Washington State Hospital Association

August 31, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1656-P, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Proposed Rule (Vol. 81, No. 135), July 14, 2016.

Dear Mr. Slavitt:

On behalf of our 102 member hospitals and health systems, the Washington State Hospital Association appreciates the opportunity to comment on the provisions contained in the Centers for Medicare & Medicaid Services' (CMS) calendar year 2017 hospital outpatient prospective payment system (OPPS) proposed rule. The proposed rule would implement the site-neutral provisions of the Bipartisan Budget Act of 2015 (BiBA).

The hospital field and more than half of the U.S. House and Senate this spring urged CMS to provide reasonable flexibility when implementing the BiBA site-neutral provisions in order to ensure that Medicare patients have continued access to the highest quality hospital care in their communities. Instead, CMS has proposed a short sighted and unworkable set of policies. Some of them provide no reimbursement for some services that hospitals will provide to Medicare beneficiaries.

The agency's proposals fail to recognize the crucial role that hospital outpatient departments serve in providing access to primary and specialty care for both Medicare and Medicaid enrollees in many communities. These hospital outpatient departments provide care that would not be available under standard fee schedule payment. We disagree with the general premise that their status is generally abused and needs to be phased out. The experience in our state has been quite the opposite. Hospital outpatient departments have been a financial lifeline to ensure and preserve access to care for our more vulnerable citizens, especially in cases where the service and payer mix is such that the Medicare and Medicaid fee schedules do not financially support the care. Access to appropriate care helps reduce avoidable emergency department visits and other costs. We recognize that the overall issue is outside of CMS's purview. That said, we believe CMS's proposed policies go far beyond the Congressional intent and do not take advantage of the flexibility that Congress provided.

WSHA urges CMS to delay the implementation of the site-neutral policies in the proposed rule by at least one year. This delay would provide the time necessary for CMS to develop a fair and flexible payment policy under which hospitals would be able to receive direct payment for their non-excepted hospital outpatient departments and for non-excepted items and services that they furnish in excepted hospital outpatient departments and more fully address the other outstanding issues.

We support the recommendations made by the American Hospital Association. Some of our specific major areas of concern are detailed in the attached document.

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Senior Vice President
Policy Development

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ATTACHMENT

WSHA Comments on CMS-1656-P

WSHA asks CMS to extend hospital-based payment to services and clinics that were under development as of November 2, 2015 even if not yet operational and billing as a hospital based location. Potentially hundreds of providers were in the process of planning and building hospital outpatient departments when Congress passed Section 603 and amended Section 1833. Without a flexible interpretation of the effective date, those providers face either forfeiting whatever investment they have made in new construction projects, acquisitions and expansions or accepting much lower reimbursement than expected when the projects were approved by hospital officials. Besides the financial implications of revising plans, these providers must find other ways to extend access to patients who would have been served by canceled projects. Below are two of many examples in our state.

> As of November 2015, one of our member hospitals, a public hospital district that serves a geographically large rural area along the isolated Olympic Peninsula in Washington State, had a board-approved strategic plan that called for it to establish an outpatient surgery center at its campus in Sequim. As of November 1, 2015 it had both preliminary architectural drawings and a timeline for construction developed. The community of Sequim, part of the district, is at least 20 miles and 30 minutes from the main hospital. It is a growing retirement community with more than 40% of its residents over the age of 65. Over the past decade, the hospital has developed an array of outpatient services at this location to improve access for Sequim area residents. The hospital's analysis identified that without provider-based reimbursement the surgery center would not be financially sustainable, and the project has now been put on hold. The consequence is that residents will need to continue to drive at least 30 minutes for care. Because the hospital's main operating rooms run at a high occupancy, patients run the risk of being "bumped" for inpatient or urgent cases, and have a higher probability of experiencing an overnight stay at an increased cost to both Medicare and the patient.
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> Another member hospital that serves the highly agricultural and diverse Yakima Valley in Central Washington had documented the need for additional psychiatrists in both its 2013 board- approved community health needs assessment and its 2015 physician supply and demand analysis. In response, and based on feedback from the community and from primary care providers, the hospital had developed plans prior to November 2015 to create several new clinics that integrate mental health and primary care. The hospital's analysis demonstrated that these clinics need to be provider based to assure a level of reimbursement that covers operating costs. There is no space within 250 yards of the main hospital, and further, for these clinics to be effective they should be placed in the various communities in the hospital's regional service area. With the new rule requirements, the new clinics are not being pursued. As a result of not moving forward, the hospital has continued to experience high rates of boarding of psychiatric patients in its ED, continued higher rates of patients being admitted with a primary psychiatric diagnosis, and decreased productivity in its existing primary care clinics as they attempt to manage patients without the on-site support of behavioral health specialists. The impact on access and the additional costs to Medicare are both real and quantifiable.

While the statute clearly grants an exception to locations that were in existence and billing Medicare at the time of enactment, it is silent on projects that were under development as of that date. Accordingly, we believe CMS has discretion to define such projects and to provide an exception for them. We propose that CMS include hospitals that had projects under development in the Sec. 603 grandfather. The term "under development" should be defined to include any project that was approved in any form by a hospital board or through a board-approved planning document as of November 2, 2015 where the parent hospital was otherwise billing under OPPS.

Payment Policy for Non-excepted Hospital Outpatient Departments Needs to Be Addressed. We are deeply concerned that CMS proposes to make *no payment* to newer "non-excepted" hospital outpatient departments for the services they provide to Medicare beneficiaries in 2017. In other words, the agency would not provide any reimbursement to these departments for the nursing, laboratory, imaging, chemotherapy, surgical and many other reasonable and necessary services they provide to Medicare beneficiaries. Such a payment policy is completely unreasonable and unsustainable. CMS should delay any restriction or reduction in payment for these services until it has a viable way to provide reasonable payment. To outright deny services because they are provided by hospital outpatient departments rather than independent clinics goes beyond the congressional intent. While it may not be simple, CMS clearly has mechanisms at its disposal that it could use to pay hospitals directly for non-excepted services.

CMS Needs to Address Legal Issues and Exposure to Stark Laws. CMS's failure to pay hospitals directly for facility services creates regulatory as well as financial concerns. In many cases, such as academic faculty practice plans at teaching hospitals, the physicians at hospital- based locations are a separate legal entity rather than direct employees of the hospital. It appears CMS would pay the physician entity the amount for the facility under the fee schedule and expect the hospitals that provide the building, nurses and other services to either obtain payment from the physicians or forgo payment altogether. This creates significant legal and financial issues for all parties. This also creates regulatory exposure for the physician entity as they are being forced to accept payment for a portion of the care they are not providing.

The proposal as drafted also raises another significant issue in potential exposure under Stark laws. If a location is no longer considered a department of the hospital, there may be new exposure under Stark for referrals that take place. *The agency has a responsibility to work to be able to provide reasonable payment to hospitals in a way that does not create undue burden or exposure. It should delay implementation of its site-neutral policies until it can administer payment in a fair and accurate manner.*

CMS Needs to Provide More Flexibility for Relocation and Rebuilding. We are particularly troubled by CMS's unreasonable and inflexible proposal to discontinue current reimbursement under the OPPS for excepted hospital outpatient departments that need to relocate or rebuild. There are many necessary and valid reasons that excepted hospital outpatient departments would need to relocate. Doing so should not cause them to lose payment. CMS should allow for relocation and rebuilding of excepted hospital outpatient departments without triggering payment cuts. A policy that prevents relocation prevents clinics from relocating to more clinically efficient and cost-effective facilities and prone to unreasonable lease arrangements due to their "captive" situation.

CMS has policies that allow other types of facilities to relocate and retain their status so long as they meet certain requirements. For example, a Critical Access Hospital can relocate and maintain

its status as long as it continues to generally serve the same geographic location and patients. The agency's proposal to limit flexibility in relocation and expansion, in combination with its proposal to withhold hospital payments altogether, would mean that hospitals and health systems that have planned to provide or expand much needed hospital-level outpatient care and services in communities with limited access to care would not be able to do so.

CMS Needs to Consider Impact on Patients and Payer Mix. We fear that CMS's rigid proposals would negatively impact access to care for beneficiaries, particularly needed services for vulnerable populations in the nation's most underserved communities. Since Medicaid programs often mirror Medicare's payment, the proposed changes could ultimately undermine the financial sustainability of access for Medicaid, as well as Medicare patients. In Washington State, many hospital outpatient departments were created to preserve access to physician practices with significant proportions of Medicare and Medicaid patients. Because of payer mix, these practices are not able to make it financially under Medicare and Medicaid fee schedules. Some serve as access points for Medicare and Medicaid services not financially sustainable in the community other than as a hospital service. Hospital outpatient departments that serve high proportions of Medicare and Medicaid enrollees receive far less than the cost of providing care. We can provide numerous examples of this in our state and recommend CMS carefully consider the impact on access of not allowing the flexibility that Congress provided in the law.

CMS Needs to Be More Flexible on Expansion of Services. CMS proposes that any expansion of services at an excepted hospital be paid at a site neutral rate if the expansion occurs on or after November 2, 2015. This is extremely problematic. Off-campus departments must be able to expand the items and services they offer to meet changes in clinical practice and the changing needs of their communities without losing their ability to be reimbursed under the OPPS. This is important since a declining amount of services for Medicare and Medicaid enrollees are available from non-hospital providers. It is particularly an issue for patients with a greater level of acuity, such as those with chronic conditions or in need of wound care. Nothing in BiBA requires that CMS treat an expansion of services this way. In fact, the plain language does not address expansion at all. CMS must ensure that patients continue to have access to the services they need at the facilities where they seek treatment. We strongly urge CMS to protect hospitals' ability to offer an expanded range of services without experiencing a loss of reimbursement.

CMS Needs to Be More Flexible On Change of Ownership. We are concerned that CMS's proposal would not permit an excepted off-campus hospital outpatient department to retain its status if it is individually acquired by another hospital. Even under current payment, hospital outpatient departments receive less than the cost of providing the care and require significant hospital subsidy to operate. Often, hospitals in financial difficulty that plan to close their inpatient hospital beds will offer to transfer their outpatient departments to better-performing hospitals in order to ensure that critical outpatient services are still accessible to patients in the community. Such acquisitions, and the ability to preserve physician capacity and services would not be financially feasible if the departments were to lose its payment. We urge CMS to allow individual hospital outpatient departments to be transferred from one hospital to another and maintain their excepted status.

CMS Needs to Clarify Impact to 340B Program. We are concerned about what may be unintended consequences to CMS's policies. We ask CMS to clarify that hospitals' ability to receive 340B pricing is not jeopardized by whether an off-campus provider based department is grandfathered or not. Our understanding at present is that 340B status would not change as long as the department is listed on a hospital's cost report as a provider-based department. We believe that Section 603 merely changes the payment amount a non-grandfathered department receives and that CMS is not altering the facility's status. We would appreciate clarification to that effect. Loss of a location's ability to receive 340B pricing on prescription drugs would severely impact its ability to service uninsured and other vulnerable patients.

Further, we seek clarification that a department would qualify for 340B pricing regardless of where it is listed on a cost report - whether or not the facility is listed as receiving technical or professional component reimbursement.

Finally, we anticipate a potential conflict and confusion between federal and state licensure if a facility is not qualified as a provider-based department on the federal side, but the hospital is seeking state licensure of the unit as a provider based department for other services, such as Medicaid payment. We would appreciate clarification, and whether CMS is working to clarify 340B-related issues with HRSA.