# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

	)	
THE AMERICAN HOSPITAL ASSOCIATION,	)	
ASSOCIATION OF AMERICAN MEDICAL	)	
COLLEGES, MERCY HEALTH MUSKEGON,	)	
CLALLAM COUNTY PUBLIC HOSPITAL	)	
NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER,	)	
and YORK HOSPITAL,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1:18-cv-2841
	)	
ALEX M. AZAR II,	)	
in his official capacity as SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
	)	ORAL HEARING REQUESTED
Defendant.	)	
	_)	

#### PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure and Local Rule 7(h),

Plaintiffs the American Hospital Association, the Association of American Medical Colleges,

Mercy Health Muskegon, Olympic Medical Center, and York Hospital respectfully request that
this Court enter summary judgment in Plaintiffs' favor because, in promulgating the "Changes to
Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and
Quality Reporting Programs" Final Rule for Calendar Year 2019 (Final Rule), the Centers for
Medicare & Medicaid Services (CMS) far exceeded the scope of the powers delegated to the
agency by Congress.

CMS's conduct is *ultra vires* for two central reasons. *First*, the Medicare statute mandates that changes to payments for covered hospital outpatients services that target only specific items or services must be budget neutral. 42 U.S.C. § 1395l(t)(9)(B). And yet the Final

Rule purports to do precisely what Congress expressly prohibited: CMS seeks to reduce total payments for covered hospital outpatient services by hundreds of millions of dollars per year by targeting a select group of services (*i.e.*, clinic visit services at excepted off-campus provider-based departments) for *non-budget-neutral* payment adjustments. CMS cannot exercise its limited authority in a manner so flagrantly inconsistent with the Medicare statute.

Second, in the Medicare statute, Congress has laid out a clear distinction between "excepted" off-campus provider-based departments, which meet specified grandfathering requirements, and "non-excepted" off-campus provider-based departments, which do not. The statute makes clear that services provided at excepted and non-excepted off-campus provider-based departments should be paid pursuant to different payment systems. 42 U.S.C. § 1395l(t)(21)(C). And yet the Final Rule effectively abolishes any distinction between excepted and non-excepted entities by subjecting them both to the same payment system and rate. That violates the clear intent of Congress and therefore is *ultra vires*.

For these reasons, and those set forth more fully in the accompanying Memorandum in Support, which is incorporated herein by reference, this Court should grant Plaintiffs' motion for summary judgment. Pursuant to Local Rule 7(f), Plaintiffs further request an oral hearing on this motion, given the importance of this issues and the complexity of the underlying regulatory scheme. A proposed order accompanies this motion.

### Respectfully submitted,

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Dated: February 1, 2019

### **CERTIFICATE OF SERVICE**

I certify that on February 1, 2019, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson
Catherine E. Stetson

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V.	)	Civil Action No. 1:18-cv-2841
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ALEX M. AZAR II,	)	
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HEALTH AND HUMAN SERVICES,	)	
D 4 1	)	
Defendant.	)	
	)	

# MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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Dated: February 1, 2019

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#### **INTRODUCTION**

Administrative agencies may act only within the constraints of the legislative authority delegated to them by Congress. And where Congress has specifically constrained an agency's authority, agencies may not take action in excess of their statutory power. These are basic tenets of administrative law. The Centers for Medicare & Medicaid Services (CMS) has run afoul of these core principles by cutting certain Medicare payments in clear violation of statutory limits on the agency's power.

On November 21, CMS published in the Federal Register a Final Rule making changes to Medicare payment rates for outpatient services for Calendar Year (CY) 2019. As relevant here, the Final Rule reduces the payment rates for certain clinic-visit services provided at hospital outpatient practice locations known as "off-campus provider-based departments" (off-campus PBDs). Off-campus PBDs are practice locations of a hospital that are not located in immediate proximity to the main building of their affiliated hospital, but are nonetheless so closely integrated with and controlled by the main hospital as to be considered a part of the hospital.

In 2015, Congress amended the Medicare statute to provide that outpatient services furnished at off-campus PBDs would be subject to a separate payment system than the one governing hospitals. However, Congress recognized that this change would unsettle the expectations of off-campus PBDs that were already billing under the hospital payment system. So Congress struck a compromise: Qualifying off-campus PBDs that were already billing under the hospital payment system (so-called "excepted PBDs") would be excepted from the new payment system. But going forward, Congress required that *newly* created or acquired off-campus PBDs (so-called "non-excepted PBDs") be paid under a different payment system, resulting in lower payment rates to those hospitals.

CMS apparently thinks otherwise. In the Final Rule, CMS announced its decision to reduce overall Medicare payments for hospital outpatient services. The agency accomplished this goal *not* by making across-the-board cuts to all payment rates for outpatient services—the only mechanism the Medicare statute contemplates for non-budget-neutral payment cuts for outpatient services—but instead by making selective cuts to the payment rates for particular services. Specifically, CMS cut the payment rate for clinic visit services provided by *excepted* PBDs so that they are now equal to the (lower) payment rate for *non-excepted* PBDs.

The payment reductions contemplated by the Final Rule contravene the clear statutory safeguards Congress crafted to constrain CMS's authority. In short: They are *ultra vires*.

CMS has exceeded the boundaries of its delegated authority in two major ways. First, the Final Rule is unlawful because it is not budget neutral. Congress has established a clear structure for CMS to make annual changes to payments for covered hospital outpatient services under Medicare. 42 U.S.C. § 1395l(t)(9)(A). Changes to payments that target only specific items or services must be budget neutral. *Id.* § 1395l(t)(9)(B). And yet the Final Rule purports to do precisely what Congress expressly prohibited: CMS seeks to reduce total payments for covered hospital outpatient services by hundreds of millions of dollars per year by targeting a select group of services (*i.e.*, clinic visit services at excepted PBDs) for *non-budget-neutral* payment adjustments. CMS cannot exercise its limited authority in a manner so flagrantly inconsistent with the Medicare statute.

Second, by subjecting excepted and non-excepted PBDs to the exact same payment system and payment rate, the Final Rule abolishes the statutory distinction between those two entities. Congress intentionally created two classes of off-campus PBDs: excepted and non-excepted ones, with the clear expectation that they would be paid differently for performing

outpatient services. Indeed, the only logical purpose for creating the two categories of entities was to grandfather excepted PBDs into the higher payment system applicable to hospitals.

CMS's attempt to override the statutory distinction between these two types of entities violates the clear intent of Congress and therefore is *ultra vires*.x

#### FACTUAL BACKGROUND

#### **Statutory Framework**

Title XVIII of the Social Security Act establishes a program of health insurance for the aged and disabled, commonly known as the Medicare Act. 42 U.S.C. § 1395 *et seq*. The Medicare Act comprises four parts. Part B covers, among other things, hospital outpatient department services (OPD services), which are services that are provided to patients on an outpatient basis. OPD services include emergency or observation services; services furnished in an outpatient setting (*e.g.*, physician visits, same-day surgery); laboratory tests billed by the hospital for outpatients; medical supplies (*e.g.*, splints and casts); preventive and screening services; and certain drugs and biologicals.

Medicare payments for OPD services are generally made under the Outpatient Prospective Payment System (OPPS), governed by 42 U.S.C. § 1395l(t). Congress specified the framework under which CMS was required to establish the OPPS in Subsections (t)(2)(A) through (H). Congress also authorized CMS to review and revise, on an annual basis, the "groups, the relative payment weights, and the wage and other adjustments" related to covered OPD services "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." *Id.* § 1395l(t)(9)(A).

The Medicare statute sets clear limits on these annual adjustments. Those limits include the one at issue here: any such adjustments must be budget-neutral. Specifically, Congress mandated: "[T]he adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made." 42 U.S.C. § 1395l(t)(9)(A). That is a mouthful, but its meaning is plain: Any adjustments under Subsection (t)(9)(A) must be budget neutral, and CMS may not reduce the total amount of Medicare Part B spending by selectively slashing the payment rates for specific types of services.

If CMS wishes to make *non*-budget-neutral cuts to payments under the OPPS, the statute provides a separate mechanism for the agency to do so, with clear limits on both when and how that non-budget-neutral authority could be exercised. First, the statute authorizes CMS to "develop a method for controlling unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 13951(t)(2)(F). Only after the agency develops that method, another statutory provision authorizes CMS to make non-budget-neutral changes to address the unnecessary increases in volume—but even then only through an across-the-board adjustment to all items or services paid under the OPPS.

Specifically, Subsection (t)(9)(C) provides that if CMS determines under Subsection (t)(2)(F) that the "volume of services ... [has] increased beyond amounts established through those methodologies," CMS "may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." *Id.* § 1395l(t)(9)(C). The conversion factor, which is updated annually, is a uniform amount that is used in the formula to calculate payment rates for *all* services or items paid under the OPPS. *Id.* § 1395l(t)(3)(C), (D). In other words, an adjustment to the conversion factor can shrink (or grow) the entire OPPS by a percentage-factor, but it cannot reduce the relative rate of payment for a particular set of services or items.

The upshot of Congress's chosen statutory structure is clear: If CMS wants to reduce outlays under OPPS, it must cut payments across the board, for all OPPS services and items, by lowering the conversion factor. In other words, if CMS wants to reduce the size of the pie, each slice can be made slightly smaller. If CMS instead wants to reduce payment for specific services (*i.e.*, to slice the pie differently), it must do so in a budget-neutral manner, by increasing payments for other services so that the pie remains the same size. But CMS *cannot* do both at the same time. In this way, the statute's structure prevents CMS from engaging in cost-control measures that will have a disproportionate impact on only some service providers and beneficiaries.

#### Off-Campus Provider-Based Departments

At issue in this lawsuit are Medicare payments for certain clinic-visit services provided by off-campus PBDs. As previously noted, off-campus PBDs are practice locations of a hospital that are not in immediate proximity to the main building of their affiliated hospital, but are nonetheless so closely integrated with and controlled by that hospital as to be considered a part of the hospital. *See* 42 C.F.R. § 413.65(e). An off-campus PBD may serve a range of critical healthcare functions and take various forms, including a stand-alone oncology clinic, an urgent care clinic, or a physician practice providing necessary specialty services (*e.g.*, cardiology, pulmonology, neurology, and urology).

Off-campus PBDs provide several unique advantages to patients and allow hospitals to better serve their communities. In some cases, there may be operational reasons for using an off-campus PBD. For example, a hospital might want to place an off-campus PBD in a location that is convenient to an under-served patient population. In other cases, a hospital may lack the space on its main campus to expand, and an off-campus PBD is opened as a matter of necessity. In

rural and other traditionally underserved areas of the country, allowing hospitals to expand their capabilities through off-campus PBDs often means that patients have access to care that they otherwise would not. *See generally* Declaration of Joanna Hiatt Kim (AHA Decl.) ¶ 10.

By law, off-campus PBDs must be integrated with their main hospitals and are subject to the same regulatory requirements as the hospital—unlike independent clinics or physician offices. *See* 42 C.F.R. § 413.65 (describing detailed regulatory requirements for off-campus facilities). As a result, off-campus PBDs typically have higher costs relative to a physician office. There are many reasons for this: The patient population that depends on the care provided at off-campus PBDs tends to be sicker and poorer than the patient population that visits independent physician offices. In addition, CMS regulations require that off-campus PBDs comply with the same Medicare Conditions of Participation governing their affiliated hospital. These requirements are more demanding than those for physician offices and clinics. Moreover, off-campus PBDs serve a greater number of functions than do standalone physician offices, providing advantages in the care for patients.

#### Section 603 of the Bipartisan Budget Act of 2015

Until November 2015, clinic-visit services at all off-campus PBDs were paid under the OPPS, at the relatively higher payment rates paid to hospitals (as compared to the rates for their physician-office counterparts). 83 Fed. Reg. 59,004–05 (Nov. 21, 2018). The total volume of outpatient services furnished at off-campus PBDs nationwide has been increasing for years, since at least 2010. *Id.* at 59,005–007. Much of that increase in volume has been necessary and

<sup>&</sup>lt;sup>1</sup> See Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices (KNG Health Consulting LLC, 2018), available at https://bit.ly/2Ed4Iaf.

<sup>&</sup>lt;sup>2</sup> See generally Hospital Outpatient Department (HOPD) Costs Higher Than Physician Offices Due to Additional Capabilities, Regulations (AHA, 2014), available at https://bit.ly/2DnkFtb.

appropriate. The Medicare-eligible population as a whole has increased during that same time period, imposing greater demands for OPD services. See Medicare Board of Trustees, 2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds 181 (2018) (increase of approximately 9.5 million Medicare Part B enrollees from 2010 to 2017 alone).<sup>3</sup> In addition, medical technology has advanced in parallel with these demographic changes, enabling more and more services to be provided on an outpatient (rather than an inpatient) basis. See Ken Abrams, Andreea Balan-Cohen & Priyanshi Durbha, Growth in Outpatient Care, Deloitte (Aug. 15, 2018).

In addition, however, one of the many factors contributing to the increase in volume of outpatient services furnished at off-campus PBDs was the acquisition of standalone physician offices by some hospitals, and the subsequent integration of those physician offices into hospital operations. See 83 Fed. Reg. 59,005–007. That phenomenon had the effect of shifting some services that otherwise would have been provided in the physician office setting to the offcampus PBD setting. 83 Fed. Reg. 59,008. CMS has long taken the view that Medicare costs could be lowered if outpatient services performed by off-campus PBDs were instead furnished in the generally less-expensive setting of a physician's office. See id. The agency has contended that off-campus PBDs should therefore be treated the same as physician offices and paid under the Medicare Physician Fee Schedule (PFS) rather than the OPPS. See id. In response, commenters pointed out that off-campus PBDs typically have higher costs than physician offices (in some cases even exceeding the Medicare payment rate for such services) and that off-campus PBDs are often able to provide services that are not available in physician offices. Critics of CMS's position also noted that paying off-campus PBDs at the lower rates paid to physician

<sup>&</sup>lt;sup>3</sup> *Available at* https://go.cms.gov/2JottiO. <sup>4</sup> *Available at* https://bit.ly/2nOkG05.

offices would upset the reasonable expectations of hospitals that acquired or built off-campus PBDs, and conformed those hospital-affiliated departments with rigorous and detailed regulatory requirements, with the understanding that they would be paid under the OPPS.<sup>5</sup>

Congress sought to address these competing concerns when it enacted Section 603 of the Bipartisan Budget Act of 2015. Pub. L. No 114-74 § 603, 129 Stat. 584, 598. Its solution was to create two classes of off-campus PBDs. Qualifying off-campus PBDs that were billing as hospital departments under the OPPS when the Act became law on November 2, 2015 (referred to as "excepted PBDs") would continue to be paid under the OPPS. *See* 42 U.S.C. §§ 1395l(t)(1)(B)(V), (t)(21) & (t)(21)(B)(ii). But going forward, Congress required that *newly* created or acquired off-campus PBDs (referred to as "non-excepted PBDs") be paid under the "applicable payment system" in order to eliminate the possibility that a payment differential would motivate a hospital's decision to open a new off-campus PBD. *Id.* § 1395l(t)(21)(C); *see also id.* § 1395l(t)(21)(B)(iii)—(vi) (codifying additional exceptions, such as allowing off-campus PBDs that were mid-build when Section 603 was enacted to continue to be paid under the OPPS).

CMS has since interpreted the statutory phrase "applicable payment system" to mean that non-excepted PBDs should be paid under the Medicare Physician Fee Schedule. 81 Fed. Reg. 79,562, 79,659 (Nov. 14, 2016). The Physician Fee Schedule has lower payment rates relative to OPPS because it is intended to reflect the costs for furnishing items or services in a physician

<sup>&</sup>lt;sup>5</sup> *Cf.* Letter from the Honorable Rob Portman, Senator, United States Senate, et al. to Seema Verma, Administrator, Centers for Medicare & Medicaid Services (Sept. 28, 2018) ("In passing Section 603, Congress was clear in its intention to grandfather existing facilities, so that only new off-campus sites would have payments reduced."), *available at* https://bit.ly/2R9yOle.

office as opposed to in a hospital.<sup>6</sup> Thus, the payment rates for excepted PBDs (under the OPPS) are generally higher than non-excepted PBDs (under the Physician Fee Schedule). 83 Fed. Reg. 59,008.

In practice, CMS does not actually abide by the statutory requirement to pay non-excepted PBDs under a separate payment system from OPPS. Rather, CMS continues to pay such non-excepted PBDs under the OPPS but applies a "PFS Relativity Adjustor," which CMS says is intended to approximate what the rate of payment "would have been" if the item or service were actually paid under the Physician Fee Schedule. *See generally* 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016); *see also* 83 Fed. Reg. 59,009.

#### **The Final Rule**

Against this backdrop, on July 31, CMS issued a Proposed Rule proposing changes to the OPPS for Calendar Year 2019, titled "Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs." As relevant here, CMS proposed that the payment rate for certain clinic-visit services provided at *excepted* PBDs be reduced to render it equal to the payment rate for services provided at *non*-excepted PBDs (referred to as the Clinic Visit Policy). 83 Fed. Reg. 37,046, 37,142 (July 31, 2018). Specifically, the Proposed Rule provided that the payment rate for clinic services furnished by excepted off-campus PBDs in CY 2019 "would now be equivalent to the payment rate for" services provided by non-excepted off-campus PBDs. *Id.* CMS estimated that this change would result in a decrease in overall payments to hospitals under the OPPS by \$760 million in CY 2019 *alone*. *Id.* at 37,143. But CMS maintained that it had the authority to make this

<sup>&</sup>lt;sup>6</sup> See 83 Fed. Reg. 59,006–008 (citing MedPAC, Report to the Congress: Medicare Payment Policy (Mar. 2018), available at https://bit.ly/2FNItVG).

equalizing adjustment in a non-budget-neutral fashion—that is, without an off-setting increase in payment rates for other OPPS services. *Id.* at 37,142.

Almost 3,000 commenters submitted comments in response to the Proposed Rule, including Plaintiffs AHA and AAMC. Among other things, Plaintiffs pointed out that CMS lacks the statutory authority to adjust payment rates in a non-budget-neutral manner under 42 U.S.C. § 1395l(t)(9)(B). Plaintiffs also explained that the Proposed Rule ran afoul of Congress's statutory mandate that CMS treat excepted and non-excepted off-campus PBDs differently.

The Final Rule was published in the Federal Register on November 21. 83 Fed. Reg. 58,818. Like the Proposed Rule, the Final Rule adjusts the payment rate for services provided by excepted PBDs so that it is "equal to" the payment rate for services provided by non-excepted PBDs. *Id.* at 58,822, 59,013. CMS also confirmed its decision to implement the adjustment in a non-budget neutral fashion, targeting only a select group of services. *Id.* at 59,014. However, CMS announced that it would be phasing in the payment reduction over a two-year period; in the first year, CY 2019, the estimated reductions in payments to hospitals would be approximately \$380 million. *Id.* Around the same time it announced the Final Rule, CMS issued a press release stressing that the Final Rule would result in "lower costs" and "an estimated amount of \$380 million" in "savings for the Medicare program" overall.<sup>7</sup>

#### Absent Judicial Relief, Plaintiffs Will Suffer Concrete and Imminent Harm

The Final Rule became effective on January 1, 2019. The Plaintiff-Hospitals and the Plaintiffs AHA's and AAMC's members have already begun to feel the effects of CMS's patently *ultra vires* conduct. Many hospitals rely heavily on the structure of Medicare payments

<sup>&</sup>lt;sup>7</sup> Press Release, CMS Finalizes Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System changes for 2019 (CMS-1695-FC), CMS.Gov (Nov. 2, 2018), available at https://go.cms.gov/2CW9jw6.

established by Congress to provide critical outpatient services for the vulnerable populations in their communities, many of whom have been historically underserved. AHA Decl. ¶ 8; Declaration of Janis M. Orlowski (AAMC Decl.) ¶ 6; Declaration of Eric Lewis (Olympic Decl.) ¶ 4, 9–14; Declaration of Kristi K. Nagengast (Mercy Decl.) ¶ 8; Declaration of Jud Knox (York Decl.) ¶ 4, 7. By reducing the payment rate for covered services provided at excepted PBDs, the Final Rule will force serious payment reductions on affected hospitals, which in turn may cause those hospitals to make difficult decisions about whether to reduce services. *See, e.g.*, AHA Decl. ¶ 9; AAMC Decl. ¶ 6; Olympic Decl. ¶ 9–14; Mercy Decl. ¶ 7–9. By CMS's own estimate, this amount will total approximately \$380 million in CY 2019 alone. 83 Fed. Reg. 59,014. This payment reduction is particularly troubling for hospitals already operating at low or negative margins. AHA Decl. ¶ 10; Olympic Decl. ¶ 8–14; Mercy Decl. ¶ 8.

For all of these reasons, affected hospitals and the vulnerable patients and communities they serve face concrete and imminent harms—both economic and noneconomic—if CMS's Final rule is allowed to stand.

#### **ARGUMENT**

It is a fundamental principle of administrative law that federal agencies may not act unless authorized to do so by Congress. "Under our system of government, Congress makes laws and the President, acting at times through agencies . . . 'faithfully execute[s]' them." *Utility Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2445 (2014) (*citing* U.S. Const., art. II, § 3). In keeping with this constitutional principle, federal agencies may promulgate rules only to the extent authorized to do so by Congress. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."); *Lyng v. Payne*, 476 U.S. 926,

937 (1986) ("an agency's power is no greater than that delegated to it by Congress"). Federal agencies similarly lack the authority to override Congress's clear commands. *See Utility Air*, 134 S. Ct. at 2445 ("An agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.").

When a federal agency acts in blatant excess of its statutory authority, that action is *ultra vires* and should be vacated. *See*, *e.g.*, *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1168 (D.C. Cir. 2003) (agency action is *ultra vires* when it "exceed[s] the agency's delegated authority under the statute."); *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988) (agency violation of "clear and mandatory" statutory provision is *ultra vires*). *See also Leedom v. Kyne*, 358 U.S. 184, 188 (1958) (recognizing a cause of action where plaintiff is not merely seeking "review" of agency decision made within its jurisdiction but rather "to strike down" agency action "made in excess of its delegated powers and contrary to a specific prohibition" in the statute). CMS's conduct here easily meets this standard.

# I. THE FINAL RULE EXCEEDS CMS'S AUTHORITY BECAUSE THE CLINIC VISIT POLICY IS NOT BUDGET NEUTRAL.

First and foremost, the Final Rule is *ultra vires* because the Clinic Visit Policy is not budget neutral, in plain violation of the statute. As a result, the Final Rule transgresses "the core administrative-law principle" that an agency lacks the authority to override Congress's commands. *See Utility Air*, 134 S. Ct. at 2446.

The Medicare statute makes clear that if CMS wishes to make changes to the payment rate for individual OPD services, it must do so "in a budget neutral manner." 42 U.S.C. § 1395l(t)(9)(B). Conversely, if CMS wishes to reduce Medicare costs by cutting payment rates to address "unnecessary increases in the volume of services," it must do so across-the-board, to all covered services. *Id.* §§ 1395(t)(2)(F), 1395l(t)(9)(C). By requiring budget neutrality for

payment reductions targeting only specific services, the statute recognizes—and puts a check on—any incentive for CMS to employ draconian cost-control measures that target only certain service providers.

And yet the Final Rule announces cuts to the payment rates for specific services without creating any off-setting increases to other payment rates. By CMS's own admission, the Clinic Visit Policy set forth in the Final Rule would reduce total hospital payments by \$380 million in CY 2019, with no offsetting increases in payments for other services. 83 Fed. Reg. at 59,014. But by reducing payment rates for selected services in a non-budget-neutral fashion, CMS flatly ignores "clear statutory terms to suit its own sense of how the statute should operate." *Utility Air*, 134 S. Ct. at 2446. It also reflects "an attempted exercise of power that had been specifically withheld." *Leedom v. Kyne*, 358 U.S. at 189. The Final Rule is therefore *ultra vires*.

In an effort to sidestep the statutory requirement that annual adjustments be budget neutral, CMS has claimed that its authority to adopt the Clinic Visit Policy flows *not* from the annual adjustment authority granted in Subsection (t)(9)(A), but instead from the agency's separate statutory authorization under Subsection (t)(2)(F) to develop a "method" for controlling unnecessary increases in the volume of services covered under the OPPS. *See* 83 Fed. Reg. 59,011.

CMS purports to ground the Clinic Visit Policy in Subsection (t)(2)(F) for a strategic purpose: that provision, unlike the rest of Subsection (t), makes no express mention of budget neutrality. For good reason, though. Subsection (t)(2)(F) does not need to address budget neutrality because it does not actually authorize the agency to make any adjustments or changes to payment rates at all. Instead, it merely authorizes CMS to "develop a method for controlling unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395l(t)(2)(F)

(emphasis added). Another statutory provision governs how that method may be *used* in actual volume-control efforts.

Specifically, Subsection (t)(9)(C) addresses what CMS should do if it wants to cut payment rates based on a finding under Subsection (t)(2)(F) that there are unnecessary increases in the volume of services: "If the Secretary determines under the methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately *adjust the update to the conversion factor* otherwise applicable in a subsequent year." *Id.* § 1395l(t)(9)(C) (emphasis added). The conversion factor, which is updated annually by CMS, is "calculated by use of a complex formula that takes into account the overall state of the economy of the United States, the number of Medicare beneficiaries, the amount of money spent in prior years, and changes in the regulations governing covered services." *See* D.J. Seidenwurm & J.H. Burleson, *The Medicare Conversion Factor*, 35 Am. J. Neuroradiology 242, 242–243 (2014). The conversion factor applies broadly to affect payments for *all* covered services under the OPPS. 42 U.S.C. §1395l(t)(2)(C) and (D). As such, it cannot be used to change the relative payment rates between and among individual services.

CMS's "far-fetched" understanding of its authority under Subsection (t)(2)(F) is possible only "through an unintuitive, creative reading" of the statutory framework that would require this Court to assume, contrary to the text and purpose of these provisions, that when Congress "expressly spelled out" how CMS could make selective cuts in Subsection (t)(9)(A), it nevertheless implied a directly contrary power by remaining "utterly silent" in Subsection (t)(2)(F). See Philip Morris USA Inc. v. United States Food & Drug Admin., 202 F. Supp. 3d 31,

<sup>&</sup>lt;sup>8</sup> *Available at* https://bit.ly/2DFJhyp.

52 (D.D.C. 2016). Had Congress meant to construct "a backdoor means" around the budget-neutrality limitation, however, one "would expect to see some affirmative indication" that it intended to do so. *Czyzewski v. Jevic Holding Corp.*, 137 S. Ct. 973, 984 (2017).

While the statute is clear on its face, it is nonetheless noteworthy that the legislative history supports its plain meaning. Subsection (t) was added to the statute by the Balanced Budget Act of 1997. The associated conference report explains that, under Subsection (t):

The Secretary would be authorized to periodically review and revise the groups, relative payment weights, and the wage and other adjustments to take into account changes in medical practice, medical technology, the addition of new services, new cost data, and other relevant information. Any adjustments made by the Secretary would be made in a budget neutral manner. If the Secretary determined that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary would be authorized to adjust the update to the conversion factor otherwise applicable in a subsequent year.

Balanced Budget Act of 1997, H.R. Rep. No. 105-217, at 784 (Conf. Rep.) (emphasis added).

And finally, lest there be any remaining doubt, CMS has effectively admitted the limitations of Subsection (t)(2)(F) in the past. For example, in 1998, CMS acknowledged that "possible legislative modification" would be necessary before it could use its authority under Subsection (t)(2)(F) to adopt measures that would implement adjustments other than those to the conversion factor. 63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998). Similarly, in 2001, CMS implicitly acknowledged that the agency's options for implementing adjustments based on a finding under Subsection (t)(2)(F) were limited to updates to the conversion factor. 66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2001) ("[S]ection 1833(t)(2)(F) requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered hospital outpatient services, and section 1833(t)(9)(C) authorizes the Secretary to adjust the update to the conversion

factor if the volume of services increased beyond the amount established under section 1833(t)(2)(F)."). CMS thus has acknowledged that changes to payment rates resulting from Subsection (t)(2)(F) must occur pursuant to an across-the-board change in the conversion factor. That is telling.

Contrary to CMS's present assertion, then, Subsection (t)(2)(F) does not confer authority to modify payment rates for specific items or services in response to unnecessary increases in the volume of OPD services. Rather, as noted above, if the methodology developed by CMS under Subsection (t)(2)(F) shows that there are unnecessary increases in the volume of OPD services, Congress has said in Subsection (t)(9)(C) that CMS's recourse is to modify the conversion factor and effectuate an across-the-board reduction in payment rates under the OPPS. And to state the obvious, in crafting the Clinic Visit Policy, CMS has not adjusted the conversion factor, 9 nor has it cut payment rates across-the-board. Instead, it has cut the payment rates for a targeted subset of services. In short, Subsection (t)(2)(F) is of no use to CMS in justifying the Final Rule.

# II. THE FINAL RULE EXCEEDS CMS'S AUTHORITY BECAUSE IT ERASES THE STATUTORY DISTINCTION BETWEEN EXCEPTED AND NON-EXCEPTED PBDs.

The Final Rule also separately is *ultra vires* because it sets the same payment rate for clinic visit services provided at both excepted and non-excepted PBDs, in violation of Congress's statutory command. Specifically, the Final Rule provides that the payment rate for services furnished at excepted PBDs will be adjusted so that it would be "equal to" the payment rate for services provided at non-excepted PBDs. 83 Fed. Reg. 59,013.

<sup>&</sup>lt;sup>9</sup> In fact, CMS has separately adjusted the conversion factor elsewhere in the Final Rule. *See* 83 Fed. Reg. 58,861.

But the Medicare statute requires CMS to pay excepted and non-excepted PBDs differently for clinic visit services. The statute creates two distinct categories of off-campus PBDs: excepted entities, which satisfy certain grandfathering requirements, and non-excepted entities. *See* 42 U.S.C. § 1395l(t)(21). Congress created that distinction in order to fashion a grandfather provision for excepted PBDs, allowing entities that had been billing before November 2015 to continue billing under the OPPS, while non-excepted entities would be subject to a different payment system (later determined by CMS to be the Medicare Physician Fee Schedule). *See id.* § 1395l(t)(21)(C); H.R. Rep. No. 114-604, at 10 (2016).

Congress necessarily understood and clearly intended that these separate payment *systems* would entail separate payment *rates*. Indeed, the only logical reason for mandating that the two classes of off-campus PBDs be subjected to different billing systems was to ensure that different payment rates would apply. CMS itself has effectively acknowledged as much by requiring non-excepted PBDs to continue to bill through the OPPS billing system (notwithstanding the plain language of the statute) and instead using a "PFS Relativity Adjustor," to approximate what the rate of payment "would have been" if the item or service were actually paid under the Physician Fee Schedule. *See generally* 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016); *see also* 83 Fed. Reg. 59,009.

Moreover, from a statutory interpretation standpoint, it would be implausible to suppose that the statutory distinction between excepted and non-excepted PBDs is meaningless and can

<sup>&</sup>lt;sup>10</sup> While not dispositive of Congress's intent when crafting Section 603 in 2015, it is nonetheless notable that when Congress amended Section 603 through the 21 Century Cures Act in 2016, a Conference Report described the "practical effect" of Section 603 as follows: "new off-campus PBD HOPDs would be eligible for only physician fee schedule or ambulatory surgical center payment rates rather than the higher hospital outpatient payment rate." H.R. Rep. No. 114-604, at 10 (2016).

simply be ignored. *See Independent Ins. Agents of America, Inc. v. Hawke*, 211 F.3d 638, 644 (D.C. Cir. 2000) ("all words in a statute are to be assigned meaning, and . . . nothing therein is to be construed as surplusage"). Put simply: Had Congress intended to allow CMS to treat excepted and non-excepted PBDs the same, it would have drawn no statutory distinction between these entities at all. And yet it did.

By decreeing that excepted and non-excepted entities will not only be billed under the same payment system but now also be subject to the same payment *rate*, CMS has entirely abolished the statutory separateness put in place by the statute, performing an end-run around the congressional mandate. The agency lacks the authority to nullify the Medicare statute in this manner. Agencies are "bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes." *Colorado River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 466 F.3d 134, 139–140 (D.C. Cir. 2006).

CMS purports to justify its Clinic Visit Policy with a resort to policy arguments. The agency explains: "To the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another." 83 Fed. Reg. 59,008; *see also id.* at 58,823, 59,011. That may or may not be true as a matter of medical practice and regulatory policy—but it is not the solution that Congress chose. The Medicare Act reflects Congress's deliberate decision to treat excepted and non-excepted PBDs differently, and to grandfather excepted PBDs so that they would continue to receive payment at hospital rates rather than physician office rates. CMS does not have the authority to do away with that statutory distinction merely because it disagrees with Congress. Policy preferences do not "give the agency carte blanche to ignore the statute"

whenever the agency decides statutory "requirements aren't worth the trouble." *Waterkeeper All. v. EPA*, 853 F.3d 527, 535 (D.C. Cir. 2017).

To the contrary. When Congress dictates policy, agencies must follow that mandate. *See Utility Air.*, 134 S. Ct. at 2446 ("[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate."); *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 91 (2002) ("Regardless of how serious the problem an administrative agency seeks to address, . . . it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law.") (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000)). Whatever advantages CMS may believe inure to a different approach, it lacks the power to override its statutory mandate when Congress has already set the agency's course.

Because Congress established a clear division between excepted and non-excepted offcampus PBDs, CMS's attempt to override that statutory distinction by paying both entities the same rate is *ultra vires*.

#### **CONCLUSION**

The Clinic Visit Policy set forth in the Final Rule is *ultra vires* because CMS has exceeded the statutory authority delegated to the agency by Congress. This Court should grant Plaintiffs' Motion for Summary Judgment, vacate the relevant portions of the Final Rule, enjoin CMS from enforcing the Clinic Visit Policy, and order CMS to provide immediate repayment of any amounts improperly withheld as a result of the agency's unauthorized conduct.

Respectfully submitted,

/s/ Catherine E. Stetson Catherine E. Stetson (D.C. Bar No. 453221) Susan M. Cook (D.C. Bar No. 462978) HOGAN LOVELLS US LLP 555 Thirteenth Street, NW Washington, DC 20004 Telephone: 202-637-5491

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cate.stetson@hoganlovells.com

Counsel for the American Hospital Association, Association of American Medical Colleges, Mercy Health Muskegon, Olympic Medical Center, and York Hospital

Dated: February 1, 2019

### **CERTIFICATE OF SERVICE**

I certify that on February 1, 2019, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all registered users.

/s/ Catherine E. Stetson Catherine E. Stetson

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

	)	
THE AMERICAN HOSPITAL ASSOCIATION,	)	
ASSOCIATION OF AMERICAN MEDICAL	)	
COLLEGES, MERCY HEALTH MUSKEGON,	)	
CLALLAM COUNTY PUBLIC HOSPITAL	)	
NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER,	)	
and YORK HOSPITAL,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1:18-cv-2841
	)	
ALEX M. AZAR II,	)	
in his official capacity as SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
	)	
Defendant.	)	
	_)	

### DECLARATION OF JOANNA HIATT KIM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

- I, Joanna Hiatt Kim, hereby declare and state the following:
- 1. My name is Joanna Hiatt Kim. I am over 21 years of age. I am an adult citizen of the United States. I reside in McLean, VA.
- 2. The facts set forth in this declaration are based on my personal knowledge and upon information available to me through the files and records of the American Hospital Association (AHA). If called upon as a witness, I could and would testify to these facts.
- 3. I am the Vice President, Payment Policy and Analysis of the AHA. I have served in this capacity since January 2016. From January 2013 through January 2016, my title was Vice President, Payment Policy. In both roles, I have been responsible for leading AHA's work on Medicare payment policy and initiatives, including those relating to outpatient payments. In

my capacity as Vice President, Payment Policy and Analysis, I have access to certain financial data relating to the impact on AHA's members of the clinic visit policy at issue in this lawsuit.

- 4. The AHA is a national, not-for-profit organization headquartered in Washington, D.C. The AHA represents and serves nearly 5,000 hospitals, health care systems, and networks, and over 43,000 individual members. Its mission is to advance the health of individuals and communities by leading, representing, and serving the hospitals, systems, and other related organizations that are accountable to the community and committed to health improvement. The AHA provides extensive education for healthcare leaders and is a source of valuable information and data on health care issues and trends. It also ensures that members' perspectives and needs are heard and addressed in national health-policy development, legislative and regulatory debates, and judicial matters. One of the critical ways in which AHA serves its mission is to protect its members' interests in connection with policy changes initiated by CMS through advocacy and litigation.
- 5. On behalf of its members, the AHA (with its co-plaintiffs) has filed this lawsuit challenging as *ultra vires* a payment reduction implemented by the Centers for Medicare & Medicaid Services (CMS) as part of the calendar year (CY) 2019 Medicare outpatient prospective payment system (OPPS) final rule (Final Rule).
- 6. Under the challenged clinic visit policy, CMS has announced that it will equalize payment for clinic visit services provided by excepted and non-excepted off-campus provider-based departments (PBDs), to be phased in over the course of two years. In CY 2019, payment for clinic visit services furnished at excepted off-campus PBDs will be reduced to 70 percent of the current OPPS payment rate. In 2020, payment to excepted off-campus provider-based departments will be fully equalized with non-excepted off-campus provider-based departments.

This will mean that payment for clinic visit services at both classes of off-campus provider-based departments will be equal to 40 percent of the then-current OPPS rate, which CMS claims approximates payment under the Medicare physician fee schedule.

- off-campus PBDs and will be negatively affected by CMS's Final Rule. These hospitals will be harmed by CMS's *ultra vires* conduct if the Final Rule is allowed to stand because they will suffer a serious reduction in payment for services provided at excepted off-campus PBDs. By seeking to remedy that harm and ensure hospitals are able to provide the full range of outpatient department services in the manner that Congress intended, this action seeks to further the interests of AHA's members that are germane to its organizational purpose.
- 8. Many hospitals rely heavily on the structure of Medicare payments established by Congress to provide critical outpatient services for the vulnerable populations in their communities, many of whom have been historically underserved. By CMS's own estimate, payment reductions resulting from the clinic visit policy set forth in the Final Rule will total approximately \$380 million in CY 2019 alone. 83 Fed. Reg. 59,014.
- 9. By reducing the payment rate for covered services provided at excepted PBDs, the Final Rule will force serious payment reductions on affected hospitals, which in turn may cause those hospitals to make difficult decisions about whether to reduce or even eliminate services. In addition, the revenue lost by hospitals will affect their ability to expand services, invest in infrastructure, and open new locations. Moreover, the payment reduction is particularly troubling for hospitals already operating at low or negative margins.
- 10. Off-campus provider-based departments help fill an important role in the medicalcare continuum for such vulnerable and underserved patients. Because they need not be located

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in immediate proximity to their affiliated hospital's main buildings, off-campus provider-based

departments can be directly embedded in the communities of patients who live miles from a

hospital's main campus. As a result, such off-campus provider-based departments are often the

lifeline for access to hospital outpatient care for these patients. If hospitals are forced to reduce

services at off-campus PBDs as a result of the payment cuts set forth in the Final Rule, patients

that are already facing medical and/or financial barriers will be forced to travel longer distances

to obtain medical care.

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

correct.

Executed this 2 day of January 2018.

Joanna Hiatt Kim

Vice President, Payment Policy and Analysis

American Hospital Association

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# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

	)
THE AMERICAN HOSPITAL ASSOCIATION,	)
ASSOCIATION OF AMERICAN MEDICAL	
COLLEGES, MERCY HEALTH MUSKEGON,	)
CLALLAM COUNTY PUBLIC HOSPITAL	)
NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER,	
and YORK HOSPITAL,	)
	)
Plaintiffs,	)
	)
v.	) Civil Action No. 1:18-cv-2841
ALEXAL AZAD Y	)
ALEX M. AZAR II,	)
in his official capacity as SECRETARY OF	)
HEALTH AND HUMAN SERVICES,	)
	)
Defendant.	)
	_)

### DECLARATION OF JANIS M. ORLOWSKI IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I, Janis M. Orlowksi, hereby declare and state the following:

- 1. My name is Janis M. Orlowski. 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 the District of Columbia.
- 2. The facts set forth in this declaration are based on my personal knowledge and upon information available to me through the files and records of the Association of American Medical Colleges (AAMC). If called upon as a witness, I could and would testify to these facts.
- 3. I am the Chief, Health Care Affairs of the AAMC. I have served in this capacity since 2013. In this role, I am responsible for all activities of the Health Care Affairs cluster, including regulatory work, data analysis in support of such work, and staffing the Council of

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Teaching Hospitals and Health Systems. In my capacity as Chief, I am familiar with the impact that the clinic visit policy at issue in this lawsuit will have on AAMC's members.

- 4. AAMC is a national, not-for-profit association based in Washington, D.C. The AAMC represents and serves all 152 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 83,000 medical students, and 110,000 resident physicians. The AAMC works to improve the nation's health by strengthening the quality of medical education and training, enhancing the search for biomedical knowledge, advancing health services research, and integrating education and research into the provision of effective health care. In addition, it is one of the AAMC's core missions to advocate and litigate on behalf of its members and patients in connection with national health-policy matters.
- 5. On behalf of its members, the AAMC (with its co-plaintiffs) has filed this lawsuit challenging as *ultra vires* a payment reduction implemented by the Centers for Medicare & Medicaid Services (CMS) as part of the calendar year (CY) 2019 Medicare outpatient prospective payment system (OPPS) final rule (Final Rule).
- 6. Many of AAMC's members have excepted off-campus provider-based departments (PBDs) and will be harmed by CMS's Final Rule if it is allowed to stand because they will suffer a serious reduction in payment for services at those excepted off-campus PBDs. By seeking to remedy that harm and ensure hospitals are able to provide the full range of outpatient department services in the manner that Congress intended, this action seeks to further the interests of AAMC's members that are germane to its organizational purpose.

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

Executed this <u>28</u> day of January 2019.

Janis M. Orlowski, M.D.

Association of American Medical Colleges

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, MERCY HEALTH MUSKEGON, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER, and YORK HOSPITAL,	) ) ) ) )	
Plaintiffs,	)	•
v.	)	Civil Action No. 1:18-cv-2841
ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Defendant.	) _)	

## DECLARATION OF ERIC LEWIS IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I, Eric Lewis, hereby declare and state the following:

- 1. My name is Eric Lewis. 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 Sequim, Washington.
- 2. The facts set forth in this declaration are based on my personal knowledge and upon information available to me through the files and records of Clallam County Public Hospital District No. 2, d/b/a Olympic Medical Center (Olympic Medical Center or OMC). If called upon as a witness, I could and would testify to these facts.
- 3. I am the Chief Executive Officer of Olympic Medical Center. I have served in this capacity since December 2006. In this role, I am responsible for the operations of OMC and implementing Board of Commissioner approved strategic plans and budgets. In my capacity as

Chief Executive Officer, I am familiar with the impact that the clinic visit policy at issue in this lawsuit will have on OMC and its operations.

- 4. Olympic Medical Center is a comprehensive healthcare provider serving the North Olympic Peninsula with a network of facilities in Clallam County, Washington. OMC primarily serves the approximately 75,000 residents of Clallam County, Washington. It provides services to all patients regardless of ability or inability to pay and regardless of insurance status. Olympic Medical Center is a large rural hospital and healthcare center designated as a Sole Community Hospital and Rural Referral Center, and operates as a safety-net hospital, employing over 100 physicians and advanced practice clinicians. Of OMC's patients, 83% rely on Government-paid insurance and 58.3% rely on Medicare.
  - 5. Olympic Medical Center is a member of the American Hospital Association.
- 6. Olympic Medical Center has filed this lawsuit (along with its co-plaintiffs) challenging as *ultra vires* a payment reduction implemented by the Centers for Medicare & Medicaid Services (CMS) as part of the calendar year (CY) 2019 Medicare outpatient prospective payment system (OPPS) final rule (Final Rule).
- 7. Olympic Medical Center furnishes outpatient services at eight excepted off-campus provider-based departments (PBDs), including a specialty physician clinic offering cardiology, gastroenterology, pulmonary medicine, neurology, urology and women's health; a sleep center; a primary care clinic; a coagulation clinic; a walk-in clinic; a cancer center providing medical oncology services and radiation oncology services in Sequim, which is 17 miles from the main hospital campus; and a primary care clinic in Port Angeles, which is approximately one mile from the hospital. Olympic Medical Center will suffer immediate and concrete harm from the outpatient-services payment reductions set forth in the Final Rule.

- 8. Olympic Medical Center estimates that the clinic visit policy set forth in the Final Rule will cause OMC over \$1.6 million in lost revenue for CY 2019 alone. That lost revenue will impose further financial strain on OMC's already-thin operating margin. Olympic Medical Center's operating margin in 2018 was 0.3% (approximately \$681,000). In 2017, OMC experienced a loss of \$2.5 million (negative 1.4% margin).
- 9. The reductions in payments for covered Medicare-funded outpatient services
  OMC faces will have a significant impact, both economic and non-economic, on its operations,
  its patients and the greater community. For example, OMC was unable to add primary care
  access in Sequim despite receiving construction bids for a needed expansion to primary care
  clinic space on November 15, 2018. Due to the physician clinic reimbursement cuts, OMC was
  forced to cancel its construction project for the additional space and those needed primary care
  services will not be added in Sequim.
- 10. Because of the cancellation of the primary care construction for expanded space in Sequim, patients who are ill and suffering may be unable to obtain primary care close to home. A survey of Clallam County residents demonstrated that there are still approximately 10,000 residents who do not have a primary care provider. Those patients will go without medical services, be forced to use OMC's Emergency Department or must travel to urban areas such as Bremerton (3-4 hours of driving round trip) or Seattle (5-8 hours driving round trip via ferry) for primary care. In Clallam County, there are very few, it any physicians available who are accepting freestanding Medicare reimbursement rates.
- 11. OMC's primary care clinic in Port Angeles, located at 8<sup>th</sup> & Vine Street, is a medical home to 8,300 patients in Clallam County but is no longer financially viable due to its distance from OMC's hospital of more than 250 yards. OMC invested substantially in the

building at 8th & Vine Street but the Medicare physician clinic cuts render this investment a liability by jeopardizing the viability of the off-campus primary care clinic services at this location. Without primary care access and expanded services for those who need primary care, Clallam County will have more emergency department (ED) and inpatient utilization at OMC. With the reduced availability of primary care access and preventive services to Medicare enrollees, the consequence will be increased visits to OMC's hospital, poorer outcomes for patients, and a higher cost for CMS. The cut to the physician clinic expense reimbursement will prevent OMC from investing in wellness, prevention, and chronic disease management services to help reduce ED and inpatient utilization. This will undermine and potentially reverse the benefits of current highly effective and well-received measures by OMC such as partnering with our local YMCA facility to offer cardiac and pulmonary rehabilitation, smoking cessation classes, balance classes, diabetes education and other wellness services. Without a robust wellness/preventive care initiative and execution plan, OMC's efforts to keep patients from high ED and hospital utilization will fall short. Patients will suffer harm from less access, having to travel further for the needed care, experiencing worse health care outcomes.

- 12. Clallam County needs more Medicare hospice services including inpatient hospice; OMC submitted a Letter of Intent on a Certificate of Need for hospice services in November 2018. Without adequate Medicare physician clinic reimbursement, OMC's ability to expand services to meet the need for hospice care is in question. The community will suffer without these necessary hospice services.
- 13. The cuts have destabilized OMC's finances and caused immediate budget harm.

  In order to serve the growing population in Sequim and to serve the needs in Clallam County,

  OMC issued long-term debt of millions of dollars to pay to establish and maintain buildings and

facilities which meet hospital ambulatory standards. OMC's payments to its bank on the building debt will not decrease even though reimbursement will be reduced substantially due to the physician clinic cuts. OMC currently has \$60 million of long-term debt which must be repaid with interest over the coming decade-plus. The Medicare cuts have caused immediate harm to OMC's ability to reasonably repay long-term debt.

- 14. The cuts have, in addition, substantially harmed the community, and the impact to Clallam County's rural economy has been immediately felt. The schools in the Port Angeles and Sequim school district rely on the tax revenue of citizens and OMC is a key contributor to the local economy as the largest employer in the county. OMC provides more than 1,500 jobs to the local economy. OMC has been growing to meet the needs of the community, adding more than 200 jobs over the last two years, but the cuts significantly limit OMC's ability to meet community health care needs.
- 15. Vacating the clinic visit policy set forth in the Final Rule and ensuring that Medicare payments for outpatient services are made in line with Congress's intent would help remedy the harm Olympic Medical Center faces from CMS's unlawful conduct.
- 16. On January 2 and January 3, 2019, Olympic Medical Center submitted claims for excepted off-campus physician clinic visit services covered by the Final Rule to its Medicare Administrative Contractor. The Medicare Administrative Contractor responded to those claims on January 28, 2019. OMC filed a Medicare Redetermination Request on January 28, 2019. True and correct copies of these documents are attached as Exhibit A.

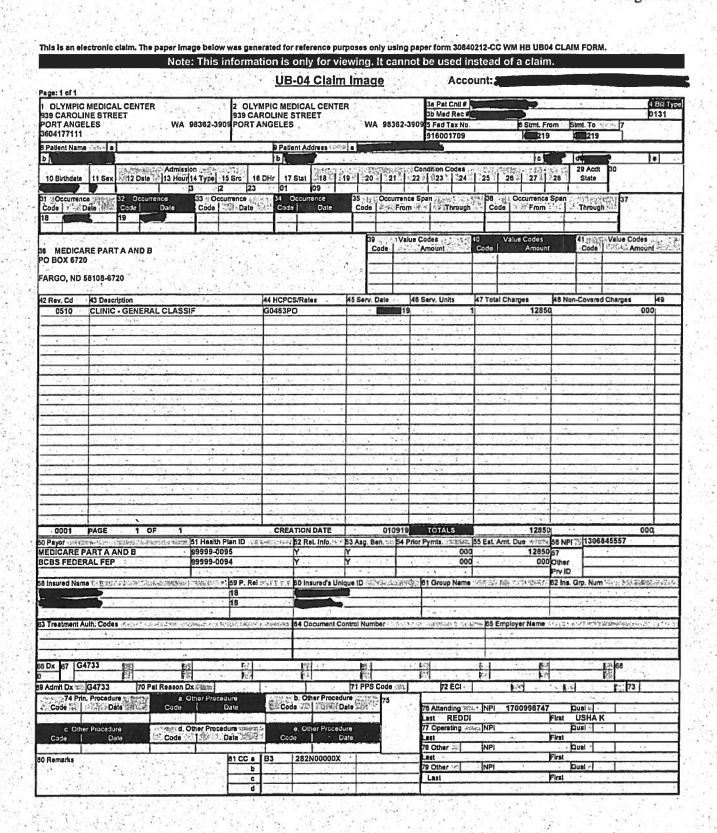
I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed this 29th day of January 2019.

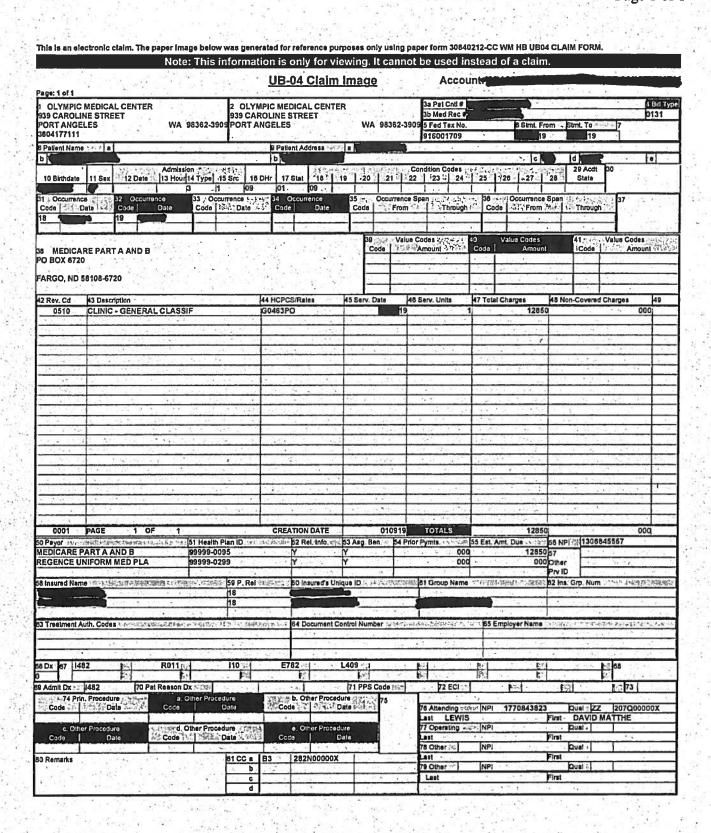
Eric Lewis, Chief Executive Officer Olympic Medical Center

## Exhibit A

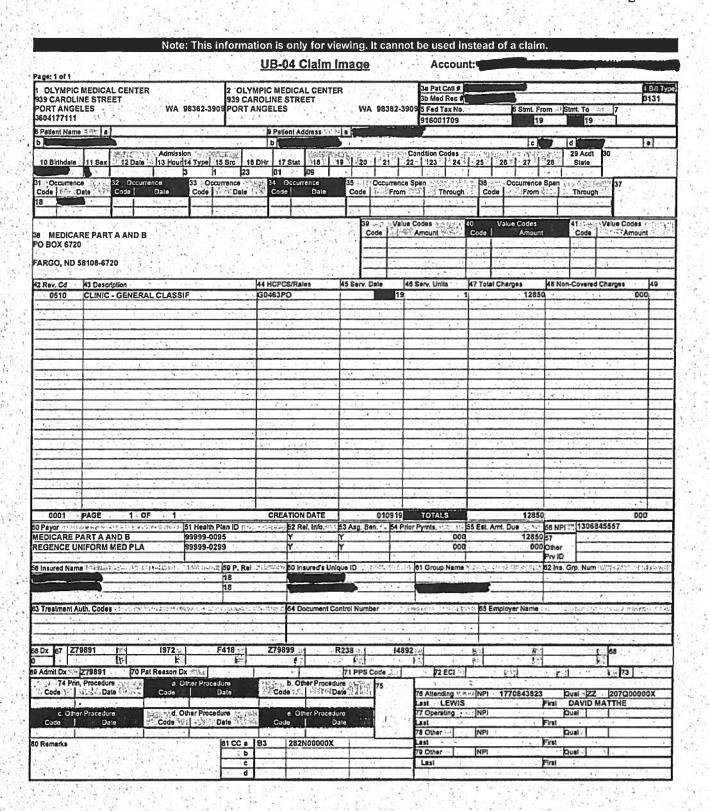
Page 1 of 1



Page 1 of 1



Page 1 of 1





Working together to provide excellence in health care.

939 Caroline Street ◆ Port Angeles, WA 98362 ◆ (360) 417-7000 ◆ www.olympicmedical.org

January 17, 2019

Noridian Healthcare Solutions Noridian JF 900 42nd St S PO Box 6720 Fargo, ND 58103-6720

Re: See representative Claim #1 – as indicated on the attached UB-04 Claim for G0463 procedure - Admit Dx G4733
Attending NPI 1700998747 Usha Reddi on 1/2/2019

### Greetings:

On Nov. 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and *ultra vires* because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The payment rate for the claimed services should be \$124.72.

Olympic Medical Center hereby demands the reimbursement level which was in effect before the above referenced rule change.

Because OMC submitted this claim last week and we have not received a remittance from Noridian yet, we don't have a claim number so we are applying a 'representative number' for reference only as indicated in the Subject line above.

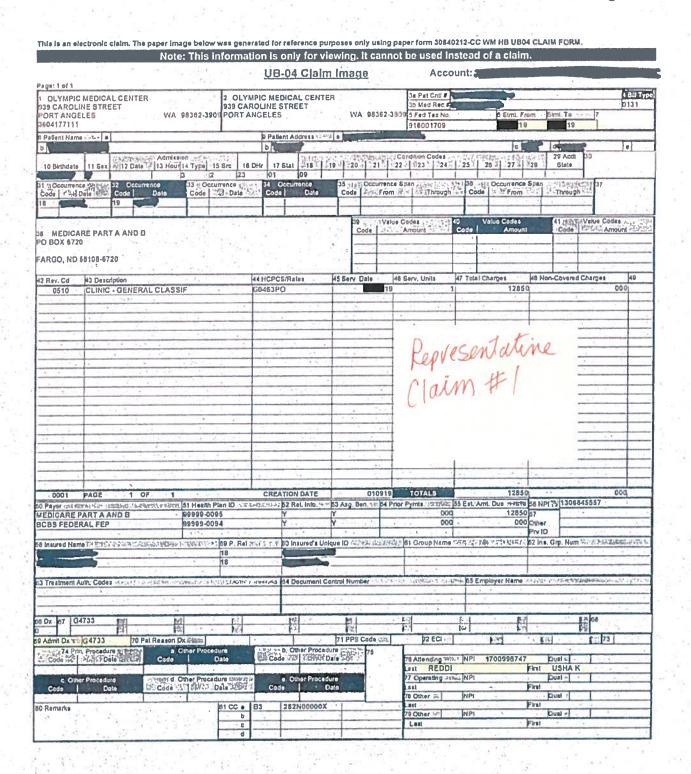
Sincerely,

Jennifer A. Burkhardt, JD WSBA #27437

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General Counsel, CHRO

Page 1 of 1





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939 Caroline Street ◆ Port Angeles, WA 98362 ◆ (360) 417-7000 ◆ www.olympicmedical.org

January 17, 2019

Noridian Healthcare Solutions Noridian JF 900 42nd St S PO Box 6720 Fargo, ND 58103-6720

> Re: See representative Claim #2 – as indicated on the attached UB-04 Claim for G0463 procedure - Admit Dx 1482 Attending NPI 1770843823 David Lewis MD on 1/2/2019

### Greetings:

On Nov. 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and *ultra vires* because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The payment rate for the claimed services should be \$124.72.

Olympic Medical Center hereby demands the reimbursement level which was in effect before the above referenced rule change.

Because OMC submitted this claim last week and we have not received a remittance from Noridian yet, we don't have a claim number so we are applying a 'representative number' for reference only as indicated in the Subject line above.

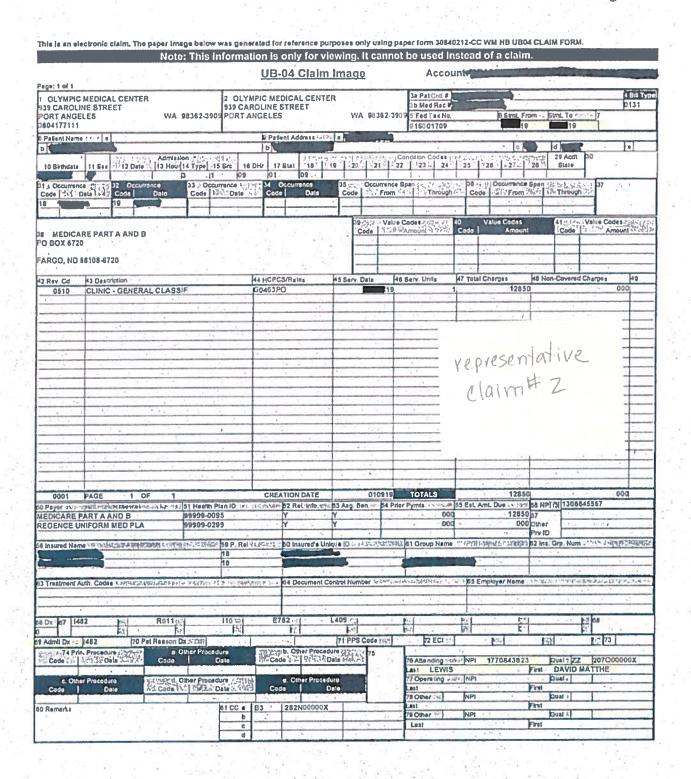
Sincerely,

Jennifer A. Burkhardt, JD WSBA #27437

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General Counsel, CHRO

Page 1 of 1





Working together to provide excellence in health care.

939 Caroline Street ◆ Port Angeles, WA 98362 ◆ (360) 417-7000 ◆ www.olympicmedical.org

January 17, 2019

Noridian Healthcare Solutions Noridian JF 900 42nd St S PO Box 6720 Fargo, ND 58103-6720

> Re: See representative Claim #3 —as indicated on the attached UB-04 Claim for G0463 procedure - Admit Dx Z79891 Attending NPI 1770843823 David Lewis MD on 1/2/2019

### Greetings:

On Nov. 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and *ultra vires* because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The payment rate for the claimed services should be \$124.72.

Olympic Medical Center hereby demands the reimbursement level which was in effect before the above referenced rule change.

Because OMC submitted this claim last week and we have not received a remittance from Noridian yet, we don't have a claim number so we are applying a 'representative number' for reference only as indicated in the Subject line above.

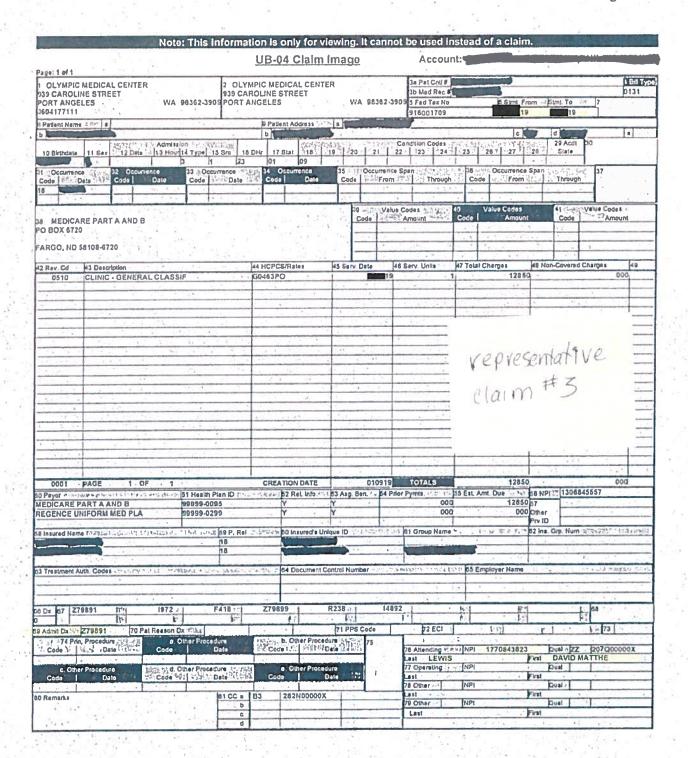
Sincerely,

Jennifer A. Burkhardt, JD WSBA #27437

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General Counsel, CHRO

Page 1 of 1



Remittance Advice Part A Response

<sup>1.</sup> For best results and full-screen printing, set your printing options to print in Landscape, 2. To print, select the printable version link and then print from your browser.

	DATE: TIME:
MEDICARE MEDA CLALLAM COUNTY PUBLIC HOSPITAL Single Claim Report	PAID DATE: 01/24/2019
Single C	TOB: 131
HOSPITAL	FYE:
M COUNTY PUBLIC!	Y PUBLIC HOSPITAL
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MEDICAF	130684555

PATIENT NAME	PATIENT CNTRL NUMBER		FRM DT COST	REPTD CHGS	DRG NBR	OUTLIER AM	T REIMB RATI	REPTD CHGS DRG NBR OUTLIER AMT REIMB RATE ALLOWED	INTEREST
25	Medicare Number	THR DT	COVD	COVD NCVD/DENIED DRG AMOUNT DEDUCT	DRG AMOUNT	r DEDUCT	MSP PRI PAY	MSP PRI PAY PROC CD AMT PAT REFUND	PAT REFUND
CLAIM # CLM STATU	CLAIM #JCLM STATUS MEDICAL REC NUMBER	R PATST		NCVDV CLAIM ADJS DRG O-C	DRG O-C	COINS	PROF COMP	PROF COMP LINE ADJ AMT PREDIEM AMT	PREDIEM AMT
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		72019 0	06	0.00	0.00	0.00	0.0	0.00	0.0
		10	0	0.0	0.0	17.76	0.0	0.0	0.0
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https://www.noridianmedicareportal.com/group/end-user/remittance?p\_auth=4ICXFsYT&p\_p\_id=remittanceadvices\_WAR\_N... 1/28/2019\_

Appeals - Noridian Medicare Portal

Page 1 of 2

Welcome Sarah Manage Account Message Center <sup>0</sup> Sig

Last Login on 1/28/2019 01:52 PM CST | Failed attempts: 0

Noridian Medicare Portal

# Home Contact Us O Help

eligibility or MBI Lookup

Claim Status

Appeals

Remittance Advices Financials

Same or Similar DME

Prior Authorizations Provider Audit Provider Enrollment

Step 1

Redetermination/ Reopening Details Step 2

Electronic Signature Step 3

Add Documents Step 4

Confirmation

## Reopening/Redetermination-Confirmation

Print Friendly

#### Attestation

The request was successfully submitted. Print a copy of this request and save it for your records. A full summary of the request will not be offered after leaving this page. A confirmation number will guarantee the most accurate inquiry results.

Confirmation Number: 1322240211

Status: Pending

Submitted: 01/28/2019

Provider/Supplier: CLALLAM COUNTY PUBLIC HOSPITAL

NPI: 1306845557 PTAN: 500072

TIN or SSN: 916001709

Medicare Contract: MEDA

Receipt Date: 01/10/2019

MSP Ind: N

Crossover Ind: Y

Last Worked Date:

Check/EFT #:

Beneficiary:

Gender:

DOB:

Medicare Number:

ICN: 21900300463504WAA

Status: PAID

Billed Amount: 128.50

Finalized Date: 01/23/2019

Provider/Supplier Paid Amount: 69.60

Speciality:

**Total Deductible:** 

#### Comments:

On November 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Federal Register 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and ultra vires. The payment reduction for clinic visit services furnished at excepted off-campus PBDs is unlawful and ultra vires because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The payment rate allowed amount for the claimed services should be \$124.79 and we are therefore demanding additional payment of \$37,43.

Line	From DOS	To DOS	HCPCS	Modifier	Diagnosis Code	Billed Amount	
1	/2019	/2019	G0463	PO		128.50	

https://www.noridianmedicareportal.com/group/end-user/appeals/-/appeals/redeterminatio...

1/28/2019

## Appeals - Noridian Medicare Portal

Page 2 of 2

#### Added Documentation

Add Document

Document Name	Date Submitted	View
INITIAL DETERMINATION	01/28/2019	View Document
Original Submission	01/28/2019	View Document

Contact Us | Portal Feedback | Alerts & Notices | System Requirements | Download Adobe



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# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Defendant.	) ) ) )
ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,	) ) )
V	) Civil Action No. 1:18-cv-2841
Plaintiffs,	)
and YORK HOSPITAL,	)
CLALLAM COUNTY PUBLIC HOSPITAL NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER,	)
COLLEGES, MERCY HEALTH MUSKEGON,	)
THE AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL	)

# DECLARATION OF JUD KNOX IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I, Jud Knox, hereby declare and state the following:

- 1. My name is Jud Knox. 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 York, Maine.
- 2. The facts set forth in this declaration are based on my personal knowledge and upon information available to me through the files and records of York Hospital. If called upon as a witness, I could and would testify to these facts.
- 3. I am the President of York Hospital. I have served in this capacity since 1982. In this role, I am responsible for the performance of the entire organization. In my capacity as President, I am familiar with the impact that the clinic visit policy at issue in this lawsuit will have on York Hospital and its operations.

- 4. York Hospital is a small community hospital located in York, Maine that serves the surrounding area and has 50 beds in operation. Founded in 1906, York is dedicated to giving back to its community: among other things, it provides support programs and services to schools, civic organizations, and non-profit groups, runs an opiate treatment facility, and offers transportation and food to patients unable to afford them. Of York's patients, almost 54% rely on Medicare. York Hospital is a member of the American Hospital Association.
- 5. York Hospital has filed this lawsuit (along with its co-plaintiffs) challenging as ultra vires a payment reduction implemented by the Centers for Medicare & Medicaid Services (CMS) as part of the calendar year (CY) 2019 Medicare outpatient prospective payment system (OPPS) final rule (Final Rule).
- 6. York Hospital furnishes outpatient services at 12 excepted off-campus provider-based departments (PBDs), including three oncology clinics, four primary care practices and specialty clinics offering psychiatry, cardiovascular care, internal medicine and GYN care. York will suffer immediate and concrete harm from the payment reductions for covered outpatient services set forth in the Final Rule.
- 7. The ultimate reductions in payments for Medicare-funded outpatient services
  York Hospital faces will have a substantial impact, both economic and non-economic, on its
  operations and its patients and the greater community. Specifically, York Hospital estimates that
  the clinic visit policy set forth in the Final Rule will cause it to suffer a \$1.1 million annual loss,
  or a .6 percent annual reduction in operating revenue.
- 8. Vacating the clinic visit policy portion of the Final Rule and ensuring that

  Medicare payments for off-campus provider based department outpatient services are made in

line with Congress's intent would help remedy the harm York Hospital faces from CMS's unlawful conduct.

9. On January 7, 2019, York Hospital submitted claims for excepted off-campus physician clinic visit services covered by the Final Rule to its Medicare Administrative Contractor. The Medicare Administrative Contractor responded to those claims on January 22, 2019. York Hospital filed a Medicare Redetermination Request on January 25, 2019. True and correct copies of these documents are attached as Exhibit A.

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

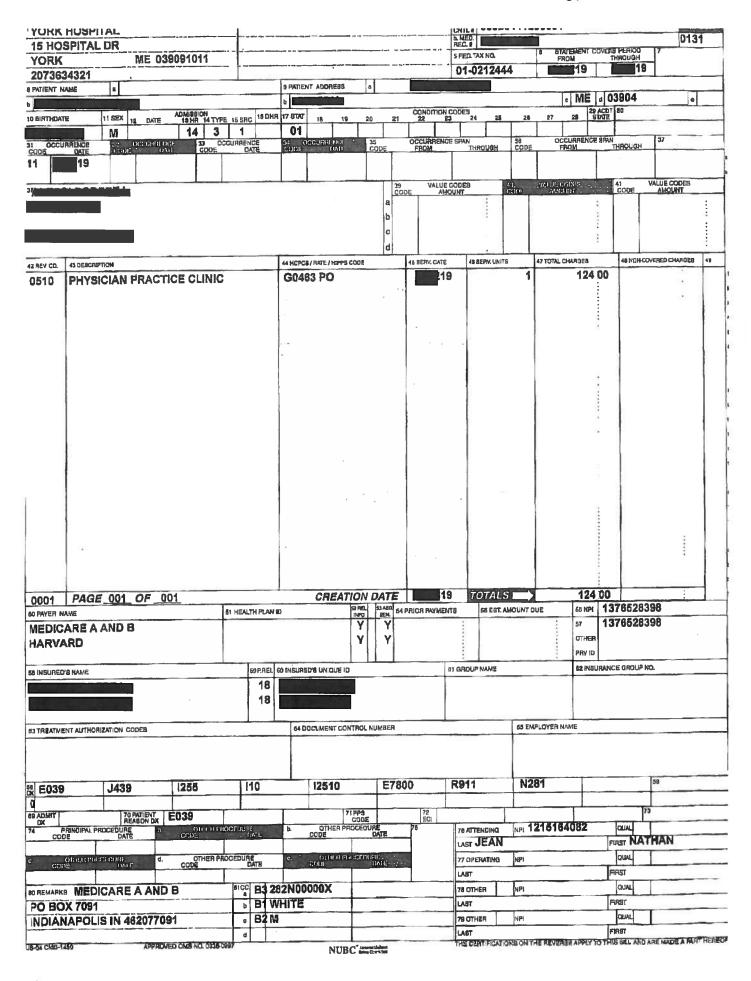
Executed this 28 day of January 2019.

3y: \_\_\_\_

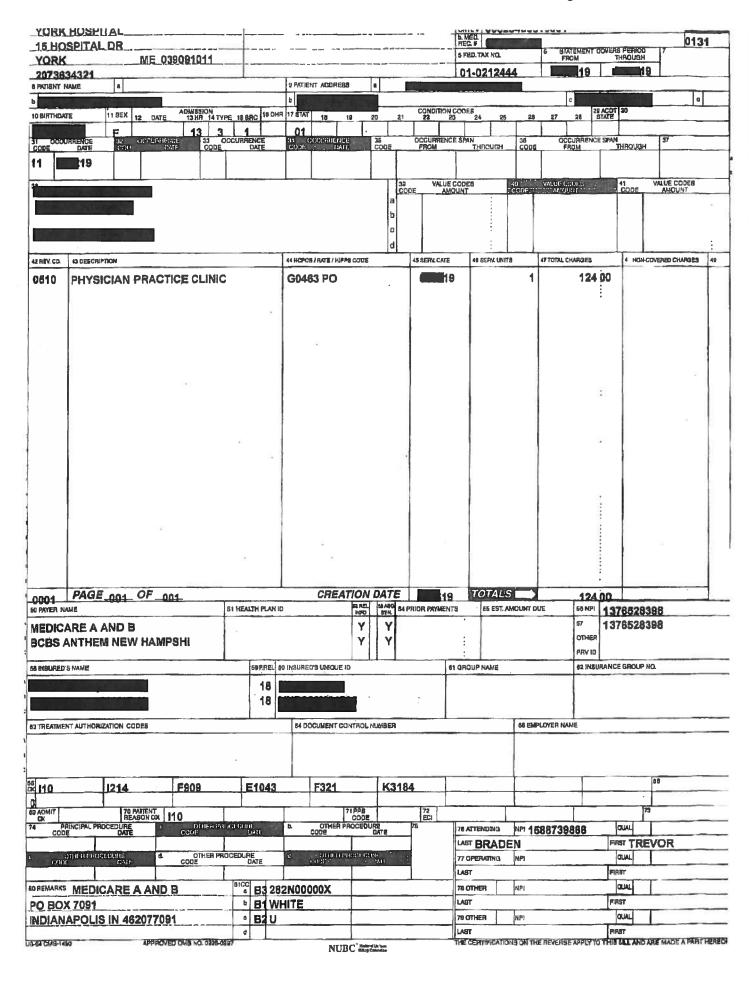
President

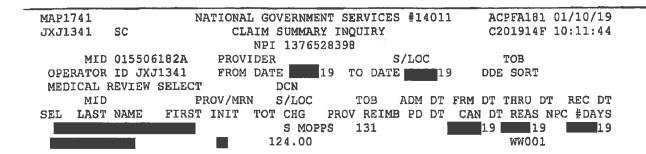
York Hospital

## Exhibit A



MAP1716 PAGE 06 NATIONAL GOVERNMENT SERVICES #14011 ACPFA181 01/21/19 SHN1844 SC INST CLAIM INQUIRY A20191AP 11:28:46 MID TOB 131 S/LOC P B9997 PROVIDER 200020 MSP ADDITIONAL INSURER INFORMATION 1ST INSURERS ADDRESS 1 1ST INSURERS ADDRESS 2 CITY ST ZIP 2ND INSURERS ADDRESS 1 2ND INSURERS ADDRESS 2 CITY ST PAYMENT DATA --- DEDUCTIBLE (82.87) COIN CROSSOVER IND 1 PARTNER ID 000030317 P 000000060 P PAID DATE 012219 PROVIDER PAYMENT .00 PAID BY PATIENT REIMB RATE .36 RECEIPT DATE 010819 PROVIDER INTEREST CHECK/EFT NO EFT1118593 CHECK/EFT ISSUE DATE 012219 PAYMENT CODE ACH PRICER DATA PIP PAY AS CASH HOSPICE PRIOR DYS OUTLIER AMT TTL BLNDED PAYMT FED SPEC GRAMM RUDMAN ORIG REIMBURSEMENT AMT .00 NET INL TECH PROV DAYS TECH PROV CHARGES OTHER INS ID CLINIC CODE 37190 < == REASON CODES PRESS PF3-EXIT PF7-PREV PAGE

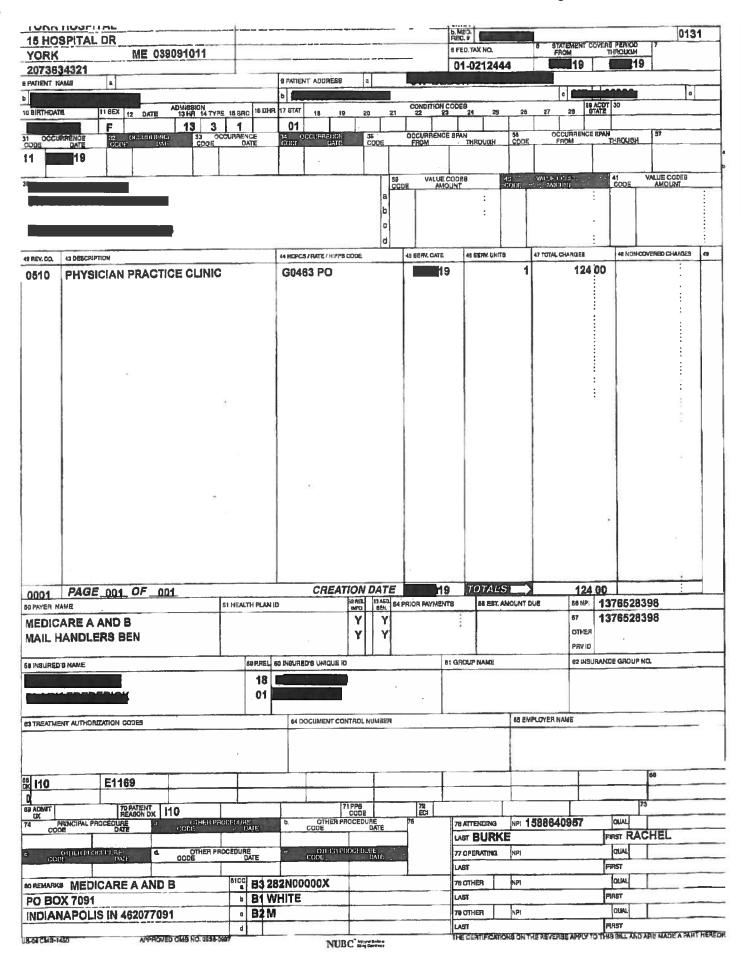




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MAP1716 PAGE 06 NATIONAL GOVERNMENT SERVICES #14011 ACPFA181 01/21/19 SHN1844 SC INST CLAIM INQUIRY A20191AP 11:24:35 TOB 131 S/LOC P B9997 PROVIDER 200020 MID MSP ADDITIONAL INSURER INFORMATION 1ST INSURERS ADDRESS 1 1ST INSURERS ADDRESS 2 CITY ST ZIP 2ND INSURERS ADDRESS 1 2ND INSURERS ADDRESS 2 CITY ZIP PAYMENT DATA --- DEDUCTIBLE COIN CROSSOVER IND 1 PARTNER ID 000000565 P PAID DATE 012219 PROVIDER PAYMENT .00 PAID BY REIMB RATE .36 RECEIPT DATE 010819 PROVIDER INTEREST PAID BY PATIENT CHECK/EFT NO EFT1118593 CHECK/EFT ISSUE DATE 012219 PAYMENT CODE ACH PIP PAY AS CASH PRICER DATA HOSPICE PRIOR DYS TTL BLNDED PAYMT OUTLIER AMT GRAMM RUDMAN ORIG REIMBURSEMENT AMT .00 NET INL TECH PROV DAYS TECH PROV CHARGES OTHER INS ID CLINIC CODE 37190 < == REASON CODES PRESS PF3-EXIT PF7-PREV PAGE





January 17, 2019

National Government Services Attn: Appeals Department P. O. Box 7111 Indianapolis, IN 46207-7111

To Whom It May Concern:

On November 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59-004-15), the payment reduction exceeds the ultra vires because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The APC Wage Adjusted payment rate, for the claimed services for York Hospital Provider Number 20-0020, should be \$118.38 effective for dates of service beginning 1/1/2019.

Sincerely,

Robin LaBonte, CFO

15 Hospital Drive, York, Maine 03909 Information: 207-363-4321 Toll Free: 877

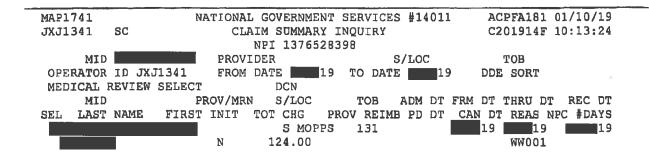
www.yorkhospital.com

Toll Free: 877-363-4321 TTY: 207-363-7433

MAP1716 PAGE 06 NATIONAL GOVERNMENT SERVICES #14011 ACPFA181 01/21/19 SHN1844 SC INST CLAIM INQUIRY A20191AP 11:25:48 TOB 131 S/LOC P B9997 PROVIDER 200020 MSP ADDITIONAL INSURER INFORMATION 1ST INSURERS ADDRESS 1 1ST INSURERS ADDRESS 2 CITY ST ZIP 2ND INSURERS ADDRESS 1 2ND INSURERS ADDRESS 2 CITY ST ZIP PAYMENT DATA --- DEDUCTIBLE COIN 82.87 CROSSOVER IND 1 PARTNER ID 000000060 P PAID DATE 012219 PROVIDER PAYMENT .00 PAID BY PATIENT REIMB RATE .36 RECEIPT DATE 010819 PROVIDER INTEREST CHECK/EFT NO EFT1118593 CHECK/EFT ISSUE DATE 012219 PAYMENT CODE ACH PRICER DATA PIP PAY AS CASH HOSPICE PRIOR DYS DRG OUTLIER AMT TTL BLNDED PAYMT FED SPEC GRAMM RUDMAN ORIG REIMBURSEMENT AMT .00 NET INL TECH PROV DAYS TECH PROV CHARGES OTHER INS ID CLINIC CODE 37190 < == REASON CODES PRESS PF3-EXIT PF7-PREV PAGE

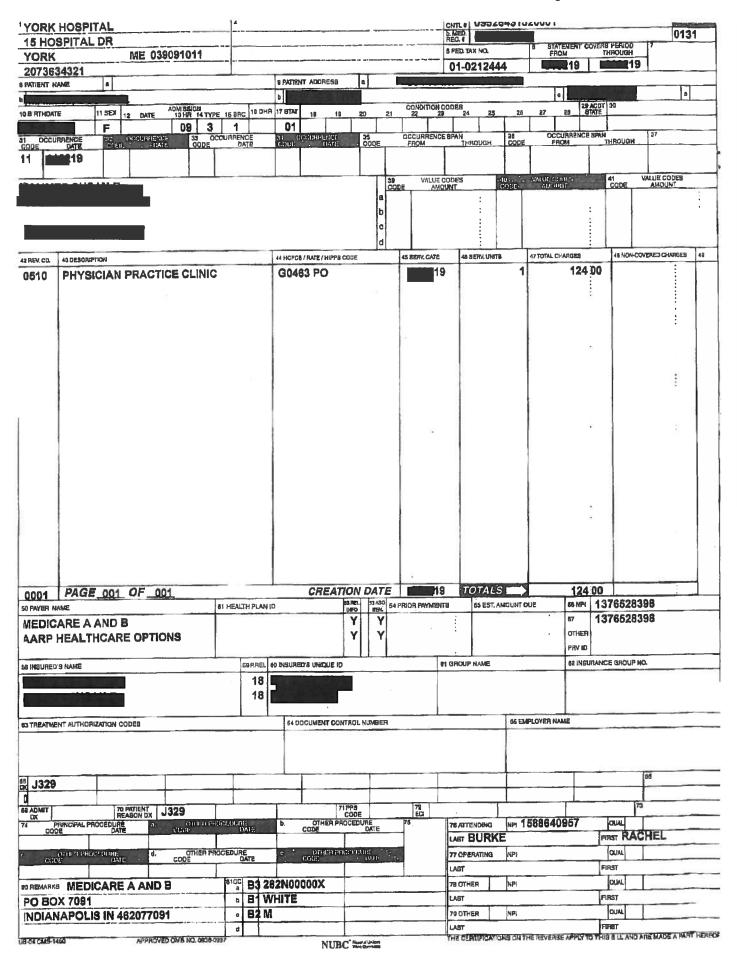
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Claim Remarks

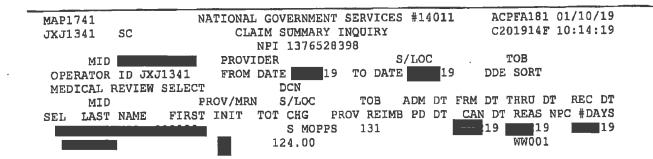


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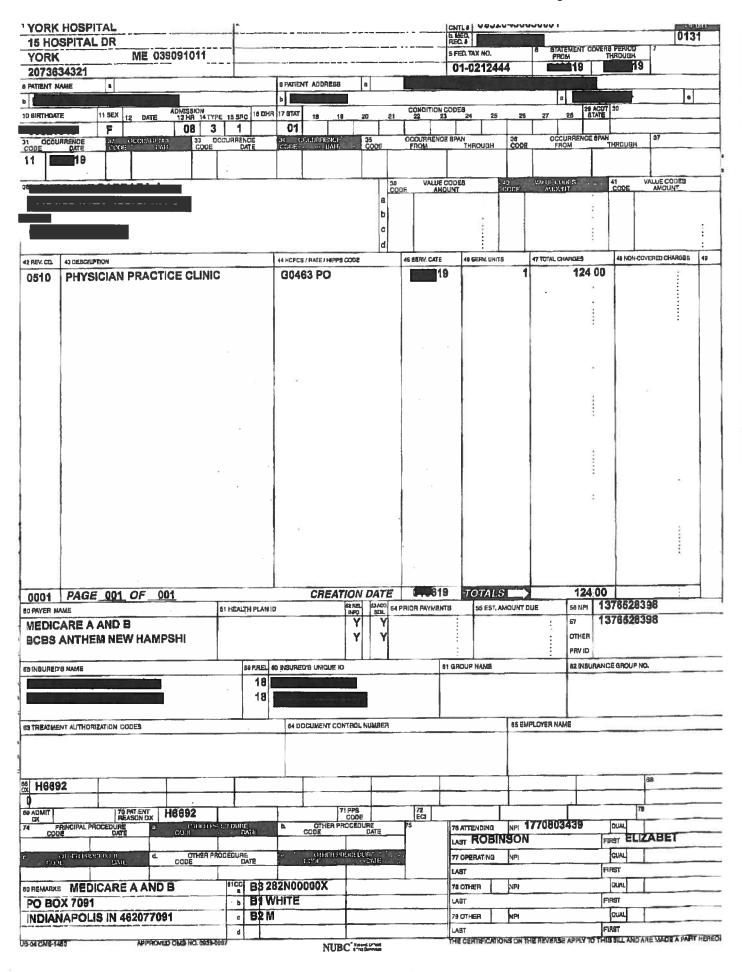
MAP1716 PAGE 06 NATIONAL GOVERNMENT SERVICES #14011 SHN1844 SC INST CLAIM INQUIRY ACPFA181 01/21/19 A20191AP 11:26:33 TOB 131 S/LOC P B9997 PROVIDER 200020 MSP ADDITIONAL INSURER INFORMATION 1ST INSURERS ADDRESS 1 1ST INSURERS ADDRESS 2 CITY ST ZIP 2ND INSURERS ADDRESS 1 2ND INSURERS ADDRESS 2 CITY ST ZIP PAYMENT DATA --- DEDUCTIBLE 82.87 COIN CROSSOVER IND PARTNER ID PAID DATE 012219 PROVIDER PAYMENT .00 PAID BY PATIENT REIMB RATE .36 RECEIPT DATE 010819 PROVIDER INTEREST CHECK/EFT NO EFT1118593 CHECK/EFT ISSUE DATE 012219 PAYMENT CODE ACH PRICER DATA HOSPICE PRIOR DYS PIP PAY AS CASH DRG OUTLIER AMT TTL BLNDED PAYMT .00 NET INL GRAMM RUDMAN ORIG REIMBURSEMENT AMT TECH PROV DAYS TECH PROV CHARGES OTHER INS ID CLINIC CODE 37190 < == REASON CODES PRESS PF3-EXIT PF7-PREV PAGE



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MAP1716 PAGE 06 NATIONAL GOVERNMENT SERVICES #14011 ACPFA181 01/21/19 A20191AP 11:31:25 INST CLAIM INQUIRY SHN1844 SC MID TOB 131 S/LOC P B9997 PROVIDER 200020 MSP ADDITIONAL INSURER INFORMATION 1ST INSURERS ADDRESS 1 1ST INSURERS ADDRESS 2 ST ZIP CITY 2ND INSURERS ADDRESS 1 2ND INSURERS ADDRESS 2 ST ZIP CITY PAYMENT DATA --- DEDUCTIBLE 82.87 COIN CROSSOVER IND 1 PARTNER ID 000030067 P .00 PAID BY PATIENT PAID DATE 012219 PROVIDER PAYMENT REIMB RATE .36 RECEIPT DATE 010719 PROVIDER INTEREST CHECK/EFT NO EFT1118593 CHECK/EFT ISSUE DATE 012219 PAYMENT CODE ACH HOSPICE PRIOR DYS PIP PAY AS CASH PRICER DATA TTL BLNDED PAYMT OUTLIER AMT FED SPEC GRAMM RUDMAN ORIG REIMBURSEMENT AMT .00 NET INL TECH PROV DAYS TECH PROV CHARGES OTHER INS ID CLINIC CODE < == REASON CODES 37190 PRESS PF3-EXIT PF7-PREV PAGE

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· TPTP A	В	NPCD A	B	 CPY F		NB	ADR	CAL DY	C/L C

THIS IS A TEMPORARY EDIT TO SUSPEND ALL CLAIMS WITH STATEMENT THRU DATE GREATER THAN 12/31/18.
NO PROVIDER ACTION IS NECESSARY.

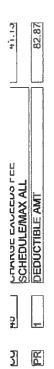
PROCESS COMPLETED --- NO MORE DATA THIS TYPE PRESS PF3-EXIT PF6-SCROLL FWD PF8-NEXT

Remittance Header												
Remittance ID: MEDA		MEDICARE PARTA		Provi	Provider Group:	MEDICARE PARTA	E PARTA			Today's Date:	01/25/2019 09:39	
Provider Number: 1376528398	28398	YORK HOSPITAL		Payo	Payor Name:	NATIONAL	NATIONAL GOVERNMENT SERVICES, INC.	IT SERVICES,	NC.	Fage:	1 of 2	
File Creation Date: 01/19/2019 Payment Date: 01/22/2019	2019			File (	File Control Number: 116300427	r. 116300427						
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Plan ID: MEDICARE		MEDICARE A & B		Clair	Claim End Date	2019		Claim Received Date:				
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			Total Billed	Cov Chgs	Non-Cov	Rejected	Deductible	Co-Ins	Cont Adj Pa	Cont Adj Paid Amount	Prof Comp	Interest
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	MEDICARE REDETERMINATION REQUEST FORM — 1 <sup>ST</sup> LEVEL OF APPEAL
1.	Beneficiary's name:
2.	Medicare number:
3.	Item or service you wish to appeal: GO463
4.	Date the service or item was received
5.	Date of the initial determination notice (please include a copy of the notice with this request): (If you received your initial determination notice more than 120 days ago, include your reason for the late filing.)  1/22/2019
5	
	5a. Name of the Medicare contractor that made the determination (not required):  NATIONAL GOVERNMENT SERVICES
	5b. Does this appeal involve an overpayment? ☐ Yes ☒ No (for providers and suppliers only)
6.	I do not agree with the determination decision on my claim because:  On Nov. 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and ultra vires.
7.	Additional information Medicare should consider:  The payment reduction for clinic visit services furnished at excepted off-campus PBDs is unlawful and ultra vires because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The wage adjusted payment rate for the claimed services should be \$118.38.
	payment rate for the claimed services should be \$110.50.
8.	<ul> <li>☐ I have evidence to submit. Please attach the evidence to this form or attach a statement explaining what you intend to submit and when you intend to submit it. You may also submit additional evidence at a later time, but all evidence must be received prior to the issuance of the redetermination.</li> <li>☒ I do not have evidence to submit.</li> </ul>
9.	The state of the s
10.	Name, address, and telephone number of person appealing: LINDA DICKSON, YORK HOSPITAL 15 HOSPITAL DRIVE, YORK MAINE, 03909 207-351-2380
11	Signature of person appealing:
12.	1/25/2019
PRIV infor	ACY ACT STATEMENT: The legal authority for the collection of information on this form is authorized by section 1869 (a)(3) of the Social Security Act. The mation provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Centers for Medicare Medicaid Services to another person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies. Additional information about

these disclosures can be found in the system of records notice for system no. 09-70-0566, as amended, available at 71 Fed. Reg. 54489 (2006) or at http://www.cms.gov/PrivacyActSystemofRecords/downloads/0566.pdf

-Remittance Header-												
Remittance ID:	MEDA	MEDICARE PART A	A	Pro	Provider Group:	MEDICAL	MEDICARE PART A		ļ	Today's Date:	01/25/2019 14:54	4:54
Provider Number:	1376528398	YORK HOSPITAL		Ра	Payor Name:	NATIONA	NATIONAL GOVERNMENT SERVICES, INC.	NT SERVICE	S, INC.	Page:	1 of 2	
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	MEDICARE REDETERMINATION REQUEST FORM — 1 <sup>ST</sup> LEVEL OF APPEAL
1.	Beneficiary's name:
2.	Medicare number:
3.	Item or service you wish to appeal: GO463
	Date the service or item was received:
5.	Date of the initial determination notice (please include a copy of the notice with this request): (If you received your initial determination notice more than I20 days ago, include your reason for the late filing.)  1/22/2019
	5a. Name of the Medicare contractor that made the determination (not required):  NATIONAL GOVERNMENT SERVICES
	5b. Does this appeal involve an overpayment? ☐ Yes ☒ No (for providers and suppliers only)
6.	I do not agree with the determination decision on my claim because:  On Nov. 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and ultra vires.
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8.	<ul> <li>I have evidence to submit. Please attach the evidence to this form or attach a statement explaining what you intend to submit and when you intend to submit it. You may also submit additional evidence at a later time, but all evidence must be received prior to the issuance of the redetermination.</li> <li>✓ I do not have evidence to submit.</li> </ul>
9.	Person appealing:   Beneficiary   Provider/Supplier   Representative
10.	Name, address, and telephone number of person appealing: LINDA DICKSON, YORK HOSPITAL 15 HOSPITAL DRIVE, YORK MAINE, 03909 207-351-2380
11.	Signature of person appealing:
12.	Date signed: 1/25/2019
PRIV infor any p and i the d these	ACY ACT STATEMENT: The legal authority for the collection of information on this form is authorized by section 1869 (a)(3) of the Social Security Act. The mation provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Centers for Medicare Medicaid Services to another person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting isclosure of information or the exchange of information between the Department of Health and Human Services and other agencies. Additional information about disclosures can be found in the system of records notice for system no. 09-70-0566, as amended, available at 71 Fed. Reg. 54489 (2006) or at //www.cms.gov/PrivacyActSystemofRecords/downloads/0566.pdf

-Remittance Header—			8									
Remittance ID:	MED A	MEDICARE PART A	PARTA	Prov	Provider Group:	MEDICARE PART A	PARTA		$\neg$ [	Today's Date:	01/25/2019 14:51	
er	1376528398	YORK HOSPITAL	PITAL	Payo	Payor Name:	NATIONAL	NATIONAL GOVERNMENT SERVICES, INC.	NT SERVICE	S, INC.	Page:	1 of 2	
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	MEDICARE REDETERMINATION REQUEST FORM — 1 <sup>ST</sup> LEVEL OF APPEAL
1.	Beneficiary's name:
2.	Medicare number:
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9.	Person appealing:   Beneficiary Provider/Supplier Representative
10.	Name, address, and telephone number of person appealing: LINDA DICKSON, YORK HOSPITAL 15 HOSPITAL DRIVE, YORK MAINE, 03909 207-351-2380
11.	Signature of person appealing:
	Date signed: 1/25/2019
PRIV infor any j and i the d	ACY ACT STATEMENT: The legal authority for the collection of information on this form is authorized by section 1869 (a)(3) of the Social Security Act. The mation provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Centers for Medicare Medicaid Services to another person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies. Additional information about a disclosures can be found in the system of records notice for system no. 09-70-0566, as amended, available at 71 Fed. Reg. 54489 (2006) or at //www.cms.gov/PrivacyActSystemofRecords/downloads/0566.pdf

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	Signature of person appealing:  Date signed: 1/25/2019
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Remittance Header-Remittance ID: Provider Number: File Creation Date: Payment Date:	MED A MEDICARE PART A 1376528398 YORK HOSPITAL 01/19/2019	PART A PITAL	Provi	Provider Group: MEDICARE Payor Name: NATIONAL File Control Number: 116300427	MEDICARE PART A NATIONAL GOVERI	MEDICARE PART A NATIONAL GOVERNMENT SERVICES, INC. 116300427	NT SERVICES		day's Date: Page:	Today's Date: 01/25/2019 14:55 Page: 1 of 2	55
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	15 HOSPITAL DRIVE, YORK MAINE, 03909 207-351-2380
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Remittance Header												
Remittance ID:	MEDA	MEDICARE PART A	ТА	Prov	Provider Group:	MEDICARE PARTA	PARTA			Today's Date: (	01/25/2019 14:56	 190
Provider Number:	1376528398	YORK HOSPITAL		Payo	Payor Name:	NATIONAL	NATIONAL GOVERNMENT SERVICES, INC.	IT SERVICES	, INC.	Page:	1 of 2	
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PR

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, MERCY HEALTH MUSKEGON, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER,	) ) ) )	
and YORK HOSPITAL,	)	
Plaintiffs,	) )	
v.	)	Civil Action No. 1:18-cv-2841
ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Defendant.	) _) _)	

## DECLARATION OF KRISTI K. NAGENGAST IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

- I, Kristi K. Nagengast, hereby declare and state the following:
- 1. My name is Kristi K. Nagengast. 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 Muskegon, Michigan.
- 2. The facts set forth in this declaration are based on my personal knowledge and upon information available to me through the files and records of Mercy Health Muskegon. If called upon as a witness, I could and would testify to these facts.
- 3. I am the Vice President of Finance for Mercy Health Muskegon. In this role, I am responsible for providing financial oversight and leadership to Mercy Health Muskegon. In my

capacity as Vice President of Finance, I am familiar with the impact that the clinic visit policy at issue in this lawsuit will have on Mercy Health Muskegon and its operations.

- 4. Mercy Health Muskegon is a Catholic nonprofit hospital that serves the greater Muskegon, Michigan area and surrounding communities. It is a teaching hospital, with more than 4,000 colleagues, and has 19,000 inpatient discharges and approximately 150,000 emergency or urgent care visits each year. Mercy Health Muskegon is a member of the American Hospital Association.
- 5. Mercy Health Muskegon has filed this lawsuit (along with its co-plaintiffs) challenging as *ultra vires* a payment reduction implemented by the Centers for Medicare & Medicaid Services (CMS) as part of the calendar year (CY) 2019 Medicare outpatient prospective payment system (OPPS) final rule (Final Rule).
- 6. Mercy Health Muskegon operates 27 off-campus PBDs, 25 of which are "excepted" off-campus PBDs. These include a sleep center, a comprehensive breast high-risk clinic, specialty clinics (including neurosurgery, cardiology, geriatrics, and gastroenterology clinics), and a number of primary care facilities capable of providing x-ray, laboratory, and pharmacy services in the same building. Mercy Health Muskegon furnishes outpatient services at these excepted off-campus PBDs and will suffer immediate and concrete harm from the outpatient-services payment reductions set forth in the Final Rule.
- 7. The ultimate reductions in payments for covered Medicare-funded outpatient services Mercy Health Muskegon faces will have a significant impact, both economic and non-economic, on its operations, its patients and the greater community. Mercy Health Muskegon estimates that the clinic visit policy set forth in the Final Rule will cause it to suffer a \$1.8

million annual loss the first year, and a \$3.6 million annual loss in future years. This equates to a 6% reduction in annual operating income the first year and a 12% reduction in future years.

- 8. Mercy Health Muskegon serves a community with substantial needs, and it does so while managing a challenging payor mix that is approximately 46% Medicare, 35% commercial, and 18% Medicaid, at the impacted PBD sites. Reduced payments for services provided to Medicare covered patients could impact Mercy Health Muskegon's ability to offer services and fund service lines which are particularly challenging to maintain from a financial perspective but are critically needed in our community, such as pain management, inpatient behavioral health, and the Muskegon Community Health Project (Health Project), the community health and well-being arm of Mercy Health Muskegon. This nationally recognized program does community-based work such as connecting patients and families to critically needed health and social support programs that address the social determinants of health such as housing, transportation, food security and safety. It also focuses on prevention work and supports the reductions of reoccurring health issues and readmissions for vulnerable patients. In 2019, the Health Project will require more than \$3 million in direct investment from Mercy Health Muskegon in order to continue operating at its current levels.
- 9. Vacating the clinic visit policy contained in the Final Rule and ensuring that Medicare payments for outpatient services are made in line with Congress's intent would help remedy the harm Mercy Health Muskegon faces from CMS's unlawful conduct.
- 10. On January 22, 2019, Mercy Health Muskegon submitted claims for excepted off-campus physician clinic visit services covered by the Final Rule to its Medicare Administrative Contractor. The Medicare Administrative Contractor has not responded to those claims yet.
  - 11. True and correct copies of these documents are attached as Exhibit A.

#### Case 1:18-cv-02841-RMC Document 14-6 Filed 02/01/19 Page 4 of 13

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

Executed this 25day of January 2019.

Kristi K. Nagengast, Vice President, Finance

Mercy Health Muskegon

### Exhibit A



January 22, 2018

Medicare AMI: WPS PBB PO Box 8800 Marion, IL 62959-0800

RE: Claim For Services -

Tax ID #38-2589966

Dear Provider Services:

On Nov. 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and *ultra vires* because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The payment rate for the claimed services should be \$456.47.

Sincerely,

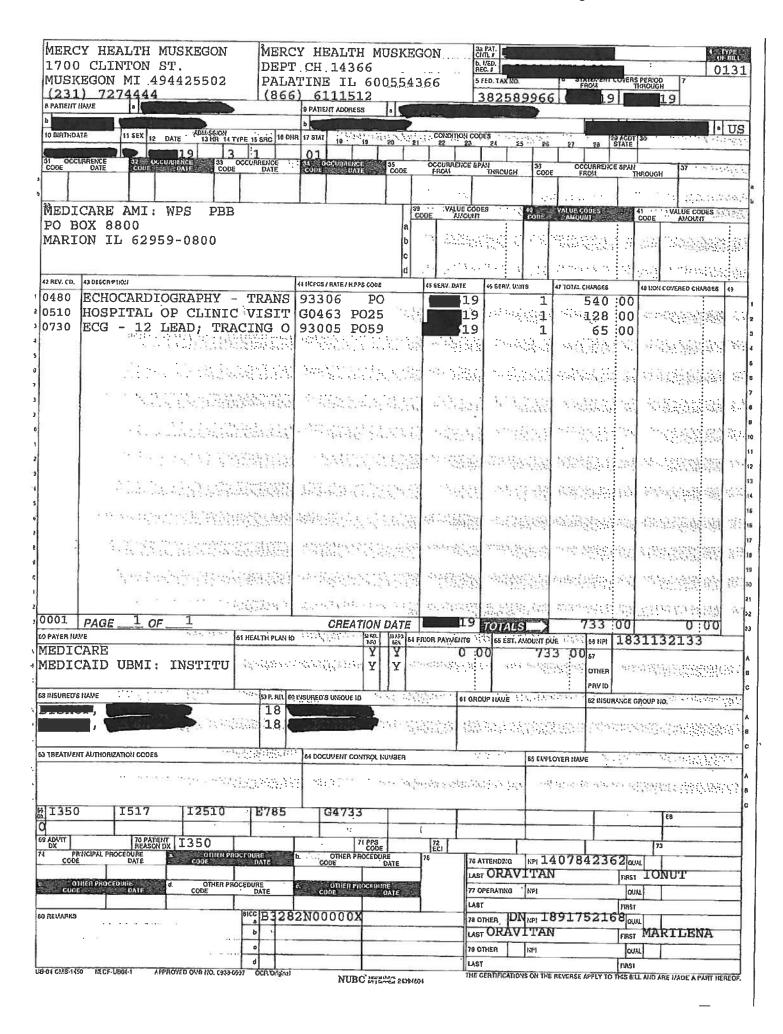
Michelle Lohman, Regional Director, Physician Revenue Cycle

Mercy Health

Cc:

Kristi K. Nagengast, Vice President Finance

Randall M. Smith, General Counsel





January 22, 2018

Medicare AMI: WPS PBB PO BOX 8800 Marion, IL 62959-0800

RE: Claim For Services -

Claim #

Tax ID #38-2589966

Dear Provider Services:

On Nov. 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and *ultra vires* because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The payment rate for the claimed services should be \$86.44.

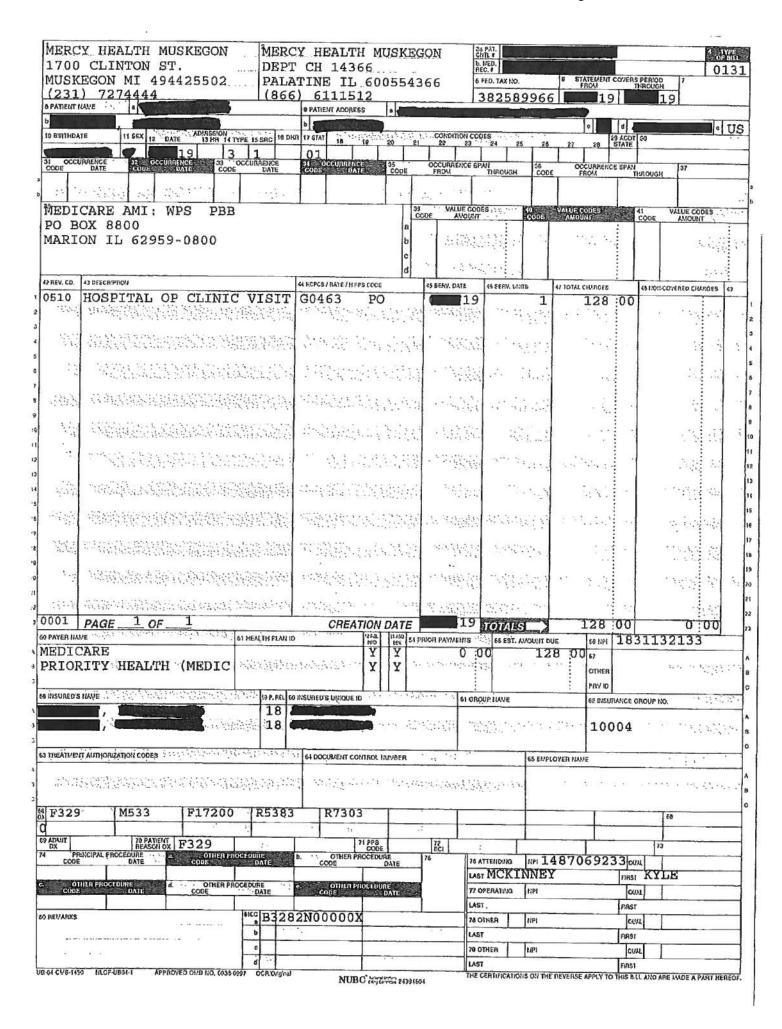
Sincerely,

Michelle Lohman Regional Director, Physician Revenue Cycle

Mercy Health

Cc: Kristi K. Nagengast, Vice President Finance

Randall M. Smith, General Counsel





January 22, 2018

Medicare AMI: WPS PBB PO Box 8800 Marion, IL 62959-0800

Dear Provider Services:

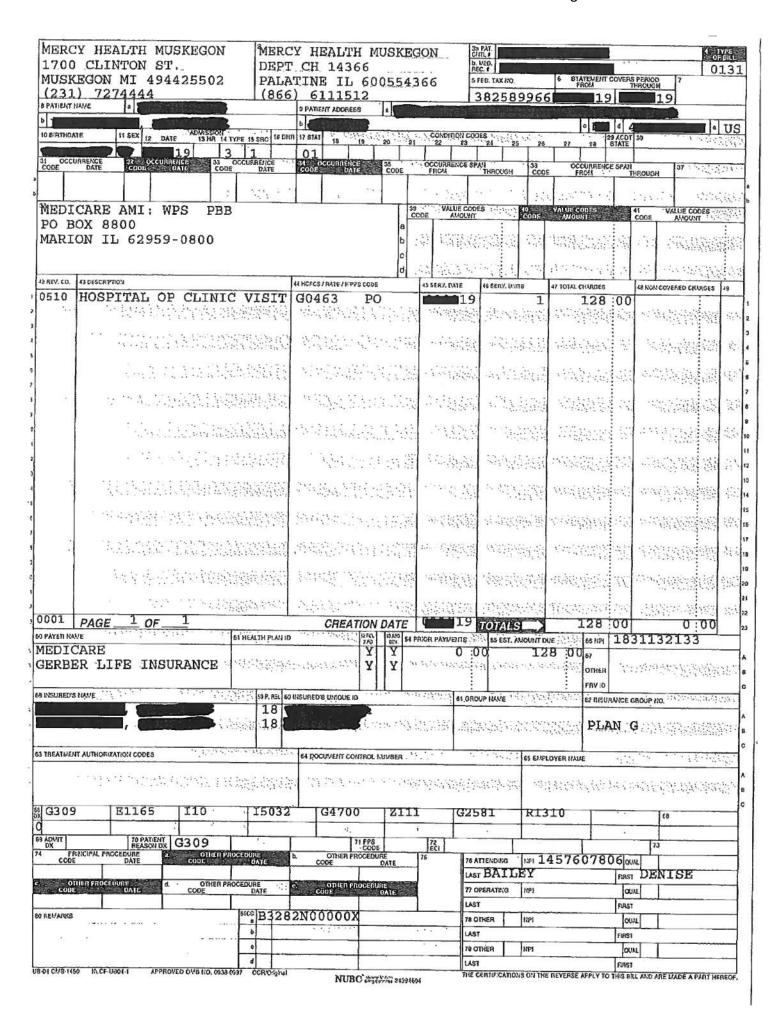
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Sincerely,

Michelle Lohman, Regional Director, Physician Revenue Cycle

Mercy Health

Cc: Kristi K. Nagengast, Vice President Finance Randall M. Smith, General Counsel





January 22, 2018

Humana Gold Plus (Medicare Replacement H) PO Box 14601 Lexington, KY 40512-4601

RE: Claim For Services - 1 Claim # Tax ID#38-2589966

Dear Provider Services:

On Nov. 21, 2018, CMS published in the Federal Register a final rule with comment period reducing Medicare payment rates for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). As explained in comments on the proposed rule (see 83 Fed. Reg. 59,004-15), the payment reduction exceeds the scope of the Secretary's statutory authority. The payment reduction is unlawful and ultra vires because it violates the statutory requirement that adjustments to payment rates be budget neutral and because it ignores the statutory distinction between excepted and non-excepted off-campus PBDs. The payment rate for the claimed services should be \$110.21.

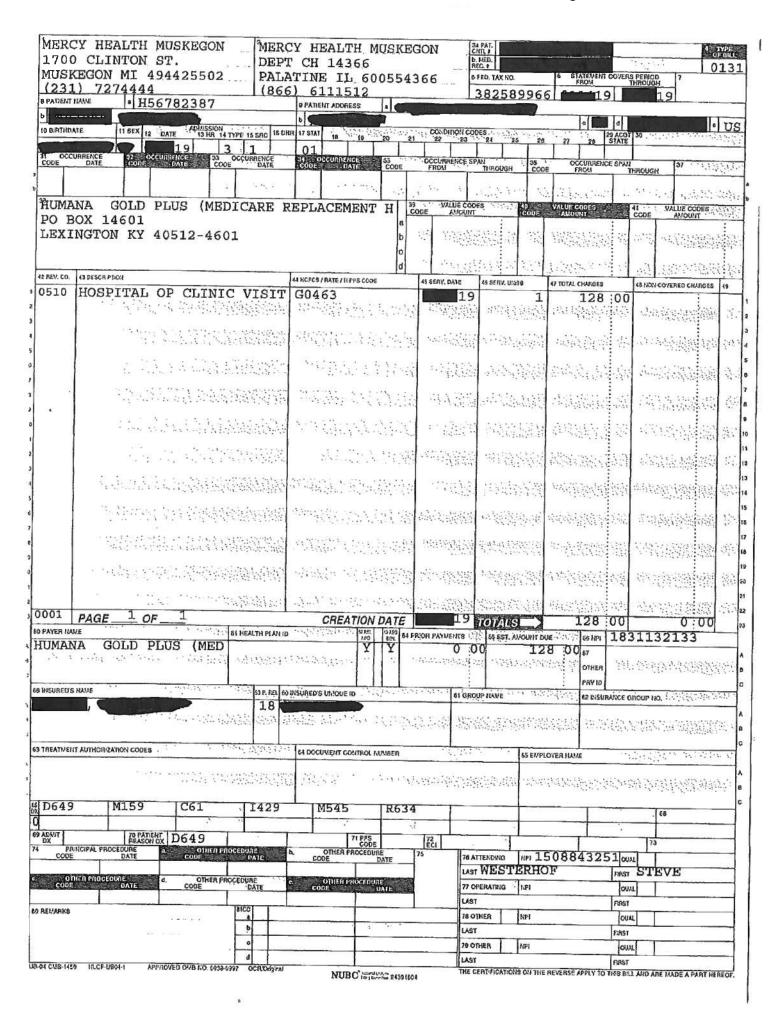
Sincerely,

Michelle Lohman, Regional Director, Physician Revenue Cycle

Mercy Health

Cc:

Kristi K. Nagengast, Vice President Finance Randall M. Smith, General Counsel



# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

	)	
THE AMERICAN HOSPITAL ASSOCIATION,	)	
ASSOCIATION OF AMERICAN MEDICAL	)	
COLLEGES, MERCY HEALTH MUSKEGON,	)	
CLALLAM COUNTY PUBLIC HOSPITAL	)	
NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER,	)	
and YORK HOSPITAL,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1:18-cv-2841
	)	
ALEX M. AZAR II,	)	
in his official capacity as SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
	)	
Defendant.	)	
	_)	

## [PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Upon consideration of Plaintiffs' Motion for Summary Judgment, the Memorandum in Support, any opposition or replies, and the arguments of counsel, it is hereby

**ORDERED** that Plaintiffs' motion be **GRANTED**; and it is further

**ORDERED** that summary judgment shall **BE**, and it hereby **IS**, **GRANTED** in favor of Plaintiffs and against Defendant on all claims; and it is further

**ORDERED** that the Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule for Calendar Year 2019 (the Final Rule) **BE**, and it hereby **IS**, declared unenforceable for the reasons set forth in this Court's separate opinion; and it is further

**ORDERED**, that the *ultra vires* portions of the Final Rule shall **BE**, and hereby **ARE**, **VACATED**; and it is further

**ORDERED**, that Defendant is hereby **ENJOINED** from enforcing the *ultra vires* portions of the Final Rule; and it is further

**ORDERED** that CMS shall conform its payment policies and conduct to the requirements of the Medicare Act; and it is further

**ORDERED** that CMS shall recalculate all payments made or due pursuant to the Final Rule and provide immediate payment of any amounts improperly withheld as a result of its *ultra vires* conduct to all affected hospitals (including but not limited to the Plaintiff-Hospitals and all affected members of the AHA and AAMC).

50 <b>ORDERED</b> , tins day or 201).	•
	The Honorable Rosemary M. Collyer
	United States District Court Judge

2019

Copies to:

Catherine E. Stetson Susan M. Cook HOGAN LOVELLS US LLP 555 Thirteenth Street, N.W. Washington, D.C. 20004

SO ORDERED this day of

Bradley P. Humphreys
Justin Sandberg
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005