-struck balance: "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.*

The Secretary also rejected commenters' concerns that the agency lacked the authority to implement the rate cut in a non-budget-neutral manner. Without further analysis, the Secretary simply repeated his position in the proposed rule that budget-neutrality was not required because he was invoking his authority under Section (t)(2)(F). *See id.* at 59,013 ("[W]e 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.”).

The Secretary’s payment adjustment went into effect on January 1, 2019. As a result of the rule, OPPS payments for E/M services performed at exempt off-campus hospital departments are 30 percent lower in 2019 than they otherwise would be, and will be decreased by an additional 30 percent for 2020 and future years. These payment cuts withhold critical funding from the Plaintiff Hospitals that is needed for these institutions to effectively serve their communities. For example:

- Plaintiff Sarasota Memorial Hospital operates off-campus hospital departments that “provide necessary services that are not commonly provided by Part B physicians in [its] community.” Ex. A (comment letter of Sarasota Memorial Hospital). The Secretary’s Final Rule will “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.*
- Likewise, for the off-campus hospital departments operated by Plaintiff Tampa Genera Hospital, “CMS’s proposed reimbursement cut for these … facilities would have a disastrous impact” on the hospital’s ability to continue treating its vulnerable patient population. Ex. B (comment letter of Tampa General Hospital).
- For Plaintiff University of Virginia Medical Center, because it already incurs “negative margins when [it] treat[s] Medicare patients in [PBDs],” the Final Rule “will hurt [its] ability to continue to provide the full range of quality safety net services that [it] currently offer[s]. 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." Ex. C (comment letter of University of Virginia Health System).

- Plaintiff University of Kansas Hospital Authority operates nineteen excepted off-campus hospital departments, which offer services that are not commonly provided by independent physician's offices in its community. Ex. D ¶ 5. The Secretary's final rule jeopardizes its ability to continue providing this care to medically vulnerable populations. *Id.* ¶ 7.

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. Ex. D at ¶ 11. 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 14–21. 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.*

ARGUMENT

I. Congress Unambiguously Provided that Excepted Off-Campus Hospital Departments Must Be Paid at OPPS Rates

Congress has left no doubt in its instructions to the Secretary for the payment of evaluation and management services. E/M services performed by a hospital are "hospital outpatient department services" that are paid under Medicare Part B's OPPS system. 42 U.S.C. § 1395*l*(t)(1). Because an off-campus hospital department is subject to the same regulatory requirements as the main campus of a hospital, the Medicare program considers that department to be part of the hospital. Accordingly, E/M services—like any other reimbursable outpatient services—performed at an off-campus hospital department are "hospital outpatient department services" in the same

way that these services performed at the hospital's main campus would be, and are paid at OPPS rates.

This treatment is appropriate, even though the OPPS rate is higher than the rate that applies for independent physician's offices under the MPFS, given that off-campus hospital departments experience higher overhead costs for the critical role that they play in providing medical services to their local communities. The payment differential has nonetheless been controversial, as some stakeholders have raised concerns that hospitals have an incentive to acquire physician's offices to gain higher Medicare reimbursement. Congress struck a legislative compromise to resolve these competing concerns by lowering payment rates only for *newly-acquired* outpatient hospital departments. In Section 603 of the Bipartisan Budget Act of 2015, Congress amended the OPPS statute to provide that the services covered under that payment system would not include items and services "furnished on or after January 1, 2017, by an off-campus outpatient department of a provider." 42 U.S.C. § 1395*l*(t)(1)(B)(v). Congress specified that, for this purpose, the phrase "off-campus outpatient department of a provider" did not include "a department of a provider … that was billing under this subsection with respect to covered [outpatient] services furnished prior to November 2, 2015," the date of Section 603's enactment. 42 U.S.C. § 1395*l*(t)(21)(B)(ii). The effect of this provision was to "grandfather" off-campus hospital departments that were operating before Section 603's enactment into the OPPS payment system. H.R. Rep. No. 114-604, at 10 (2016).

Congress's instructions to the Secretary are unambiguous; new off-campus hospital departments are to be paid at the lower rates, while pre-existing off-campus hospital departments will continue to be paid for their services at OPPS rates. Congress's "legislative compromise" on this score, which carefully balanced the competing concerns that had been presented to it, "[is] not

for us to judge or second-guess." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 461 (2002). Congress carefully crafted a legislative remedy that addressed the Secretary's concerns while at the same time protected hospitals' reliance interests, and the Secretary was obliged to give respect to the precise terms that Congress chose to resolve the issue. "As with other problems of interpreting the intent of Congress in fashioning various details of this legislative compromise, the wisest course is to adhere closely to what Congress has written." *Rodriguez v. Compass Shipping Co., Ltd.*, 451 U.S. 596, 617 (1981); *see also United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 497 (2001) (courts lack the "discretion" to "reject the balance that Congress has struck in a statute").

By deciding that an excepted off-campus hospital department should continue to receive the same payment rate for the same services as they received "at the time of enactment" of Section 603, 81 Fed. Reg. at 79,704, Congress affirmed that the services furnished in that department are necessary. If Congress had wanted to eliminate OPPS reimbursement for all off-campus hospital department services—or even just the subset of E/M services at issue here—it could have done so. But instead, Congress chose a different path, which the Secretary cannot now abandon because he does not like the result. The Secretary complains that excepted off-campus hospital departments "continue to receive full OPPS payment," 83 Fed. Reg. at 59,012, but that is the precise outcome Congress intended when it "effectively grandfathered *any* off-campus PBD HOPD that was billing outpatient services" as of November 2, 2015. H.R. Rep. No. 114-604 at 10 (emphasis added). If the Secretary was unsatisfied with the Congressional policy, his only option to address his concerns was to do what he told the GAO was necessary: seek additional authorization from Congress.

The Secretary did not in any way dispute that Section 603 requires that excepted off-campus hospital departments be paid for their services at OPPS rates. Quite the contrary, at the

time of its enactment, he acknowledged Section 603's obvious purpose and conceded that he lacked the authority to revisit Congress's decision. *See* 2015 GAO Report at 16. But he now purports, for the first time ever, to invoke a different provision from the original OPPS statute, 42 U.S.C. § 1395*l*(t)(2)(F), which, he asserts, permits him to override the instructions that Congress gave him only three years ago. Section (t)(2)(F) does no such thing; it simply authorizes the Secretary to "develop a method for controlling unnecessary increases in the volume of covered OPD services." *Id.* Well-established principles of statutory interpretation foreclose the Secretary's attempt to creatively interpret the general language of this older statute to override the precise instructions that Congress gave him much more recently:

> 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. … [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.

FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 143 (2000) (internal quotation marks, citation, and original alterations omitted); *see also Indep. Ins. Agents of Am. v. Hawke*, 211 F.3d 638, 643 (D.C. Cir. 2000). Congress spoke more recently, and more specifically, in 2015 when it enacted Section 603 to preserve OPPS rates for existing off-campus hospital departments. It reaffirmed that rule in 2016 when it enacted a second round of legislation to clarify the scope of that protection for existing departments. The Secretary may not rely on a more general authority, found in a statute enacted more than twenty years earlier, to override Congress's specific instructions to him.

II. The Secretary's Targeted Payment Cut Is Not a "Method" to Address "Unnecessary Increases" in the Volume of Outpatient Services

The Secretary's error in this regard is even more glaring, given that the statute he invoked, 42 U.S.C. § 1395*l*(t)(2)(F), does not authorize him to adopt targeted payment cuts for particular outpatient services. The Secretary erred in three ways in his reading of this provision. First, Section (t)(2)(F) grants the Secretary the power to develop a "method" for the operation of the OPPS system as a whole; that authorization to adopt a generally-applicable rule of procedure does not grant the Secretary the power to target a particular form of medical service that he disfavors and to cut payments for that service. Second, Section (t)(2)(F) instructs the Secretary to use his power to develop a "method" so as to control "unnecessary increases in the volume of covered OPD services." But Congress found that E/M services performed by excepted off-campus hospital departments were necessary when it enacted Section 603 and specifically decided to preserve OPPS payment rates for those services; Section (t)(2)(F) does not authorize the Secretary to second-guess Congress' judgment on that score. Third, the Secretary did not find that there had been any increase, unnecessary or otherwise, in the *volume* of these services; instead, he expressly found that the same amount of services were being performed at more costly locations. Section (t)(2)(F), then, simply does not authorize the Secretary to override the rate of payment that Congress has chosen.

1. As noted, the OPPS statute directs the Secretary to develop a prospective payment system that governs payment rates for the various covered outpatient department services. 42 U.S.C. § 1395*l*(t)(1). More specifically, the statute instructs the Secretary to develop a classification system for covered OPD services, and to establish groups of covered OPD services that will be treated similarly for payment purposes. *Id.* § 1395*l*(t)(2)(A), (B). The Secretary is then instructed to follow a specific formula in setting a payment rate for each particular service or

group, *id.* § 1395*l*(t)(4), which is based on the "medicare OPD fee schedule amount" that is determined for each group of services, *id.* § 1395*l*(t)(3)(D). That amount is in turn based on a calculation of the statutorily-specified "payment weight" for each service multiplied by a "pre-deductible payment percentage" and a "conversion factor." *Id.* For this purpose, the "conversion factor" is a base amount that is applicable to all services covered by OPPS; the payment for any particular service is determined by multiplying the other elements of the statutory formula for that particular service by the generally-applicable "conversion factor." *Id.* § 1395*l*(t)(3)(C). (The Secretary has calculated the conversion factor for the OPPS system for 2019 to be $79.49. 83 Fed. Reg. at 58,863.)

The statute authorizes the Secretary to review "the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)," *i.e.*, 42 U.S.C. § 1395*l*(t)(2), "to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." 42 U.S.C. § 1395*l*(t)(9)(A). That review may result in an adjustment to the payment amount for particular services or groups of services. *Id.* Any such payment adjustment must be calculated in a budget-neutral fashion, such that the total amount of payment under the OPPS system for a given year remains the same. *Id.* § 1395*l*(t)(9)(B). Here again the statute is clear: any such payment adjustment to a particular group of services must be calculated in a budget-neutral fashion, such that the total amount of payment under the OPPS system for a given year remains the same. *Id.* § 1395*l*(t)(9)(B).

Separate and apart from his authority to adjust rates for specific services, the statute also authorizes the Secretary to develop a "method" to "control[] unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395*l*(t)(2)(F). The statute is not directed to the calculation of particular payment amounts for particular outpatient services, but instead grants the Secretary

authority to undertake system-wide, generally-applicable modifications to the OPPS system that would potentially affect all covered OPD services. Although the Secretary has never, before 2018, invoked his "method" authority under Section (t)(2)(F), when he has previously considered doing so, he has treated that authority as one authorizing systematic approaches to the OPPS methodology, rather than individualized tinkering with particular payment rates for favored or disfavored groups of outpatient services. For example, the Secretary has considered invoking paragraph (t)(2)(F) to "establish broader payment bundles" across the OPPS system to create an incentive for hospitals to provide more efficient care. *See* 72 Fed. Reg. 66,580, 66,613 (Nov. 27, 2007). In the event the "method" adopted by the Secretary does not achieve its intended effect, the Secretary is then authorized to make adjustments for a later year to the OPPS "conversion factor," which would have the effect of lowering payment rates for all covered OPD services across the board. 42 U.S.C. § 1395*l*(t)(9)(C).

This understanding comports with the common-sense meaning of Section (t)(2)(F). The "method" that the statute authorizes the Secretary to develop is "[a] mode of organizing, operating, or performing something, esp. to achieve a goal." Black's Law Dictionary at 1141 (10th ed. 2014). The "something" that is being organized here, of course, is the OPPS system itself. The statute, then, authorizes the Secretary to adopt a systematic method that applies in the same manner across the OPPS system. *See also* Merriam-Webster Online, *Method*, *available at:* www.merriam-webster.com/dictionary/method (defining "method" as "a systematic procedure" or "a systematic plan").[2]

[2] The OPPS statute describes one particular power that the Secretary may invoke after he exercises his "methods" authority under Section (t)(2)(F). If he develops a method under that provision to control unnecessary increases in the volume of outpatient services, and then later determines that despite his adoption of that method the volume of services "increased beyond amounts established through those methodologies," he may adjust the update to the conversion factor in a later year.

This authority to develop a "method" stands in stark contrast to the authority to adjust payment rates under Section (t)(9)(A). If the Secretary wishes to adjust the payment rates for a particular outpatient service, he must follow the procedures of that provision to find that, for example, "changes in medical practice" or the other statutory factors justify the payment adjustment, 42 U.S.C. § 1395*l*(t)(9)(A), and he must make the adjustment in a budget-neutral manner, *id.* § 1395*l*(t)(9)(B). Under the Secretary's new reading of the OPPS statute, however, he could avoid Section (t)(9)(A) altogether by simply declaring any adjustment to payment rates for a particular service to be his "method" for controlling increases in volume. That the Secretary's new-found reading of Section (t)(2)(F) "would render superfluous other provisions in the same enactment" is a powerful indication that his reading is incorrect. *Marinello v. United States*, 138 S. Ct. 1101, 1107 (2018) (internal quotation marks omitted).

2. What is more, even if the Secretary's authority to adopt a "method" under Section (t)(2)(F) included the authority to cut payment rates for particular services that he disfavors, he could only exercise that power "for controlling unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395*l*(t)(2)(F). The Secretary apparently considers the volume of E/M services provided in excepted hospital outpatient departments to be "unnecessary." He acknowledges, however, that Congress considered precisely the same question in 2015, and that it chose to maintain OPPS rates for hospital outpatient departments that were already in operation then, while at the same time cutting payment rates for newly-acquired outpatient hospital

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42 U.S.C. § 1395*l*(t)(9)(C). Notably, the Secretary must first try the methodology he develops under Section (t)(2)(F) before proceeding to an adjustment to payment rates. And, even, when he does so, the only authority the statute grants to him is to adjust the conversion factor. As noted, the "conversion factor" is a figure that is generally applicable to all OPPS services. *Id.* § 1395*l*(t)(3). The statute does not afford him the option to cut payments for particular services under his (t)(2)(F) authority.

departments. The Secretary candidly based his invocation of Section (t)(2)(F) on his disagreement with Congress's treatment of the issue. *See* 83 Fed. Reg. at 59,008 ("While the changes required by the section 603 amendments to section 1833(t) of the Act address *some of the concerns* …, the majority of hospital off-campus departments continue to receive full OPPS payment …. *Therefore*, the current site-based payment creates an incentive for an unnecessary increase in the volume of this type of OPD service.") (emphases added).

The generally-worded authority to address "unnecessary increases" in volume, however, does not carry with it the power to second-guess Congress's decision as to what is necessary. *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), is directly on point. There, Congress had specified a statutory reimbursement formula for branded prescription drugs, which CMS considered to be overly generous because it paid more than the statutory reimbursement formula for the generic form of those drugs. The agency thus sought to depart from that formula by invoking a general authority to pay for "reasonable and necessary" items and services, reasoning that it was not "reasonable or necessary" to pay for a branded drug at more than its generic rate. The court rejected the agency's attempt to perform "an end-run around the statute" in this manner, noting that the attempt, if successful, "would fundamentally alter the reimbursement scheme." *Id.* at 1282. "[W]e think it quite 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.* (internal quotation marks omitted).

So too here. Congress found that the volume of E/M services performed in excepted hospital outpatient departments to be "necessary" by specifically preserving OPPS payment rates for those services when it addressed the matter in 2015. The fact that the Secretary wishes that

Congress had resolved the issue differently does not give him license to ignore the legislature's judgment as to the appropriate payment rate for those services. *See also Whitman v. American Trucking Ass'n*, 531 U.S. 457, 468 (2001) ("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."); *Amgen*, 357 F.3d at 117 (the OPPS statute does not grant the Secretary the authority to make "basic and fundamental changes" to Congress's statutory scheme).

3. Nor, in any event, did the Secretary act in response to an "increase" in the volume of outpatient services, let alone an "unnecessary" one. The Secretary has never explained or even found that the volume of E/M services has been unnecessary; instead, he has opined that the payment rate that Congress directed him to pay for those services was too generous. In fact, several commenters urged the Secretary during the comment period to find that the OPPS payment rate for E/M services at hospital outpatient departments had increased, and unnecessarily so. *See* 83 Fed. Reg. at 59,010. The Secretary studiously declined to make such a finding, however. Instead, he based his rule on his belief that the OPPS payment rates "are affecting site-of-service decision-making." *Id.* He reasoned that his rule would ensure that "the beneficiary can safely receive *the same services* in a lower cost setting." *Id.* (emphasis added). In other words, the Secretary did not conclude that there had been any increase in the volume of E/M services; he instead found only that the same volume of services could be provided at a lower cost.[3] Section (t)(2)(F) does not speak to cost, however, but only to volume; there is a fundamental mismatch between the issue that the Secretary sought to address and the statute he invoked to do so. Therefore, not only did

[3] Under the final rule, E/M services provided by an excepted hospital outpatient department will continue to be paid under the OPPS system, but only after the Secretary applies a modifier code to reduce what would otherwise be the OPPS rate by 30 percent in 2019 and 60 percent in later years. *See* 83 Fed. Reg. at 59,013–59,014.

the Secretary misconstrue (t)(2)(F) to assume powers not delegated to him by Congress—*i.e.*, modifying the statutorily-prescribed rates for services provided by excepted off-campus PBDs—the Secretary failed to fulfill the basic threshold requirements of Section (t)(2)(F) itself.

III. Even if the Secretary Had the Power to Adopt a Targeted Payment Cut, He Could Only Do So in a Budget-Neutral Manner

For the reasons explained above, the Secretary erred in construing Section (t)(2)(F) to grant him the power to pick and choose particular outpatient services, within the entire suite of OPPS services, that he would target for a cut in payment rates. But, even if Section (t)(2)(F) gave him that power, he could only do so in a budget-neutral manner. As noted, Section (t)(9)(A)—a statute subject to different conditions, and one not invoked by the Secretary—grants him the power to "revise the groups, the relative payment weights, and the wage and other adjustments" described in paragraph (2)." 42 U.S.C. § 1395*l*(t)(9)(A). In other words, that statute grants the Secretary the authority, under certain circumstances, to revise payment amounts for specific outpatient services. But, "[i]f the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures … increase or decrease from the estimated amount of expenditures under [OPPS] that would have been made if the adjustments had not been made." 42 U.S.C. § 1395*l*(t)(9)(B). That is to say, an adjustment in payment amounts for one outpatient service must be matched with a change in the rate of payment for the remaining outpatient services so that the total amount spent under the OPPS system remains the same.

In the Final Rule, the Secretary has cut the OPPS payment rate for E/M services provided by excepted hospital outpatient departments by 30 percent for 2019, and by 60 percent for later years. This is, quite obviously, an "adjustment" in the amount of payment that providers will receive for these outpatient services, and Section (t)(9)(B) accordingly requires that this adjustment be offset by a corresponding increase in payment for other OPPS services. The Secretary,

however, reasoned that he need not follow budget neutrality because he had chosen to describe his payment cut as a "method" rather than as an "adjustment." "Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a 'method' for controlling unnecessary increases in the volume of covered OPD services, not an adjustment." 83 Fed. Reg. at 59,009.[4]

This Humpty Dumpty approach to statutory interpretation cannot be squared with the statute that Congress actually enacted.[5] Whether or not the Secretary's payment adjustment may fairly be described as a "method" under Section (t)(2)(F)—and it cannot, for the reasons already explained—it still would plainly qualify also as an "adjustment" to the payment rate for E/M services provided by excepted hospital outpatient departments. Indeed, even the Secretary could not avoid describing a cut in payment rates for these services as an "adjustment" in his Final Rule. *See* 83 Fed. Reg. at 59,012 (referring to "the more specific payment adjustment" enacted in Section 603). And Congress spoke comprehensively when it described the extent of the Secretary's obligation to maintain budget neutrality under the OPPS. Budget neutrality applies for any of the

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[4] The Secretary also reasoned that his authority under Section (t)(9)(C) to adjust the conversion factor in a later year, after he adopts a volume-control method, implies that he has the same power in the first year that he adopts such a method. 83 Fed. Reg. at 59,009. This is incorrect; that power kicks in only after the Secretary tries such a method and finds that the volume of outpatient services has still unnecessarily increased. 42 U.S.C. § 1395*l*(t)(9)(C). This necessarily means that the Secretary lacks that power until after he makes that finding. *See Indep. Ins. Agents of Am.*, 211 F.3d at 643. This dispute is beside the point, in any event, as the Secretary did not attempt to "adjust" the "conversion factor"; as explained above, the conversion factor is a number that applies for all OPPS services, and thus may be "adjusted" only in a way that affects the entire system, rather than a particular form of medical service that the Secretary dislikes.

[5] "'When I use a word,' Humpty Dumpty said, in a rather scornful tone, 'it means just what I choose it to mean—neither more nor less." *TVA v. Hill*, 437 U.S. 153, 173 n.18 (1978) (quoting Through the Looking Glass, in *The Complete Works of Lewis Carroll* 196 (1939)).

"adjustments under subparagraph (A)," 42 U.S.C. § 1395*l*(t)(9)(B), and that subparagraph in turn refers to "revis[ions to] the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)," *id.* § 1395*l*(t)(9)(A). The authority that the Secretary invokes to adopt a "method" of volume control under section (t)(2)(F) is within the same paragraph. Thus, if that provision gives the Secretary the authority to target a particular form of medical service that he disfavors for a payment cut at all, that adjustment in payment rates must be applied in a budget-neutral way.

It is telling that, when Congress has chosen to give the Secretary the power to make non-budget-neutral adjustments in OPPS payment rates, it has done so explicitly. *See* 42 U.S.C. §§ 1395*l*(t)(7)(I), (t)(16)(D)(iii), (t)(16)(F)(iii), (t)(18)(C), (t)(19)(A), (t)(20). Congress certainly knew how to give the Secretary the same power here if it had wished to do so. *See Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 176 (1994). It is apparent, however, that Congress did not wish to grant the Secretary the power to cut payment rates for E/M services provided by excepted hospital outpatient departments at all. To the contrary, when Congress spoke on the subject, it specifically preserved OPPS rates for those services. The Secretary erred by disregarding Congress's instructions to him on this score.

CONCLUSION

The Secretary's Final Rule violates the explicit Congressional command that off-campus hospital outpatient departments that were operating in 2015 must continue to be paid at OPPS rates, and is *ultra vires*. Even if the Secretary had the authority to override Congressional will on this issue—and he does not—he could only do so in a budget-neutral manner. The Secretary's Final Rule adjusting OPPS payment rates for off-campus hospital outpatient departments should be invalidated, and the Secretary should be instructed to pay the Plaintiff Hospitals for the services that their off-campus hospital departments perform at OPPS rates. The Plaintiff Hospitals accordingly respectfully request that their motion for summary judgment be granted.

Dated: February 15, 2019

Respectfully submitted,

/s/ *Mark D. Polston*

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CERTIFICATE OF SERVICE

I hereby certify that I have this day served the foregoing via the Court's CM/ECF on all counsel of record.

/s/ *Mark D. Polston*
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Exhibit A

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 <u>*not*</u> "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, <u>if appropriate</u>, 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 <u>before</u> 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 <u>predates</u> the enactment of Section 603 and the stringent limitations directly imposed by Congress that are already preventing any <u>new</u> 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

September 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1695-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS-1695-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Ms. Verma:

On behalf of the patients and staff of Tampa General Hospital (TGH) we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) CY 2019 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment System proposed rule. TGH appreciates and supports the Centers for Medicare & Medicaid Services' (CMS) work to improve the delivery of high-quality health care across the health care continuum.

Tampa General Hospital, with over 1,000 beds is one of the most comprehensive medical facilities in Florida serving over 1 dozen counties with a population in excess of 4 million. We are the area's only level 1 trauma center and the region's leading safety net hospital, committed to providing quality health care to all patients regardless of ability to pay. Our hospital is home to one of the largest organ transplant centers in the country, having performed more than 6,000 adult solid organs transplants. We are a nationally certified comprehensive stroke center and offer other nationally recognized services in pulmonology, orthopedics, urology, diabetes & endocrinology, gastroenterology, the Thyroid Cancer & Parathyroid Institute and the Children's Medical Center including the Jennifer Leigh Muma Neonatal Intensive Care Unit. In addition, we are the primary teaching hospital for the USF Health Morsani College of Medicine. Tampa General is committed to providing area residents with excellent and compassionate health care ranging from the simplest to the most complex medical services. In 2017 we provided more than 102,000 emergency department visits.

Based on our review of the proposed rule, we respectfully suggest CMS' consideration of the following recommendations.

CMS's Proposal to Further Reduce Payments for Excepted Off-Campus Provider-Based Departments Would Harm Our Ability to Treat Patients

When Congress passed Section 603 of the Bipartisan Budget Act of 2015, a clear distinction was established between hospital outpatient departments (HOPDs) that were billing under the OPPS at that point in time versus all new HOPDs. In passing Section 603, Congress was clear in its intention to grandfather existing facilities, so

that only new off-campus sites would be subject to reduced payments. Thus, we are disappointed that CMS has proposed significant cuts to HOPDs for CY 2019, for they are counter to the intent of Section 603 and will jeopardize access to care for our nation's seniors. While the proposed rule notes an admirable intent to reduce copayments for beneficiaries by implementing these cuts, and while we share the goal of reducing out of pocket costs, we are concerned that a reduction in out of pocket spending for the estimated 14% of all Medicare beneficiaries that have no Medicare cost-sharing supplemental insurance (per a Kaiser Family Foundation 2010 study) in this instance comes at the expense of all Medicare beneficiaries' ability to access the right care in the right setting.

TGH has historically operated 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 average physician's offices. 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. For a significant number of these visits, the only billable code is the HCPCS code G0463 which is being targeted by CMS under this proposal for a -60% rate cut. Simply put, CMS' proposed reimbursement cut for these TGH facilities would have a disastrous impact. CMS' proposal to ignore the grandfathered status of these facilities and pay the "PFS-equivalent" (Physician Fee Schedule) rate for evaluation and management (E&M) services furnished at such facilities is contrary to Congressional intent as evidenced by Section 603. Therefore, we ask that that CMS ensure these facilities be treated as Congress intended and protected from the proposed cuts.

CMS's Proposal to Further Limit Payments for Services Provided in Excepted Off-Campus Provider-Based Departments Would Harm Our Ability to Treat Patients

CMS' proposal to reduce payment to 40 percent of the current HOPD rate for grandfathered off-campus HOPDs that begin to furnish a new service from a clinical family not offered prior to November 1, 2015 would unfairly penalize grandfathered off-campus HOPDs that expand the critical services they offer to meet the changing needs of their patients. As communities and their health care needs change, it is essential that off-campus HOPDs be able to add needed services. If CMS places a barrier to doing so, the result will likely be a negative impact on patients who may be required to travel longer distances to receive care or who may be unable to access that care at all. Therefore, we ask that that CMS ensure these facilities be treated as Congress intended and protected from the proposed cuts.

CMS's Proposal to Reduce Payments for Drugs Acquired Through the 340B Program Would Harm Our Ability to Treat Patients Without Reducing Patient Costs

TGH strongly opposes this CMS proposal, which is a cut to hospitals like us that treat the most vulnerable and underserved patients and communities, and we urge CMS to rescind the proposal. Expansion of the payment reduction to non-excepted off-campus hospital outpatient departments would further limit our ability to provide critical services to low-income and rural patients, such as infusion services that address chronic and life-threatening conditions. As a teaching hospital that participates in the 340B Program, we use the savings from the program to expand services and provide medications and treatments to patients who may not otherwise have access. Cutting Medicare payments for 340B drugs undermines the purpose of the 340B Program and reduces critical drug reimbursements needed by teaching hospitals and other safety net providers. These proposed dramatic cuts to drug reimbursements will require hospitals like us to reduce or eliminate services elsewhere, including the critical programs to assist low-income patients that 340B was designed to support.

These cuts will likely result in Medicare and other patients losing access to important services that preserve the health of their communities and could result in higher hospital use of emergency rooms and increased hospital admissions, with resultant higher costs and poorer health outcomes for vulnerable populations. CMS's proposal would harm our ability to treat low-income patients without reducing costs for hospital patients, Medicare beneficiaries, or the Medicare program. CMS proposes to implement the payment reduction in a budget neutral manner, ensuring that any reduction in spending for 340B drugs would be offset by increased spending and copayments for other services. Thus, not only does the proposal *not* reduce costs for Medicare beneficiaries, but it could actually increase costs by limiting 340B hospitals' ability to continue providing the same level of assistance to low-income beneficiaries and the uninsured that the 340B program currently helps them provide.

CMS's Proposal to Reduce Payments for Biosimilars Acquired Through the 340B Program Would Harm Our Ability to Treat Patients Without Reducing Patient Costs

TGH strongly opposes this CMS proposal, which is a cut to hospitals like us that treat the most vulnerable and underserved patients and communities, and we urge CMS to rescind the proposal. As a teaching hospital that participates in the 340B Program we use the savings from the program to expand services and provide medications and treatments to patients who may not otherwise have access, including infusion for oncology services as more biosimilars become available. The expansion of cutting Medicare payments for biosimilars undermines the purpose of the 340B Program and reduces critical drug reimbursements needed by teaching hospitals and other safety net providers. These proposed dramatic cuts to drug reimbursements will require hospitals like us to reduce or eliminate services elsewhere, including the critical programs to assist low-income patients that 340B was designed to support. These cuts will likely result in Medicare and other patients losing access to important services that preserve the health of their communities and could result in higher hospital use of emergency rooms and increased hospital admissions, with resultant higher costs and poorer health outcomes for vulnerable populations. CMS's proposal would harm our ability to treat low-income patients without reducing costs for hospital patients, Medicare beneficiaries, or the Medicare program. CMS proposes to implement the payment reduction in a budget neutral manner, ensuring that any reduction in spending for 340B drugs would be offset by increased spending and copayments for other services. Thus, not only does the proposal *not* reduce costs for Medicare beneficiaries, but it could actually increase costs by limiting 340B hospitals' ability to continue providing the same level of assistance to low-income beneficiaries and the uninsured that the 340B program currently helps them provide.

CMS Does Not Have the Authority to Reduce Payments to 340B Hospitals

CMS's proposal would violate the 340B statute, which expressly defines the types of hospitals that may receive the benefits of 340B discounts, by seizing 340B discounts from safety net hospitals and transferring the funds to providers that Congress excluded from the 340B program. The proposal would also violate the Medicare statute, which forbids CMS from setting different prices for the same drug based on the status of the provider.

Request for Information on Price Transparency

TGH appreciates the opportunity to respond to CMS' request for information about price transparency and supports CMS' efforts to improve transparency and ensure patients have access to vital information to make informed decisions about their care. However, any proposal to require that hospitals make available

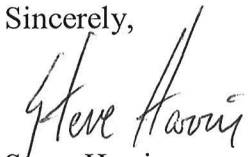
a list of standard charges will be misleading to patients and cause excess administrative burden on essential hospitals. Any guidelines towards price transparency should address physician out-of-network bills and additional fees for emergency visits. Simply put, chargemaster data are not helpful to patients for determining what they are likely to pay for a particular service or hospital stay. Pricing at the unit level is misleading because of varying degrees of bundled pricing at various hospitals and publicizing prices at the unit level would be of little value for patients as the frequency of services are not always known before patient care is delivered. Many patients will generally have no idea of what their encounter will be unless planned or elective, therefore there would be no benefit of knowing this information in advance. However, patients are interested in their out-of-pocket costs, but disclosing charge information instead will increase patients' confusion. In an effort to continue to improve price transparency, we suggest that insurers are best positioned to provide relevant payment information and should build on the pricing transparency guiding policies established by the Healthcare Financial Management Association (HFMA). TGH commends the current administration for their attempts to reduce regulatory and administrative burden, and similarly, CMS' transparency requirements should not increase administrative or regulatory burden on hospitals without providing any meaningful benefit to patients.

CMS' Proposal to Collect data on Services Furnished in Off-Campus Provider-Based Emergency Departments is Administratively Burdensome

CMS' proposal to create and require a HCPCS modifier (ER – Items and services furnished by a provider-based off-campus emergency department) to be reported with every claim line for outpatient hospital-based emergency department UB-04 form (CM Form 1450) for hospital outpatient services is administratively burdensome. If CMS does move forward with mandating this costly endeavor, hospitals must be given additional time to adapt billing systems to accommodate the claims modifier, allow for testing to ensure the modifier is working correctly, and educate staff who must append the modifier. CMS should not finalize this proposal until it can develop a more reasonable methodology for obtaining this information.

TGH appreciates CMS' consideration of these comments and welcomes the opportunity to provide additional information to the agency. If you have questions, please contact Ron Costanzo, Director of Reimbursement at 813-844-4801 or rcostanzo@tgh.org.

Sincerely,



Steve Harris
Vice-President of Payor & Government Affairs
Tampa General Hospital

Exhibit C

UNIVERSITY of VIRGINIA HEALTH SYSTEM

Office of the Chief Executive Officer of the Medical Center

September 21, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013
Baltimore, MD 21244-1850

Dear Administrator Verma:

On behalf of University of Virginia Health System (UVAHS), I appreciate the opportunity to comment on provisions of the Medicare Program: *Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for Potential CMS Innovation.* Our letter addresses proposed payment changes to: Magnetic Resonance-Guided Focused Ultrasound Surgery; excepted off-campus provider-based departments of a hospital; and Part B separately payable drugs in off-campus non-excepted provider based departments of a hospital eligible for the 340B program.

UVAHS includes an academic medical center located in Charlottesville, Virginia with the UVA School of Medicine and its strong biomedical research enterprise, a 612-bed hospital, a level I trauma center, nationally recognized cancer, stroke, heart and pediatric centers along with several primary and specialty clinics throughout Virginia. More than 65 percent of UVA Medical Center's patients are Medicare, Medicaid and indigent patients. Relative to other hospitals in our state, UVA Medical Center provides a disproportionate share of services to Virginia's indigent and Medicaid beneficiaries, thus serving as a key safety net provider in Virginia. (In FY18, UVA Medical Center provided $294.3 million in uncompensated care.)

Proposed Procedures Assigned to New Technology APC Groups for CY 2019: Magnetic Resonance-Guided Focused Ultrasound Surgery

As part of the proposed procedures assigned to new technology APC groups for magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, CMS is proposing to reassign the procedures described by CPT code 0398T from APC 1576 (New

PO Box 800809 | Charlottesville, VA 22908-0809
434.243.9308 | Fax 434.243.9328

Technology—Level 39 ($15,001-$20,000)) to APC 1575 (New Technology—Level 38 ($10,001-$15,000)), with a proposed payment rate of $12,500.50, a decrease from the current rate of $17,500.

UVAHS is proud to be leading the way to treat patients with essential tremors thanks to the pioneering work of Dr. Jeff Elias, a professor of neurological surgery and neurology at the School of Medicine, who led the clinical trial that resulted in Food and Drug Administration approval of the approach to treat the condition. Essential tremor (ET), a condition that affects an estimated 10 million Americans, can compromise basic life skills, making anything that requires a steady hand, such as eating, drinking or writing, impossible for patients with the condition. The focused ultrasound treatment, an innovative and incision-free alternative to brain surgery, can have immediate life-changing results for candidates eligible for the procedure, significantly improving tremors and motor function within months after treatment.

We are disappointed CMS is proposing a 26 percent reduction in reimbursement for this life altering treatment. CMS' decision is based on what appears to be a very limited sample from two years of claims data, which does not provide a statistically valid analysis to justify a $5,000 reduction. When UVAHS submitted charges for the treatment, we put forth the MRgFUS procedure as a package price based upon non-coverage from CMS (and other insurance carriers). More specifically, our historic charges were reflective of the costs associated with the sharing of space and equipment primarily used for clinical research. With MRgFUS now a covered service, additional investments and dedicated resources are needed to develop our MRgFUS program in order to provide adequate access and service to patients that can benefit from this transformative treatment. We would be pleased to discuss this you in further detail.

Instead of reducing payment for CPT code 0398T and reassigning it to APC 1575, we recommend CMS reevaluate its analysis and increase the payment to ensure adoption of this new clinical treatment. The current rate and the proposed reduction fail to cover the costs to support a viable program, especially for Medicare beneficiaries who comprise approximately 80 percent of our treated patients to date. Inadequate reimbursement could limit current patients' access to care should providers determine they are unable to cover the costs associated with the expensive technology and human resources needed to treat patients with ET. At a minimum, we urge CMS to maintain the current payment level at $17,500 for up to two more years in order to gather sufficient claims data from providers and allow for a more comprehensive analysis to support APC assignment and its related payment levels. This approach would continue to encourage provider adoption of this valuable treatment, especially for Medicare beneficiaries, who comprise approximately 80 percent of our treated patients to date.

Despite the fact that Medicare payment for this treatment has been available since January 1, 2017, Medicare coverage for MRgFUS for ET has been determined at the local level and variable at best. While coverage for MRgFUS for ET is now approved in 38 states, only 1/2 of these states were approved in April and July of this year. Many of Dr. Elias' patients have been waiting for Medicare and private payers to cover the treatment. No doubt the Local Coverage Determination process has delayed the submission of claims in order for CMS to analyze the appropriate reimbursement. We urge CMS to consider the impact this has had on claims submissions and the ability to generate enough data to determine adequate payment.

Last, we urge CMS to consider how inadequate reimbursement for MRgUS for ET could also dampen the scientific innovation currently being translated for other indications. Dr. Elias' work has ignited further clinical research on focused ultrasound at UVA and opened a new discussion in the field of neurological surgery around the treatment of movement disorders. For example, current clinical trials of MRgFUS include Parkinson's disease, epilepsy, brain tumors, depression, and neuropathic pain (important for opioid epidemic). Translational research is also occurring for focused ultrasound's use in Alzheimer's' disease, traumatic brain injury, stroke, various psychiatric disorders and more. While ET affects an estimated 10 million Americans, the above conditions touch many, many more. MRgFUS hold the promise that this technology could become the preferred surgical intervention for neurological disorders such as Parkinson's disease and replace radiation treatment or surgical resection for many forms of cancer and other invasive growths.

Proposal to Control Unnecessary Increases in the Volume of Outpatient Services and Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider

Section 603 of the Bipartisan Budget Act (BBA) requires that off-campus provider-based departments (PBDs) that were not billing Medicare prior to November 2, 2015 ("non-excepted") be paid "under the applicable payment system" (i.e. physician fee schedule) beginning January 1, 2017, rather than the outpatient prospective payment system (OPPS). Currently, non-excepted off-campus PBDs are paid equivalent to the physician fee schedule rate (40 percent of the amount that would have been paid for those services under the OPPS). In its proposed rule, CMS proposes to reduce payments by 60 percent for clinic visit services in excepted off-campus PBDs, meaning CMS would apply the "PFS relativity adjuster" (40 percent of the OPPS payment) to both excepted and non-excepted off-campus PBDs. In addition, CMS proposes to reduce payments for new lines of service at excepted off-campus PBDs. The agency would implement this proposal in a non-budget neutral manner, an estimated reduction of $760 million in CY 2019 nationwide. UVAHS estimates the proposal would reduce UVA Medical Center's outpatient payments by $7-8 million annually.

UVAHS objects to these payment policies and urges CMS to withdraw its proposal.

UVAHS believes CMS has misconstrued Congressional intent with its proposal to cut payments for hospital clinic services in excepted off-campus hospital PBDs. In 2015, Congress clearly intended to preserve the existing outpatient payment rate for excepted off-campus PBDs while reducing payment rates for non-excepted PBDs. In addition, the statutory language does not support limiting payment for expanded services in excepted locations as outlined in the rule. CMS is usurping Congress' authority to pay these departments differentially, violating the separation of powers doctrine.

Furthermore, CMS' proposal to track and identify claims for new services at excepted PBDs is administratively burdensome to operationalize. Hospitals would be asked to continually determine whether services at the excepted PBD were furnished during a baseline period (from Nov. 1, 2014 through Nov. 1, 2015); determine whether they fall within any of the 19 proposed

clinical families of services and if not, bill for the service at the lower payment rate of 40 percent of the OPPS using a new PN modifier. Since hospitals currently append the PO modifier for services in excepted PBDs, hospitals would have to track which services received the PO modifier and which services received the PN modifier.

Proposal to Apply the 340B Drug Payment Policy to Non-excepted Off-Campus Departments of a Hospital

In CY 2018, CMS finalized an OPPS policy to reduce payment for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. However, because services furnished in non-excepted off-campus PBDs were no longer considered to be covered outpatient department services, 340B-acquired drugs furnished in these settings were not subject to this policy and continued to be paid at ASP plus 6 percent in 2018. In its CY 2019 proposed rule, CMS expresses concern that the difference in the payment amount for 340B-acquired drugs furnished in excepted and non-excepted off-campus PBDs creates an incentive for hospitals to move drug administration services for these 340B-acquired drugs to non-excepted PBDs. Therefore, for CY 2019, CMS proposes to pay for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program at a rate of ASP minus 22.5 percent when they are furnished by non-excepted off-campus PBDs. This policy would *not* apply to rural sole community hospitals, children's hospitals or PPS-exempt cancer hospitals. The agency estimates that this payment change would result in a cut of $48.5 million in CY 2019.

By continuing to apply last year's policy of cutting Medicare reimbursement to hospitals for outpatient drugs as well as proposing to expand the number of sites that would receive reduced reimbursement for Part B separately payable drugs, CMS is cutting Medicare payments needed by teaching hospitals and other safety net providers to provide vital access to discounted prescription drugs and biologics for our low income, uninsured, and underinsured patients. CMS is also curtailing the intent of the 340B program, which is to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rep. No. 102-384, pt. 2 (1992). At no cost to the taxpayers, the program allows eligible safety net health care providers ("covered entities") to purchase outpatient drugs at discounted price from drug manufacturers. To be eligible, hospitals must serve a disproportionate share of uninsured and low-income patients, and as such, UVAHS is an eligible entity for the 340B program. CMS is also undermining the program's intent by redistributing the savings from the payment reductions from 340B providers to non-340B hospitals and for-profit hospitals. Because CMS is maintaining budget neutrality, CMS is increasing reimbursement for other outpatient services, effectively redistributing the 340B savings to all hospitals providing a wide variety of outpatient services, regardless of service to the most vulnerable populations. Hospitals treating fewer low-income patients benefit at the expense of hospitals serving the most vulnerable patients. This is in direct conflict with the identified purpose of the 340B program, which is to help those hospitals that disproportionately treat low income and the uninsured.

The 340B program provides much more than affordable prescription drugs—it supports better care and better health outcomes for patients. Along with offering vital access to health care—

including drugs and biologics—for our low income, underinsured, and uninsured patients, UVAHS is utilizing it savings to expand patient care and increase health activities. Some of the ways our savings have been used to further the purpose of the program include providing patient medication assistance programs which enable patients to obtain deeply discounted or free medications from manufacturers, offering pharmacy services through an outpatient pharmacy that serves patients 24 hours a day, 7 days a week, and offering pharmacy services to underserved patients who are at high risk for hospital readmissions.

UVA estimates it will continue to lose $8 million annually in Part B Medicare reimbursement as a result of CMS' policy. Payment reductions could result in the reduction of specialty services we currently provide, including the level of uncompensated care, home health services and dialysis services. It may also reduce the discounts and/or expense savings we provide on drugs for our low-income and/or rural patients. As an example, without the 340B program, one current UVA patient with diabetes, hypertension, high cholesterol, and heart disease would not have been able to afford the high cost of name-brand, long-acting insulins, in addition to the 11 other medications necessary to treat the chronic illnesses, costing over $24,000 a year — well over double the patient's annual income. **We urge CMS to revert to the original payment methodology of ASP + 6 percent at all hospitals and withdraw the proposed policy to non-excepted departments.**

CMS OPPS and Physician Fee Schedule Proposals Will Impact Access to Care

CMS' 340B proposal, taken together with its proposal to reduce OPPS payments at excepted PBDs and the Evaluation & Management (E & M) payment proposal in the CY19 Medicare Physician Fee Schedule proposed rule (CMS-1693-P), disproportionately hit academic medical centers. While the impact of the E & M changes would vary based on specialty and patient characteristics, physicians, such as those at academic medical centers who typically see more complex patients, would receive lower reimbursement. CMS has already imposed significant cuts on newer off-campus hospital outpatient departments (HOPDs). UVAHS suffers negative margins when we treat Medicare patients in HOPDs, and these cuts reduce our Medicare reimbursement even more. The proposed payment reductions 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 a public institution like UVA Medical Center who serves all citizens regardless of their ability to pay for care.

Studies show that HOPDs frequently serve as the sole source of care for low-income and otherwise underserved populations of Medicare beneficiaries, accepting patients who otherwise face difficulty being seen in physician offices. HOPDs serve as comprehensive and coordinated care settings for patients with chronic or complex conditions and provide access to stand-by emergency and trauma care not provided in a physician's office. Many centers of excellence are based in hospital settings and provide outstanding team-based, patient centered care and HOPDs provide wraparound services, such as translators and other social services.

Further reductions in hospital outpatient department reimbursement may ultimately lead to a reduction of these services that affect vulnerable patient populations—especially those with complex medical problems. CMS' proposals to further reduce OPPS payments are unreasonable

and unsustainable. Safety net hospitals like UVA will suffer financial hardship and beneficiaries in some areas may find access to care is decreased. Moreover, training opportunities for medical students and residents in these ambulatory sites also may be limited. **We urge CMS to rethink the impact of the combined proposals on academic medical centers and ensure that hospital PBDs are adequately reimbursed for the cost of providing comprehensive, coordinated care to complex patient populations.**

We thank you for the opportunity to respond to this proposed regulatory change.

Sincerely,

Pamela M. Sutton-Wallace
Chief Executive Officer
University of Virginia Medical Center

Exhibit D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY 4000 Cambridge Street Kansas City, KS 66160 ET AL.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 19-CV-132
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.	)	

DECLARATION OF DANIEL W. PETERS IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

I, Daniel W. Peters, hereby declare and state the following:

1. My name is Daniel W. Peters. I am over 21 years of age and competent to testify to the facts set forth herein. I am an adult citizen of the United States. I reside in Olathe, Kansas.

2. The facts set forth in this declaration are based on my personal knowledge and information available to me in my capacity as discussed herein. I could and would testify to these facts if called upon as a witness.

3. I am the SVP and General Counsel of The University of Kansas Hospital Authority ("UKHA"). I have served as General Counsel for UKHA since June 2011. In this capacity, I

oversee aspects of regulatory compliance and cooperate with numerous UKHA executive leaders regarding hospital and physician reimbursement matters, including oversight of Hospital provider based departments of UKHA.

4. UKHA is an academic medical center serving the areas of Kansas City, the states of Kansas and Missouri and across the United States. UKHA serves a population of approximately 1.9 million people in its primary service area. In the areas it serves, UKHA provides services to a growing and aging patient population that includes areas of the community that are socio-economically disadvantaged and underserved. Approximately thirty-seven (37%) percent of UKHA's patients are Medicare beneficiaries. As an academic medical center, UKHA provides a unique complement of additional benefits to the community and the region, such as adult and pediatric behavioral health services, a nationally verified level 1 trauma center, the regions only National Cancer Institute-designated cancer center, and advanced cardiovascular, neurosciences and transplantation services, among others.

5. UKHA operates approximately nineteen excepted off-campus hospital department locations that are recognized by Medicare as "provider-based departments" ("PBDs") established prior to November 2, 2015. These nineteen excepted off-campus PBD's provide approximately sixty-four different lines of treatment services to UKHA patients, some of which are not commonly provided by freestanding physician offices in our community. In other words, the community relies on UKHA's PBDs to receive timely and necessary care when they otherwise may face significant barriers to receiving such care.

6. UKHA and co-plaintiffs have set forth a legal challenge to the Secretary's final rule, effective January 1, 2019, that eliminates the higher, Outpatient Prospective Payment System ("OPPS") reimbursement rate for evaluation and management ("E/M") services provided by

excepted off-campus PBDs, and instead, will only reimburse for E/M services at the lower, Medicare Physician Fee Schedule ("MPFS") rate that nonexcepted off-campus PBDs receive. *See* 83 Fed. Reg. 58,818 (Nov. 21, 2018).

7. UKHA faces immediate and definite harm as a result of the rate cuts to E/M services that became effective January 1, 2019. The rate cuts have created a projected annual estimated negative impact to UKHA of $6,000,000.00. This financial blow to the operations of UKHA's PBDs—already strained from steadily increasing costs in the healthcare marketplace and reimbursement cuts from the government and private insurers alike—jeopardizes its ability to continue providing care for the medically vulnerable populations often treated by its PBDs.

8. The University of Kansas Hospital outpatient cancer center in Westwood, Kansas, for example, is an excepted PBD that serves the Kansas City metropolitan area and the region. This cancer center location at the Westwood campus offers certain highly specialized services related to bone marrow transplant and treatment of blood diseases, which are not commonly provided by freestanding physician offices in this area and not available in a similar capacity at other locations in the region.

9. The University of Kansas Hospital, Sarcoma Center similarly provides much-needed specialized orthopedic oncology services for patients throughout the Midwest. There are no other meaningful orthopedic oncology providers offering comparable services in the area. The next closest providers filling a need for this type of service in the area would require a patient to travel hundreds of miles for comparable services.

10. UKHA can drive innovation, pursue excellence in education, and offer unique and additional benefits to its community through its role as an academic medical center. The added financial hit from the E/M rate cuts jeopardizes this work.

11. For dates of service of between January 2–7, 2019, UKHA submitted claims for excepted off-campus E/M services to its Medicare Administrative Contractor ("MAC"). The MAC paid these E/M claims at the lower MPFS rate set by the Secretary's final rule. UKHA appealed these claims through a Request for Redetermination on February 6, 2019. These documents are attached as Exhibit A.

12. I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed this 15th of February 2019.

Daniel W. Peters,
Senior VP & General Counsel
The University of Kansas Hospital Authority

Attachment A

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

UNIVERSITY OF KANSAS HOSP
PO BOX 955915
ST LOUIS MO 63195

3 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

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

10 BIRTHDATE [redacted] 11 SEX [redacted] 12 ADMISSION DATE 13 HR 14 TYPE 3 15 SRC 1 16 DHR 17 STAT 01 18 09 19 20 21 22 23 24 25 26 27 28 CONDITION CODES 29 ACDT STATE 30

31 OCCURRENCE CODE DATE: a 18 [redacted] b
32 OCCURRENCE CODE DATE
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34 OCCURRENCE CODE DATE
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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
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
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51 HEALTH PLAN ID
52 REL INFO: Y
53 ASG BEN: Y
54 PRIOR PAYMENTS
55 EST. AMOUNT DUE
56 NPI 1649259656
57 OTHER PRV ID

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

63 TREATMENT AUTHORIZATION CODES
64 DOCUMENT CONTROL NUMBER
65 EMPLOYER NAME

66 DX: 0 C8318 I4891 I509 R197 Z7901 C8310 67

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
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c. OTHER PROCEDURE CODE DATE
d. OTHER PROCEDURE CODE DATE
e. OTHER PROCEDURE CODE DATE

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80 REMARKS
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UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC 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]
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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9 PATIENT ADDRESS a [redacted]
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10 BIRTHDATE [redacted] 11 SEX [redacted] 12 DATE 13 HR 14 TYPE 3 15 SRC 1 16 DHR 17 STAT 01
CONDITION CODES 18 09 19 30 20 21 22 23 24 25 26 27 28
29 ACDT STATE 30

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

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51 HEALTH PLAN ID

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56 NPI 1649259656
57 OTHER PRV ID

58 INSURED'S NAME
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60 INSURED'S UNIQUE ID [redacted]

61 GROUP NAME

62 INSURANCE GROUP NO. PLAN J

63 TREATMENT AUTHORIZATION CODES
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64 DOCUMENT CONTROL NUMBER

65 EMPLOYER NAME

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69 ADMIT DX

70 PATIENT REASON DX C674

71 PPS CODE

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74 PRINCIPAL PROCEDURE CODE DATE
a. OTHER PROCEDURE CODE DATE
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76 ATTENDING NPI 1003813940 QUAL
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UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee LIC3910506 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]
TYPE OF BILL 0131

5 FED. TAX NO. [redacted]
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8 PATIENT NAME a [redacted]
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9 PATIENT ADDRESS a [redacted]
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c [redacted] e US

10 BIRTHDATE [redacted]
11 SEX [redacted]
12 ADMISSION DATE
13 HR
14 TYPE 3
15 SRC 1
16 DHR
17 STAT 01
18 19 20 21 CONDITION CODES 22 23 24 25 26 27 28
29 ACDT STATE
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31 OCCURRENCE CODE DATE
a 18 [redacted]
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34 OCCURRENCE CODE DATE
35 OCCURRENCE SPAN CODE FROM THROUGH
36 OCCURRENCE SPAN CODE FROM THROUGH
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38 MEDICARE PART A AND B
PO BOX 7576
MADISON WI 537077576

39 VALUE CODES CODE AMOUNT
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0001	PAGE 1 OF 1	CREATION DATE	020819	TOTALS	12500	000	

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

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

63 TREATMENT AUTHORIZATION CODES
64 DOCUMENT CONTROL NUMBER
65 EMPLOYER NAME

66 DX C8589 H9192 D696
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67 ADMIT DX
68 PATIENT REASON DX C8589
69 PPS CODE
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72 ECI
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74 PRINCIPAL PROCEDURE CODE DATE
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b. OTHER PROCEDURE CODE DATE
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e. OTHER PROCEDURE CODE DATE

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79 OTHER NPI QUAL
LAST FIRST

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

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]
PAGE 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 [redacted]
11 SEX [redacted]
12 ADMISSION DATE 13 HR 14 TYPE 3 15 SRC 1
16 DHR
17 STAT 01
18 19 20 21 CONDITION CODES 22 23 24 25 26 27 28
29 ACDT STATE
30

31 OCCURRENCE CODE DATE
32 OCCURRENCE CODE DATE
33 OCCURRENCE CODE DATE
34 OCCURRENCE CODE DATE
35 OCCURRENCE SPAN CODE FROM THROUGH
36 OCCURRENCE SPAN CODE FROM THROUGH
37

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
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
0300	LAB/GENERAL	36415 PO	[redacted]19	1	4100		
0301	LAB/CHEMISTRY	80053 PO	[redacted]19	1	3300		
0305	LAB/HEMOTOLOGY	85025 PO	[redacted]19	1	1400		
0510	CLINIC	G0463 PO	[redacted]19	1	1200		
0001	PAGE 1 OF 1		CREATION DATE	020819	TOTALS	6420 0	00

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

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

63 TREATMENT AUTHORIZATION CODES
64 DOCUMENT CONTROL NUMBER
65 EMPLOYER NAME

66 DX 0: C50911 C7951 C7800 Z170 Z923 Z85118 Z79811 C499 68
69 ADMIT DX
70 PATIENT REASON DX C50911
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 1932533809 QUAL
LAST HELDSTAB FIRST JAIMIE
77 OPERATING NPI QUAL
LAST FIRST
78 OTHER DN NPI 1649259656 QUAL
LAST NO PCP FIRST NA
79 OTHER NPI QUAL
LAST FIRST

80 REMARKS
81CC a B3 282N00000X
b
c
d

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC LIC1310505 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
7

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

10 BIRTHDATE [redacted]
11 SEX [redacted]
12 ADMISSION DATE 13 HR 14 TYPE 15 SRC 16 DHR
3 1
17 STAT 01 09
18 19 20 21 22 23 24 25 26 27 28 CONDITION CODES
29 ACDT STATE 30

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

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
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
0510	CLINIC	G0463 PO	[redacted]19	1	12500		
0001	PAGE 1 OF 1	CREATION DATE	020819	TOTALS	12500	000	

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

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: D649 G8929 D509 E1140 E538 Z87891 Z903 68
0

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
c. OTHER PROCEDURE CODE DATE
d. OTHER PROCEDURE CODE DATE
e. OTHER PROCEDURE CODE DATE
75

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

81CC a B3 282N00000X
b
c
d

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC LI033105200 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]
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 [redacted]
11 SEX [redacted]
12 ADMISSION DATE
13 HR
14 TYPE 3
15 SRC 1
16 DHR
17 STAT
CONDITION CODES 18 01 19 09 20 30 21 22 23 24 25 26 27 28
29 ACCT STATE
30

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

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

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

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0300	LAB/GENERAL	36415 POQ1	[redacted]19	1	41 00		
0301	LAB/CHEMISTRY	80053 POQ1	[redacted]19	1	333 00		
0301	LAB/CHEMISTRY	82652 PO	[redacted]19	1	411 00		
0305	LAB/HEMOTOLOGY	85025 POQ1	[redacted]19	1	143 00		
0510	CLINIC	G0463 POQ1	[redacted]19	1	132 00		
0001	PAGE 1 OF 1	CREATION DATE	020819	TOTALS	1060 00	0 00	

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

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

63 TREATMENT AUTHORIZATION CODES
64 DOCUMENT CONTROL NUMBER
65 EMPLOYER NAME

66 DIAGNOSIS CODES: C221 Z006 R945 D696 E119 E8339 I10 Z98890 0
67
68
69 ADMIT DX
70 PATIENT REASON DX C221
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 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 National Uniform Billing Committee UB93010506 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 [redacted] 11 SEX [redacted]
12 ADMISSION DATE 13 HR 14 TYPE 3 15 SRC 2 16 DHR 17 STAT 01 09
18 19 20 21 22 23 24 25 26 27 28 CONDITION CODES
29 ACCT STATE 30

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

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

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

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0510	CLINIC	G0463	[redacted]19	1	116 00		

0001 PAGE 1 OF 1 CREATION DATE 020819 TOTALS 116 00 000

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

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

63 TREATMENT AUTHORIZATION CODES
64 DOCUMENT CONTROL NUMBER
65 EMPLOYER NAME

66 DX: C50511 Z170 0
67
68 ADMIT DX
69
70 PATIENT REASON DX C50511 Z170
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 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 National Uniform Billing Committee UC03310506 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:**	~~2~~ 8
Re:	Redetermination Requests	**Date:**	2/6/19

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

Comments:

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

CONFIDENTIAL - FOIA EXEMPT AND HIPAA CONFIDENTIAL
Protected Health Information (PHI) regulated under HIPAA and accompanying regulations which prohibit unauthorized access, use or disclosure.

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.

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS CONFIDENTIAL AND/OR PRIVILEGED. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY CALLING TOLL FREE AT 1 (866) 518-3285 AND CONFIRM DESTRUCTION OF THE INFORMATION. THANK YOU.

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:

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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:

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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:

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THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS CONFIDENTIAL AND/OR PRIVILEGED. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY CALLING TOLL FREE AT 1 (866) 518-3285 AND CONFIRM DESTRUCTION OF THE INFORMATION. THANK YOU.

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.
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- ALL REQUESTS WILL BE PROCESSED IN ACCORDANCE WITH INTERNET ONLY MANUAL (IOM) 100-04 CHAPTER 29 AND 34.

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS CONFIDENTIAL AND/OR PRIVILEGED. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY CALLING TOLL FREE AT 1 (866) 518-3285 AND CONFIRM DESTRUCTION OF THE INFORMATION. THANK YOU.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:19-cv-00132-RMC
ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services,	)	Oral Argument Requested
Defendant.	)	

[PROPOSED] ORDER GRANTING
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Upon consideration of the Plaintiffs' motion for summary judgment and the opposition thereto, the Court ORDERS that the motion is GRANTED. The Clerk of the Court is directed to entered judgment in the Plaintiffs' favor.

SO ORDERED

Dated: _____, 2019

_____
HONORABLE ROSEMARY M. COLLYER
UNITED STATES DISTRICT COURT JUDGE