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August 26, 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, July 14, 2016.

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2017 hospital outpatient prospective payment system (OPPS) proposed rule that would implement the site-neutral provisions of the Bipartisan Budget Act of 2015 (BiBA). We are extremely concerned about CMS's suggested implementation of this provision, including the interaction between CMS's proposals and the federal fraud and abuse laws.

The hospital field and more than half of the U.S. House of Representatives 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 that provide no reimbursement to hospitals for the services they provide to Medicare beneficiaries. The agency's proposals would prevent affected hospitals from being able to provide necessary, innovative and high-quality health care to their communities and cannot be reasonably implemented. **CMS must delay these site-neutral policies until it can adopt much-needed changes in order to provide fair and equitable payment to hospitals.**

The AHA will submit more detailed comments on the proposed implementation of the BiBA site-neutral provisions, along with other feedback on proposed changes to the OPPS, in a



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separate letter to the agency. This letter focuses on one critical aspect of CMS's site-neutral proposal – the interaction between CMS's proposal and the federal fraud and abuse laws. **Specifically, the AHA is extremely concerned that the proposed site-neutral policies raise significant compliance risks under the Stark law and the Anti-kickback statute (AKS).**

CMS's proposed implementation of the BiBA requirements would put non-excepted hospital outpatient departments (HOPDs) between the proverbial rock and a hard place by forcing them to choose between potential fraud and abuse risk and disruption of the care they provide to Medicare beneficiaries. Specifically, non-excepted HOPDs could face significant compliance risk whether they maintain their existing financial arrangements with physicians – in many cases, providing physicians with a windfall in the form of reimbursement for HOPD services for which they paid nothing – or amend those arrangements, potentially running afoul of the complex rules that govern physician contracts under the AKS and Stark law. These concerns are described in more detail in the attached Aug. 22 Hogan Lovells [memorandum](#) titled "Proposed 2017 Medicare Outpatient 'Site-Neutral' Changes – Concerns Under Fraud and Abuse Laws."

Because CMS cannot finalize its proposal without forcing impacted hospitals to accept significant compliance risk, it must 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 the their non-excepted HOPDs and for non-excepted items and services that they furnish in excepted HOPDs.

Again, we appreciate the opportunity to share our concerns. If your team has any questions or would like to discuss further, Maureen Mudron, deputy general counsel, is the point of contact at AHA. You can reach her at mmudron@aha.org or 202-626-2301.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

Enclosure: [Proposed 2017 Medicare Outpatient "Site-Neutral" Changes – Concerns Under Fraud and Abuse Laws](#)

Cc: Daniel R. Levinson, Inspector General, Department of Health and Human Services

TO American Hospital Association

FROM Hogan Lovells

DATE August 22, 2016

SUBJECT Proposed 2017 Medicare Outpatient "Site-Neutral" Changes—Concerns Under Fraud and Abuse Laws

The Centers for Medicare & Medicaid Services (“CMS”) recently issued a proposed rule¹ that would revamp the way Medicare reimburses hospitals and physicians for services performed at certain off-campus hospital outpatient departments (“HOPDs”). If adopted, these “site-neutral” payment rules would force some hospitals into new financial arrangements with referring physicians that present substantial compliance risk—and the very real potential for investigation or prosecution—under the federal fraud and abuse laws. In effect, the proposed rule would deem off-campus HOPDs that opened, or changed service lines or locations, in the last 10-months to be physician-owned clinics for reimbursement purposes, but not for operational purposes. The result would be that for any service provided to a Medicare beneficiary in such an off-campus HOPD, the hospital would remain responsible to staff, equip and maintain the facility, but 100% of Medicare reimbursement for the service would be paid to the treating physician, even when the physician is independent of the hospital. Were CMS to adopt the proposed rule, hospitals and treating physicians would be forced to choose between the substantial legal risk of entering into altered financial arrangements subject to scrutiny as well as potentially significant financial and criminal penalties under the fraud and abuse laws, on the one hand, or disrupting the delivery of patient care on the other.

A fundamental tenet of the fraud and abuse laws is that hospitals cannot provide free goods or services to referring physicians. In guidance under the federal Anti-Kickback Statute (“AKS”), the Office of Inspector General (“OIG”) for the Department of Health and Human Services has long warned that the provision of items and services for use in a physician’s practice that have the effect of reducing the physician’s cost of doing business can be remuneration implicating the statute’s felony provisions if offered or provided with the intent to unlawfully induce or reward referrals. In similar guidance under the physician self-referral law,² commonly referred to as the Stark Law, CMS has long held that providing items or services to a physician of any value greater than \$396 in a calendar year (adjusted annually for inflation), or leasing or providing office space, equipment or services to a physician for less than fair market value, can trigger the referral and billing prohibitions of that statute, regardless of intent. And both the OIG and CMS along with the Department of Justice and the federal courts have made it clear that paying a referring physician more than the fair market value of his or her services can have a catastrophic financial consequence for a hospital prosecuted under either statute. Those prosecutions may be brought by either a government prosecutor or, as is more often the case, a whistleblower seeking a bounty under the *qui tam*

¹81 Fed. Reg. 45,604 (July 14, 2016).

²Social Security Act § 1877; 42 U.S.C § 1395nn.

provisions of the civil False Claims Act, a statute whose penalties recently escalated to between \$11,000 and \$22,000 for each claim submitted in violation of the statutes plus, arguably, three times the amount Medicare paid on those claims.

Apparently recognizing the legal risks occasioned by any financial relationship between referring physicians and a hospital, in the proposed rule, CMS solicited comments on these fraud and abuse concerns. The unfortunate consequence of the rule, if adopted, will be to compel certain existing HOPDs (i.e., those off-campus HOPDs that opened, relocated or changed service lines after November 2, 2015) to assume substantial new legal compliance risks, along with the associated expense of defending against the investigations and whistleblower litigation that are likely to follow. While CMS has indicated that it may eventually develop a new payment system for such off-campus HOPDs after 2017, the details and effects of that yet-to-be-designed model are wholly unknown and unpredictable at this point. Until then, CMS would wedge these HOPDs into an ill-fitting physician payment system, and leave hospitals to face the daunting challenge of negotiating a series of new and complicated financial arrangements with referring physicians that would be necessary to continue offering services to patients at these existing hospital owned and operated clinics.

The following exemplify the unfortunate circumstances in which some of the affected hospitals could find themselves.

Providing free goods and services to physicians. Under the proposed rule, hospitals that rely on community physicians to staff off-campus HOPDs that opened, relocated or changed service lines after November 2, 2015, risk violating one of the basic commandments of the AKS and Stark Law: Hospitals should not provide free benefits to referring doctors. Going back several decades, CMS and the OIG have repeatedly warned that hospitals, laboratories and other facilities should not provide items, services or space to physicians free of charge if those facilities want to avoid fraud and abuse liability. CMS and the OIG have identified an array of benefits to physicians that may be problematic—ranging from the use of office space, medical equipment, and nursing or other staff services, all the way to low-value benefits such as a fax machine, sterile gloves, specimen collection needles, and registration fees for continuing medical education courses. Even where the benefits themselves have very little value, CMS and the OIG have alerted hospitals about severe compliance risks that may result.

The inevitable consequence of the proposed changes to the HOPD rules, however, is that community physicians would stand to receive a windfall from practicing at affected HOPDs. Specifically, physicians providing services at such off-campus HOPDs would be paid by Medicare to cover expenses as if the physicians owned and operated the facility, even though they would not. Normally, Medicare pays physicians at a lower “facility rate” when they practice at HOPDs, because the hospital pays and receives reimbursement for the overhead expenses of providing the service—the building, equipment, non-physician clinical staff, medical supplies, patient health records, air conditioning, bed sheets, and the like. As long as hospitals continue to operate HOPDs, the proposed rule does not change the fact that the hospitals will remain financially responsible for these costs of providing care.³ Thus, under CMS’s proposal, hospitals would provide physicians the

³See 42 C.F.R. § 413.65(d)(3) (requiring that the expenses of an HOPD be integrated with the hospital). In the proposed rule, CMS has made clear that off-campus HOPDs that are not excepted from the new site-neutral provision would nevertheless continue to be considered HOPDs.

completely free benefit of reimbursement for HOPD services for which they paid nothing. Community physicians would effectively receive this benefit from the hospital every time they are paid by Medicare for providing services in an HOPD affected by the proposed rule.⁴ Given the potentially substantial windfall to physicians and the prospect of False Claims Act enforcement, hospitals should not be forced into having to negotiate themselves out of this situation.

Further, it is unlikely that hospitals would have a realistic option to avoid these risks, especially without significant disruption to patient care. If the proposed rule is adopted, in the short time before its January 1, 2017 effective date, it simply would not be feasible for most hospitals to make wholesale changes to their existing HOPD clinical care arrangements.⁵ Thus, if hospitals attempted to keep the affected HOPDs open, they would find themselves between a rock and a hard place, choosing between potential fraud and abuse risk and disruption to patient care. Moreover, even if hospitals somehow could negotiate new contracts with physicians, as CMS seems to contemplate, hospitals may still be subject to fraud and abuse liability if they are unable to do so in a way that assures these arrangements are fully consistent with fair market value and the other requirements of the fraud and abuse laws, as well as under CMS and OIG guidance limiting how often physician contracts may be amended (as discussed below).

Unable to revise existing contracts. In an attempt to address the problems identified above and other consequences of the proposed rule, including those discussed below, hospitals would need to turn on a dime to restructure their “business arrangements” in order to operate affected HOPD facilities as of January 1, 2017. In adjusting to an alien payment system for off-campus HOPDs after that time, it is inevitable that hospitals would need to amend (and perhaps re-amend) their business arrangements in ways that are not yet foreseen. In addition, hospitals would likely need to transform these arrangements anew in 2018 or whenever the off-campus HOPD payment system may be changed again.

⁴For example, a physician visiting a patient in a hospital’s wound care clinic to monitor a patient’s progress, perhaps while the patient is recovering after an inpatient stay, would be paid more for the same visit under the proposed system for 2017 than he or she would be paid if the physician saw the patient at a hospital outpatient clinic that is not subject to the payment change in proposed rule. Under the proposed rule, the physician would be paid as if the clinic was a physician office where the physician pays the rent and other overhead costs—but in actuality, the hospital would be taking on those expenses.

⁵CMS did not specify how hospitals could address the many challenges posed by the proposed rule, recognizing only that business arrangements may change. See 81 Fed. Reg. 45,689. Two unrealistic outcomes that CMS may be expecting are (1) that hospitals would enroll affected HOPDs in Medicare as physician practices and, before the end of 2016, find a way to employ or contract with enough physicians to continue providing care at those HOPDs, or (2) community physicians currently practicing at off-campus HOPDs would “lease” (i.e., pay for) the HOPD’s space, equipment, staff and supplies, so that the physicians could legitimately bill Medicare at the non-facility rate. It would be nearly impossible for hospitals to secure these arrangements before January 1, 2017. But even if the timing were plausible, hospitals would have little or no leverage with physicians in negotiating these arrangements given the inflexible demands of the proposed rule and the need to continue providing patient care.

There are many operational barriers to such rapid and wholesale changes, including negotiations for hospitals to receive payment from physicians and other practitioners who expect hospitals to fulfill their existing contractual obligations on the terms specified in the agreements. By making physicians the recipients of Medicare payments, CMS would strengthen the hand of physicians who may logically seek to pay as little as possible for the items and services being provided by the hospital, potentially even less than fair market value.

Even aside from these points, though, CMS and the OIG have taken a limited view of the number of times and circumstances in which hospitals may amend their clinical contracts. For example, numerous Stark Law exceptions and AKS safe harbors require that compensation terms be “set in advance” for the duration of the arrangement between the parties. CMS has interpreted the “set in advance” condition to require that the terms of amended physician compensation must remain in place for at least one year following amendment. This could present a compliance concern, for example, where a hospital has already amended a physician contract this year or where a hospital does fully not anticipate the changes that would be required under the proposed system and later needs to revise its physician contracts. In short, especially under CMS and OIG interpretations, steadiness of contractual terms is key to satisfying critical protections under the fraud and abuse laws, but the proposed rule would require substantial changes and produce contractual turmoil.

Paying physicians for supervision for which the physician is personally responsible. Another basic principle of the Stark Law and AKS under longstanding CMS and OIG guidance is that hospitals should not pay physicians for services that the hospitals do not reasonably need, or pay physicians to provide services that the physician is already required to provide on his or her own. By abruptly terminating payment under OPSS payment and switching to physician payment, CMS would put hospitals at risk of violating this principle as well, specifically in relation to hospitals’ arrangements that are designed to comply with CMS’s supervision rules for HOPDs.

As a condition of receiving Medicare payment under existing Medicare rules, off-campus HOPDs must have a physician or advanced practitioner physically present to directly supervise most therapeutic services, at all times.⁶ If an off-campus HOPD does not arrange with a clinician to supervise these services, the hospital risks a False Claims Act lawsuit or an action by Medicare to recoup payment for the HOPD services.

Under the proposed rule, the HOPD supervision requirement (and other conditions of hospital payment) would seemingly no longer apply because services in the HOPD would be billed as *physician* services and the physicians would be responsible for supervising the care at their own expense. But the rules that will be used by other payers, especially federal healthcare programs such as Tricare and Medicaid, may not immediately be clear, and between confusion over the relevant payer rules and risks in terminating existing contracts, hospitals may be stuck with paying physicians for supervision under their current contracts, even where CMS would now pay the physicians directly for some portion of those services. This is especially likely because HOPDs would be required to have supervision in place until the moment the proposed rule becomes effective, at midnight on January 1, 2017. That is a problem for HOPD supervision contracts with community physicians, with whom hospitals often contract to supervise outpatient services. By

⁶See 42 C.F.R. § 410.27(a)(1)(iv); 73 Fed. Reg. 68702 (Nov. 18, 2008).

continuing to honor their contractual obligations to pay physicians for supervision, hospitals would be paying physicians for something that they are required to do themselves in order to be paid by Medicare. This is precisely the conduct that CMS and the OIG have repeatedly exhorted hospitals against.⁷ Again, CMS should not be putting hospitals in this difficult position.

* * * *

The CMS proposed site-neutral changes would potentially create unavoidable collateral risks under the federal fraud and abuse laws, by pushing hospitals into altered arrangements similar to those that CMS and the OIG have admonished over the years, while also placing hospitals at a significant disadvantage in the complex renegotiation of those arrangements. Alongside other compliance concerns referenced by CMS in the proposed rule, hospitals with new or changed off-campus HOPDs may be confronted with substantial legal risks as they continue to strive to provide high-quality care.

⁷Specifically, hospitals would risk running afoul of two conditions that are almost universally required to be met in order to receive protection under a Stark Law exception or an AKS safe harbor—that payments must be “fair market value” for services actually performed and serve a “commercially reasonable” or “legitimate business” purpose. See, e.g., 42 C.F.R. § 411.357(d); 42 C.F.R. § 1001.952(d).