## 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. 1:20-80
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 respectfully request summary judgment in their favor in connection with CMS's 2020 Final Rule governing Medicare payments for hospital outpatient services. In September 2019, this Court declared CMS's 2019 Final Rule, based on the same Clinic Visit Policy as that reflected in the 2020 Final Rule, to be *ultra vires*. Notwithstanding this Court's ruling, CMS proceeded with another rulemaking for CY 2020, in which it implemented the same payment rate reduction that this Court had already declared unlawful.

For the same reasons this Court articulated in vacating the relevant portions of the 2019 Final Rule, the payment reductions contemplated by the 2020 Final Rule contravene the clear statutory safeguards crafted by Congress to constrain CMS's authority. For this reason, as well as those set forth more fully in the attached Memorandum in Support (incorporated herein by

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reference), this Court should again grant summary judgment in favor of Plaintiffs, 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.

Plaintiffs notified Defendant of their intent to file this motion on January 21 and 31,

2020. Defendant intends to oppose. A proposed Order is attached hereto.

Respectfully submitted,

<u>/s/ Catherine E. Stetson</u> 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 Fax: 202-637-5910 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 2, 2020

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Plaintiffs,	)	
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v.	)	Civil Action No. 1:20-80
	)	
ALEX M. AZAR II,	)	
in his official capacity as SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
	)	
Defendant.	)	
	)	

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

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

Dated: February 2, 2020

Counsel for 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

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#### **INTRODUCTION**

In September 2019, this Court issued a decision finding portions of the CMS rulemaking governing Medicare payments for hospital outpatient services for Calendar Year (CY) 2019 to be *ultra vires*, vacating those portions of the 2019 Final Rule. CMS filed a motion to modify the Court's order to permit remand without vacatur, which the Court denied. Notwithstanding this Court's rulings, CMS proceeded with a fresh rulemaking for CY 2020, in which it implemented the same payment rate reduction that this Court had already declared unlawful.

For the same reasons this Court articulated in vacating the relevant portions of the 2019 Final Rule, the payment reductions contemplated by the 2020 Final Rule contravene the clear statutory safeguards crafted by Congress to constrain CMS's authority. As this Court has already noted, CMS's decision to proceed with implementing payment reductions for CY 2020 even after this Court declared them unlawful "appears to set the agency above the law." *American Hospital Ass'n v. Azar*, No. 18-2841 (D.D.C.) (RMC) (*AHA I*), ECF No. 50 at 7. Plaintiffs request an expedient decision on summary judgment finding the 2020 Final Rule to be *ultra vires* for the same reasons as the 2019 Final Rule—especially since CMS has now recommenced paying hospital claims at the lower, unlawful payment rate in CY 2020.

#### FACTUAL BACKGROUND

#### The 2019 OPPS Final Rule

In July 2018, CMS issued a proposed rule that would reduce Medicare payments under the hospital outpatient prospective payment system (OPPS) for CY 2019, titled *Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs* (CY 2019 Proposed Rule). As relevant here, the agency proposed that the Medicare payment rate for certain clinic-visit services provided at excepted off-campus

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provider based departments (PBDs) would be reduced to render it equal to the payment rate for services provided at *non*-excepted off-campus PBDs. 83 Fed. Reg. 37,046, 37,142 (July 31, 2018). CMS estimated that this change—referred to as the "Clinic Visit Policy"—would result in a decrease in overall payments to hospitals under the OPPS by \$760 million in CY 2019. *Id.* at 37,143.

The 2019 OPPS Final Rule was published in the Federal Register in November 2018. 83 Fed. Reg. 58,818 (Nov. 21, 2018). Like the Proposed Rule, the 2019 Final Rule adjusted the payment rate for services provided by excepted off-campus PBDs so that it was "equal to" the payment rate for services provided by non-excepted off-campus PBDs. *Id.* at 58,822, 59,013. However, in response to public comments, CMS announced that the payment reduction would now be phased in over a two-year period. 83 Fed. Reg. at 59,014.

#### This Court Vacates The Unlawful Portion of the 2019 OPPS Final Rule

Shortly after publication of the 2019 OPPS Final Rule, Plaintiffs filed a lawsuit, challenging the agency's site neutral payment policy as unlawful. Following cross-motions for summary judgment, this Court held the Clinic Visit Policy to be *ultra vires* and vacated that portion of the 2019 Final Rule.

In its 2019 Opinion, this Court recognized that the Clinic Visit Policy is "manifestly inconsistent" with the OPPS crafted by Congress. *AHA I*, ECF No. 31 at 19. In order to sidestep the budget neutrality requirement of 42 U.S.C. § 1395*l*(t)(9)(B), CMS purported to have developed a "method for controlling unnecessary increases in the volume of covered OPD services" under 42 U.S.C. § 1395*l*(t)(2)(F). But this Court appropriately found that this purported "method" was in reality "a selective cut to Medicare funding which targets only certain services and providers"—in other words, a "price-setting tool." *AHA I*, ECF No. 31 at

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17.<sup>1</sup> That was (and is) unlawful, for two main reasons. First, the Court explained that given the number of tools that Congress gave to CMS as the "base ingredients of an Outpatient Prospective Payment System payment over which CMS has discretion," such as wage adjustments and the generally applicable conversion factor, the not-similarly-included "method" provision in subsection (t)(2)(F) "cannot affect" those payment-rate factors "directly" in a non-budget-neutral fashion. *Id.* at 19–22. As the Court noted, "CMS cannot shoehorn a 'method' into the multifaceted congressional payment scheme when Congress's clear directions lack any such reference." *Id.* at 20. Second, CMS's expansive interpretation of the term "method" as used in a "single sentence" to allow the agency, at its sole discretion, to make virtually unlimited payment cuts that are both targeted and non-budget-neutral would be similarly inconsistent with the "great detail" and "granularity" in Congress's "extraordinarily detailed scheme" governing relative payment weights across different covered services. *Id.* at 22–26.

Following the Court's decision vacating portions of the 2019 Final Rule, CMS moved to modify the Court's order and/or to stay its effect. The Court denied that motion, concluding that "vacatur was appropriate and that a stay was not." *See AHA I,* Orders, ECF No. 39 (Oct. 21, 2019) and ECF No. 50 (Dec. 16, 2019). The Government has appealed to the D.C. Circuit, and briefing is under way.

#### CMS Readopts The Clinic Visit Policy In The 2020 Final Rule

While Plaintiffs' lawsuit challenging the 2019 Final Rule was still pending in this Court, CMS issued its proposed OPPS rule for CY 2020. 84 Fed. Reg. 39,398 (Aug. 9, 2019). Crossreferencing the basis given in the 2019 Final Rule and with little further elaboration, the agency

<sup>&</sup>lt;sup>1</sup> This Court also rejected the Government's argument that judicial review of the Clinic Visit Policy was precluded under 42 U.S.C. § 13951(t)(12)(A). See AHA I, ECF No. 31 at 14.

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announced that "CY 2020 will be the second year of the 2-year transition of this policy" instituted in 2019. 84 Fed. Reg. 39,512–513.

CMS published the 2020 Final Rule in November 2019, almost two months after this Court vacated the agency's 2019 Final Rule in relevant part. 84 Fed. Reg. 61,142 (Nov. 12, 2019). Rather than retreating from its *ultra vires* conduct, CMS doubled down by completing the two-year phase-in contemplated by the 2019 Final Rule. In response to comments reiterating that the agency lacked statutory authority to implement the rule, the agency asserted: "We respectfully disagree with the district court and continue to believe the Secretary has the authority to address unnecessary increases in the volume of outpatient services." 84 Fed. Reg. 61,142. Once the 2020 Final Rule became effective in January, CMS began paying hospitals at the lower payment rate contemplated by the 2020 Final Rule.

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

The 2020 Final Rule became effective on January 1, 2020. The Plaintiff-Hospitals and the members of the American Hospital Association and Association of American Medical Colleges have already begun to feel the effects of CMS's patently *ultra vires* conduct—and are suffering under the even steeper payment cut in CY 2020. 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. AHA Decl. ¶ 8; Declaration of Janis M. Orlowski (AAMC Decl.) ¶ 6; Declaration of Eric Lewis (Olympic Decl.) ¶¶ 9–14; Declaration of Kristi K. Nagengast (Mercy Decl.) ¶¶ 7– 8; Declaration of Jud Knox (York Decl.) ¶ 7. By reducing the payment rate for covered services provided at excepted off-campus 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. ¶¶ 9-10; AAMC Decl. ¶ 6; Olympic Decl. ¶¶ 9–14; Mercy Decl. ¶¶ 7–9. By CMS's own estimate, this amount will now total approximately \$800 million in CY 2020. 84 Fed. Reg. 61,369. This payment reduction is particularly troubling for hospitals already operating at low or negative margins. AHA Decl. ¶ 10; Olympic Decl. ¶¶ 8–14; Mercy Decl. ¶¶ 7–8.

#### ARGUMENT

This Court has already held that CMS's conduct here is unlawful.<sup>2</sup> As it noted in rejecting the identical payment cut for CY 2019: "The Court finds that the 'method' developed by CMS to cut costs is impermissible and violates its obligations under the statute. While the intention of CMS is clear, it would acquire unilateral authority to pick and choose what to pay for OPD services, which clearly was not Congress' intention." *See AHA I*, ECF No. 31 at 26. The 2020 Final Rule, which rests on the same legal footing, is fatally flawed for the same reasons.

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

First, the Final Rule is *ultra vires* because the Clinic Visit Policy is not budget neutral, in plain violation of the statute. 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

<sup>&</sup>lt;sup>2</sup> Given the unusual nature of this case, in which CMS relied in a new rulemaking on an alreadyrejected theory of its authority, Plaintiffs incorporate by reference the materials submitted in support of their challenge to the 2019 Final Rule. *See AHA I*, ECF Nos. 14, 22 & 23.

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incentive for CMS to employ draconian cost-control measures that target only certain service providers.

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. § 13951(t)(2)(F) (emphasis added). Another statutory provision then 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) (emphases 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

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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).<sup>3</sup> The conversion factor applies broadly to affect payments for *all* covered services under the OPPS. 42 U.S.C. § 13951(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). *Philip Morris USA Inc. v. United States Food & Drug Admin.*, 202 F. Supp. 3d 31, 52 (D.D.C. 2016). Had Congress meant to construct "a backdoor means" around the budgetneutrality 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* 

<sup>&</sup>lt;sup>3</sup> Available at https://bit.ly/2DFJhyp.

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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 of course, as this Court has noted, the agency's position also is inconsistent with the statutory scheme as a whole. "CMS cannot shoehorn a 'method' into the multi-faceted congressional payment scheme when Congress's clear directions lack any such reference." *AHA I*, ECF No. 31 at 20. In addition, CMS's expansive interpretation of the term "method" to allow the agency, at its sole discretion, to make virtually unlimited payment cuts that are both targeted and non-budget-neutral is similarly inconsistent with the "great detail" and "granularity" in Congress's "extraordinarily detailed scheme" governing relative payment weights across different covered services. *Id.* at 22–26.

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).").

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Both admissions are telling, and undermine any claim to deference that the Government might make. *See, e.g., Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016).

# II. THE FINAL RULE ERASES THE STATUTORY DISTINCTION BETWEEN EXCEPTED AND NON-EXCEPTED OFF-CAMPUS 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 off-campus PBDs, in violation of Congress's statutory command. Specifically, the Final Rule provides that the payment rate for services furnished at excepted off-campus PBDs will be adjusted so that it would be equal to the payment rate for services provided at non-excepted off-campus PBDs. 84 Fed. Reg. 61,369.

But the Medicare statute requires CMS to pay excepted and non-excepted off-campus 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 off-campus 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.<sup>4</sup> CMS itself has effectively acknowledged as much by

<sup>&</sup>lt;sup>4</sup> It is notable that when Congress amended Section 603 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).

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requiring non-excepted off-campus 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 off-campus PBDs is meaningless. *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 off-campus PBDs the same, it would have drawn no statutory distinction between these entities at all. And yet it did.

#### **CONCLUSION**

Like the Clinic Visit Policy set forth in the 2019 Final Rule, the Clinic Visit Policy set forth in the 2020 Final Rule is *ultra vires* because CMS has, again, exceeded its statutory authority. This Court should again grant summary judgment in favor of Plaintiffs, 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,

<u>/s/ Catherine E. Stetson</u> 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 Fax: 202-637-5910 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 2, 2020

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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. 1:20-cv-80
	)	
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, Virginia.

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

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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 the Centers for Medicare & Medicaid Services (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 CMS as part of the calendar year (CY) 2020 Medicare outpatient prospective payment system (OPPS) final rule (2020 Final Rule).

6. Under the challenged clinic visit policy, CMS 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 2020, payment to excepted off-campus provider-based departments were fully equalized with non-excepted off-campus provider-based departments were fully equalized with non-excepted off-campus provider-based departments. This means that payment for clinic visit services at excepted off-campus provider-based departments will be equal to 40 percent of the OPPS rate (that is, 60 percent *less than* the OPPS rate). 84 Fed. Reg. 61,369.

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7. Many of AHA's members, including the named hospital plaintiffs, have excepted off-campus PBDs and will be negatively affected by CMS's 2020 Final Rule. These hospitals will be harmed by CMS's *ultra vires* conduct if the 2020 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 2020 Final Rule will total approximately \$800 million in CY 2020. 84 Fed. Reg. 61,369.

9. By reducing the payment rate for covered services provided at excepted offcampus PBDs, the 2020 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 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* 

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lifeline for access to hospital outpatient care for patient in need of financial assistance living in rural communities that lack their own main hospital. If hospitals are forced to reduce services at off-campus PBDs as a result of the payment cuts set forth in the 2020 Final Rule, patients that are already facing medical and/or financial barriers will be forced to travel even 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 29th day of January 2020.

Joanna Hiatt/Kim Vice President, Payment Policy American Hospital Association

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

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### 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

#### Case 1:20-cv-00080-TFH Document 14-3 Filed 02/02/20 Page 2 of 3

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 154 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 173,000 faculty members, 89,000 medical students, and 120,000 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) 2020 Medicare outpatient prospective payment system (OPPS) final rule (2020 Final Rule).

6. Many of AAMC's members, including Mercy Health Muskegon, have excepted off-campus provider-based departments (PBDs) and will be harmed by CMS's 2020 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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## Case 1:20-cv-00080-TFH Document 14-3 Filed 02/02/20 Page 3 of 3

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

Executed this 27th day of January 2020.

Ju m

Janis M. Orlowski, M.D. Association of American Medical Colleges

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

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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.

ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 1:20-cv-80

## 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

#### Case 1:20-cv-00080-TFH Document 14-4 Filed 02/02/20 Page 2 of 7

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 and of the Association of American Medical Colleges.

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) 2020 Medicare outpatient prospective payment system (OPPS) final rule (2020 Final Rule).

6. Mercy Health Muskegon operates 40 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 2020 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 2020 Final Rule will cause it to suffer a \$3.6 million loss in CY 2020, a 21% reduction in annual operating income.

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#### Case 1:20-cv-00080-TFH Document 14-4 Filed 02/02/20 Page 3 of 7

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 2020, the Health Project will require more than \$3.5 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 2020 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. Since January 1, 2020, Mercy Health Muskegon has submitted claims for excepted off-campus physician clinic visit services covered by the 2020 Final Rule to its Medicare Administrative Contractor. The Medicare Administrative Contractor has issued initial determinations on those claims and Mercy Health Muskegon filed a Medicare Redetermination Request for some of those claims on January 24, 2020. True and correct copies of these documents are attached as Exhibit A.

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## Case 1:20-cv-00080-TFH Document 14-4 Filed 02/02/20 Page 4 of 7

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

Executed this 31st day of January 2020.

lagngy It By:

Kristi K. Nagengast, Vice President, Finance Mercy Health Muskegon

# MERCY HEALTH

MercyHealth.com

January 24, 2020

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WPS GHA Part A MAC J8 Michigan Medicare Appeals PO Box 8604 Madison, WI 53708-8604

For calendar year 2019, CMS reduced payments for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). On Nov. 12, 2019, CMS published in the Federal Register a final rule with comment period further reducing Medicare payment rates for clinic visit services at excepted off-campus PBDs effective January 1, 2020. 84 Fed. Reg. 61,142 (Nov. 12, 2019).

As explained in comments on both the 2019 and 2020 proposed rule (see 84 Fed. Reg. 61,365-69), and as previously held by the court in *American Hospital Association v. Azar*, No. 18-2841-RMC (D.D.C.), the payment reduction exceeds the scope of the Secretary's statutory authority and is ultra vires. 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.

We have begun to submit claims for clinic visit services furnished after December 31, 2019 under code G0463 and the payment rate for the claimed services should be \$115.93. We request that all claims billed under that code be paid at the rate that would be in effect if the above-described payment reductions for 2019 and 2020 had not been adopted.

Julie McGrath Supervisor, Government Billing and Follow up Medical Groups & Provider Services – Trinity Health

Cc: Randall M. Smith, General Counsel

General Campus 1700 Ook Avenue Misslangso, Mi 49444 231,672,7000

860,369,4125

Hackiey Campus 1700 Cinteo Street Notkegen 30 49492 231,726,1511 100,8754672 Lakeshore Campus 72.5. State Street Shiriby, M149455 234.864.2156 Mercy Campus 1500 L. Stictman Boulevard Miskogon, All 49444 2316 / 2 2000 600-168 4125

# Case 1:20-cv-00080-TFH Document 14-4 Filed 02/02/20 Page 6 of 7

Medicare Part A Request for Redetermination
Date Requested: 2020 DCN/Claim# (claim being appealed):
Does this appeal involve an overpayment? Ves* No *Please provide a copy of the overpayment letter.
If yes, what type of overpayment?  Recovery Auditor (RA)  CERT  PSC/ZPIC  Medical Review  Probe Review  Patient Name:
Medicare ID: Date(s) of service:2020
Item(s) and/or service(s) at issue in appeal: PAYMENT REDUCTION FOR CPT G0463
Additional information Medicare should consider: SEE ATTACHED LETTER
If past the 120-day redetermination timely filing limit, please answer the following question:         Reason for unlimely filing and additional documentation, as indicated below, needed to support timeliness:         Tracking proof of correct address and date sent         Copy of original redetermination request with date sent         Date, time, and name (complete first name and last initial), and phone number of representative spoken to if you received prior approval to submit the claim untimely.
Reason:
Provider Number: 231-726-3511 NPI: 1831132133
Applicant Name/Title (printed): Julie McGrath Supervisor Billing & Follow Up Applicant Address: 34375 W 12 MILE RD FARMINGTON HILLS, MI 48331
Applicant Phone Number: 734-343-3872
Applicant Signature: UIL: M: UTM Date Signed: 1/24/2020
Relationship to Patient (check all that apply)
Mall Request to:IndianaMichiganWPS GHAWPS GHAPart A J8 MAC IndianaPart A MAC J8 MichiganMedicare AppealsMedicare AppealsPO Box 8602PO Box 8604Madison, WI 53708-8602Madison, WI 53708-8604

https://www.wpsgha.com

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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. 1:20-cv-80
	)	
ALEX M. AZAR II,	)	
in his official capacity as SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
D-61	)	
Defendant.	)	
	)	

## 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.

#### Case 1:20-cv-00080-TFH Document 14-5 Filed 02/02/20 Page 2 of 13

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) 2020 Medicare outpatient prospective payment system (OPPS) final rule (Final Rule).

6. York Hospital furnishes outpatient services at 12 excepted off-campus providerbased 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 2020 Final Rule will cause it to suffer a \$2.8 million annual loss, or a .7% percent annual reduction in operating revenue.

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

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#### Case 1:20-cv-00080-TFH Document 14-5 Filed 02/02/20 Page 3 of 13

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

9. On January 13, 2020, York Hospital submitted claims for excepted off-campus physician clinic visit services covered by the Final Rule to its Medicare Administrative Contractor. On January 7, 2020, York Hospital sent a letter to its Medicare Administrative Contractor requesting that payment on such claims be paid at the rate that would be in effect if the 2020 Final Rule had not been adopted. The Medicare Administrative Contractor issued an initial determination on those claims on January 21, 2020. York Hospital filed a Medicare Redetermination Request on January 21, 2020. 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 28th day of January 2020.

Jud Knox President York Høspital



January 7, 2020

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

To Whom It May Concern:

For calendar year 2019, CMS reduced payments for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). On Nov. 12, 2019, CMS published in the Federal Register a final rule with comment period further reducing Medicare payment rates for clinic visit services at excepted off-campus PBDs effective January 1, 2020. 84 Fed. Reg. 61,142 (Nov. 12, 2019).

As explained in comments on both the 2019 and 2020 proposed rule (see 84 Fed. Reg. 61,365-69), and as previously held by the court in *American Hospital Association v. Azar*, No. 18-2841-RMC (D.D.C.), the payment reduction exceeds the scope of the Secretary's statutory authority and is ultra vires. 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 for York Hospital, Provider Number 20-0020, should be \$118.38.

We have begun to submit claims for clinic visit services furnished after December 31, 2019 under code G0463 and request that all claims billed under that code be paid at the rate that would be in effect if the above-described payment reductions for 2019 and 2020 had not been adopted.

Sincerely,

Robin LaBonte, CFO

Offering healthcare services and community sites in York, Wells, Kittery and the Berwicks

15 Hospital Drive, York, ME 03909 | (207) 363-4321 | (877) 363-4321 toll free | (207) 363-7433 TTY | www.yorkhospital.com



January 21, 2020

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 offcampus 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 \$118.78 effective for dates of service beginning 1/1/2020.

Sincerely,

na tang serahan s

Linda Dickson

 15 Hospital Drive, York, Maine 03909

 Information: 207-363-4321
 Toll Free: 877-363-4321

 www.yorkhospital.com
 TTY: 207-363-7433

OMB Exempt

# MEDICARE REDETERMINATION REQUEST FORM — 1st LEVEL OF APPEAL

Beneficiary's name (First, Middle, Last)

Medicare number	Item or service you wish to appeal
	GO463
Date the service or item was received (mm/dd/yyyy)	Date of the initial determination notice (mm/ddhyyy) (please include a copy of the
2020	notice with this request) 01/21/2020

If you received your Initial determination notice more than 120 days ago, include your reason for the late filing:

Name of the Medicare contractor that made the determination	(not required)	(for pr	Does this appeal Involve an overpayment? (for providers and suppliers only) Yes 2 No		
I do not agree with the determination decision on my claim be	cause:				
On Nov. 21, 2018 CMS published in the Federal Register a visit services at certain off-campus provider- based departm proposed rule (see 83 Fed. Reg. 59,004-15), the payment r payment reduction is unlawful and ultra vires.					
Additional information Medicare should consider:					
The payment reduction for clinic visit services furnished at the statutory requirement that adjustments to payment rate excepted and non-excepted off-campus PBD's. The wage					
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I have evidence to submit. Please attach the evidence to this form or attach a statement submit and when you intend to submit it. You may also subm time, but all evidence must be received prior to the issuance of	IL SOCILIOUSI AAInchick a	tend to			
Person appealing:	Email of person appea Idickson@yorkhospit		_		
Name of person appealing (First, Middle, Last) Linda Anne Dickson					
Street address of person appealing 15 Hospital Drive					
City York		Sta ME		Zip code 03909	
Telephone number of person appealing (Include area code) 207 351 2380	Date of appe 01/22/2015	al (mmiddiyyyy) )	optiona	)	
Privacy Act Statement: The legal authority for the collection on Act. The information provided will be used to further documen failure to provide all or any part of the requested information or be disclosed by the Centers for Medicare & Medicaid Services t and to comply with Federal laws requiring or permitting the di Health and Human Services and other agencies. Additional infor	t your appeal. Sobmission by affect the determinat pranother person or governmenter	ion of your appe ernment agency	al Information	nation you furnish on this form r th respect to the Medicare Program mation between the Departmen	

no. 09-70-0566, as amended, available at 83 Fed. Reg. 6591 (2/14/2018) or at https://www.hhs.gov/fola/privacy/soms/cms-soms.html

Form CMS-20027 (01/20)

Medicare National	Standard Intermediary Remittance Advice FPE: 12/31/2020 PAID: 01/21/2020 CLM#: 872 TOB: 131
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Claim Remarks

## Case 1:20-cv-00080-TFH Document 14-5 Filed 02/02/20 Page 9 of 13

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OMB Exempt

## MEDICARE REDETERMINATION REQUEST FORM — 1st LEVEL OF APPEAL

Beneficiary's name (First, Middle, Last)

Medicare number	Item or service you wish to appeal
	GO463
Date the service or item was received (mm/ddlyyyy)	Date of the Initial determination notice (mm/ddiyyyy) (please include a copy of the notice with this request) $0.1/21/2020$
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if you received your initial determination notice more than 120 days ago, include your reason for the late filing:

Does this appeal involve an overpayment? (for providers and suppliers only)

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 reducint Medicare payment rates for clinic visit services at certain off-campus provider- based departments (excepted off-campus PBD's) As explained in commants 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.

Additional Information Medicare should consider:

The payment reduction for clinic visit services furnished at excepted off-campus PBD's is unlawful and ultra vires because if voliaties 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 PBD's. The wage adjusted payment rate for the claimed services should be \$118.78.

I have evidence to submit. Please attach the evidence to this form or attach a statement submit and when you intend to submit it. You may also submit time, but all evidence must be received prior to the issuance	of the redetermination.		have evidence to submit.
Person appealing:	Email of person appealing (optic Idickson@yorkhospital.com	onal)	
Name of person appealing (First, Middle, Last) Linda Anne Dickson			
Street address of person appealing 15 Hospital Drive			
City York		Støte ME	Zip code 03909
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Privacy 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 information 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 any 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 enother person or government agency only with respect to the Medicare Program and to comply with Federal laws requiring or permitting the 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 83 Fed. Reg. 6591 (2/14/2018) or at <u>https://www.hhs.gov/foia/privacy/sorms/cms-torms.html</u>

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## Case 1:20-cv-00080-TFH Document 14-5 Filed 02/02/20 Page 13 of 13

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

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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.

ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,

Defendant.

Civil Action No. 1:20-cv-80

### 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

## Case 1:20-cv-00080-TFH Document 14-6 Filed 02/02/20 Page 2 of 13

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 77,000 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 105 physicians and advanced practice clinicians. Of OMC's patients, 83.4% rely on Government-paid insurance and 59.2% 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) 2020 Medicare outpatient prospective payment system (OPPS) final rule (2020 Final Rule).

7. Olympic Medical Center furnishes outpatient services at nine excepted offcampus 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; an orthopedic 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

## Case 1:20-cv-00080-TFH Document 14-6 Filed 02/02/20 Page 3 of 13

immediate and concrete harm from the outpatient-services payment reductions set forth in the 2020 Final Rule.

8. Olympic Medical Center estimates that the clinic visit policy set forth in the 2020 Final Rule will cause OMC over \$3.0 million in lost revenue for CY 2020 alone. That lost revenue will impose further financial strain on OMC.

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 9,000 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 approximately 3,000 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

## Case 1:20-cv-00080-TFH Document 14-6 Filed 02/02/20 Page 4 of 13

substantially in the building at 8<sup>th</sup> & 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, patient harm due to poorer outcomes, and a higher cost for CMS. The cut to the physician clinic expense reimbursement will prevent or substantially slow 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 a huge challenge. 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,

## Case 1:20-cv-00080-TFH Document 14-6 Filed 02/02/20 Page 5 of 13

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 \$55 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 1,550 jobs to the local economy. OMC has been growing to meet the needs of the community, adding more than 250 jobs over the last three 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, 2020, Olympic Medical Center submitted claims for excepted offcampus physician clinic visit services covered by the Final Rule to its Medicare Administrative Contractor. On January 3, 2020, Olympic Medical Center wrote to its Medicare Administrative Contractor and requested that all such claims be paid at the rate that would have been in effect if the 2020 Final Rule had not been adopted. The Medicare Administrative Contractor issued initial determinations on those claims on January 24, 2020. OMC filed a Medicare

## Case 1:20-cv-00080-TFH Document 14-6 Filed 02/02/20 Page 6 of 13

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Redetermination Request on January 27, 2020. 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 31st day of January 2020.

1. 1. 1

Ene Lemis

Eric Lewis, Chief Executive Officer Olympic Medical Center



Working together to provide excellence in health care.

939 Caroline Street 

Port Angeles, WA 98362 

(360) 417-7000 

www.olympicmedical.org

Olympic Medical Center 939 Carolyn Street Port Angeles, WA 98362

January 3, 2020

Noridian JF Part A 900 42<sup>nd</sup> Street South P.O. Box 6720 Fargo, ND 58103-2119

Dear Noridian Healthcare Services:

For calendar year 2019, CMS reduced payments for clinic visit services at certain off-campus provider-based departments (excepted off-campus PBDs). On Nov. 12, 2019, CMS published in the Federal Register a final rule with comment period further reducing Medicare payment rates for clinic visit services at excepted off-campus PBDs effective January 1, 2020. 84 Fed. Reg. 61,142 (Nov. 12, 2019).

As explained in comments on both the 2019 and 2020 proposed rule (see 84 Fed. Reg. 61,365-69), and as previously held by the court in *American Hospital Association v. Azar*, No. 18-2841-RMC (D.D.C.), the payment reduction exceeds the scope of the Secretary's statutory authority and is ultra vires. 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 \$126.47.

We have begun to submit claims for clinic visit services furnished after December 31, 2019 under code G0463 and request that all claims billed under that code be paid at the rate that would be in effect if the above-described payment reductions for 2019 and 2020 had not been adopted.

Thank you for your review,

anna Weber

Yoanna Weber Director, Revenue Cycle Management Olympic Medical Center

Page 1 of 1

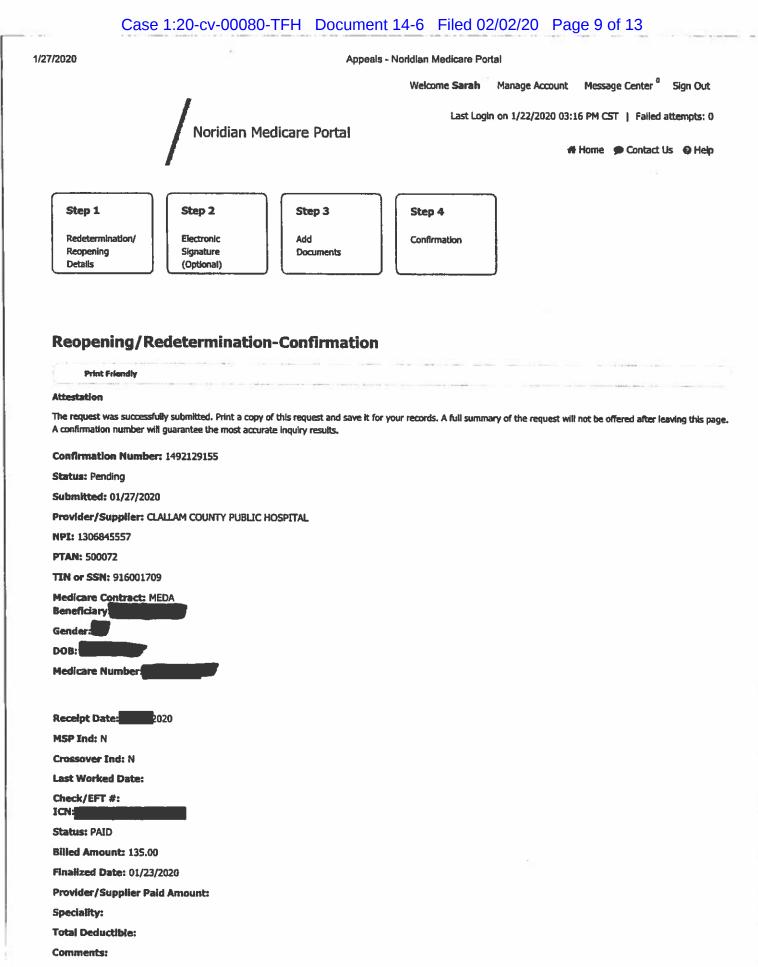
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N817 ALERT: APPLICABLE LABORATORIES ARE REQUIRED TO COLLECT AND REPORTPRIVATE PAYOR DATA AND REPORT THAT DATA TO CMS BETWEEN JANUARY 1,- MARCH 31, 2020.



https://www.noridianmedicareportal.com/group/end-user/appeals/-/appeals/redetermination/review/1492129155

## Case 1:20-cv-00080-TFH Document 14-6 Filed 02/02/20 Page 10 of 13

#### 1/27/2020

#### Appeals - Noridian Medicare Portal

On Nov. 12, 2019, CMS published in the Federal Register a final rule with comment period further reducing Medicare payment rates for clinic visit services at excepted off-campus PBDs effective January 1, 2020. 84 Fed. Reg. 61,142 (Nov. 12, 2019). As explained in comments on both the 2019 and 2020 proposed rule (see 84 Fed. Reg. 61,365-69), and as previously held by the court in American Hospital Association v. Azar, No. 18-2841-RMC (D.D.C.), the payment reduction exceeds the scope of the Secretary's statutory authority and is ultra vires. 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 \$126.47. Please reprocess our claim to pay the correct non-reduced rate.

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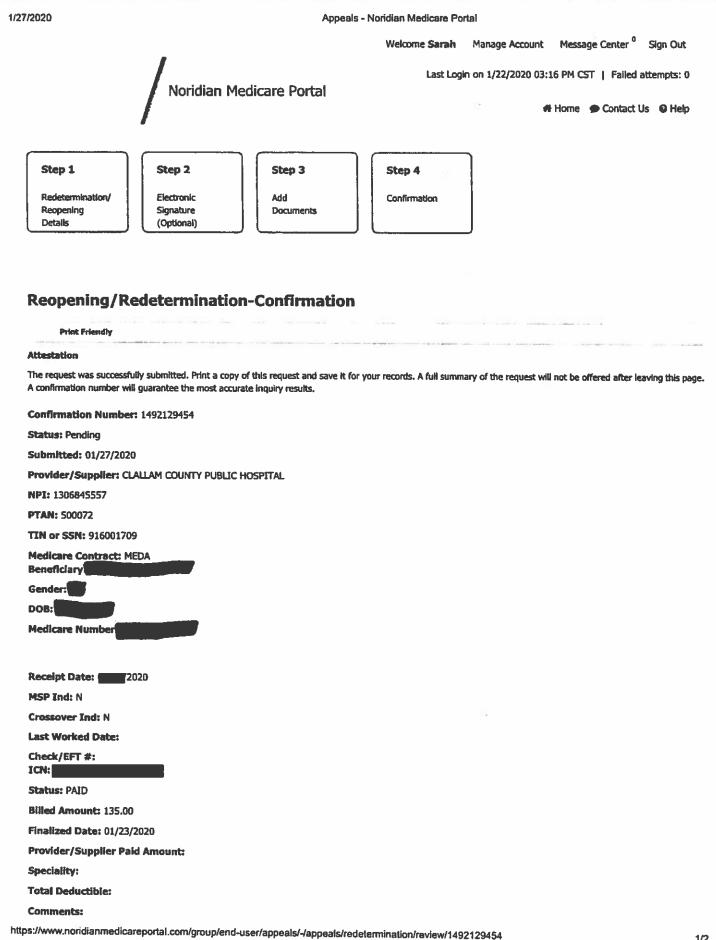
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### Case 1:20-cv-00080-TFH Document 14-6 Filed 02/02/20 Page 12 of 13



## Case 1:20-cv-00080-TFH Document 14-6 Filed 02/02/20 Page 13 of 13

#### 1/27/2020

#### **Appeals - Noridian Medicare Portal**

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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. 1:20-cv-80
	)	
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, Defendant's response

thereto, and the entire record herein, good cause having been shown, it is hereby

ORDERED, that Plaintiffs' Motion for Summary Judgment shall be, and hereby IS,

GRANTED; and it is further

ORDERED, that the Clinic Visit Policy set forth in the 2020 Final Rule shall be, and

hereby IS, VACATED; and it is further

ORDERED, that Defendant is hereby immediately ENJOINED from enforcing the Clinic

Visit Policy; and it is further

ORDERED, that Defendant shall immediately be required to repay any amounts

improperly withheld as a result of its unauthorized conduct.

SO ORDERED this \_\_ day of February, 2020.

United States District Court Judge