

PUBLICATION

CMS Re-proposes Ban on Per-Click Fees for Space and Equipment Leases under Stark [Ober|Kaler]

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In the CY 2017 Medicare Physician Fee Schedule (CY 2017 MPFS), the Centers for Medicare & Medicaid Services (CMS) issued proposed updates to the physician self-referral law (Stark law). The primary Stark law update focused on unit-based compensation in certain leases of office space or equipment. The D.C. Circuit Court (the Court) prompted CMS to re-address this issue in *Council for Urological Interests v. Burwell* on June 12, 2015,¹ which challenged CMS's rulemaking authority related to the FY 2009 IPPS final rule.

In the current proposed rule, CMS provides an overview of the Stark law's regulatory history. Within this background, CMS highlights and excerpts several passages from the regulatory history addressing certain per-unit-of-service (per-click) compensation formulas. A 1993 Conference Committee Report and CMS rulemakings formed the basis of Council for Urological Interests' (CUI's) case against the Secretary. CUI challenged the Secretary's authority related to the prohibition on per-click rental charges for the lease of equipment found at §411.357(b)(4)(ii)(B).

The Court concluded that “[t]he text of the statute does not unambiguously preclude the Secretary from using her authority to add a requirement that bans per-click leases. To the contrary, the statutory text of the exception clearly provides the Secretary with the discretion to impose any additional requirements that she deems necessary ‘to protect against program or patient abuse.’”² Although the Court determined that the Secretary was not outright prohibited from considering and perhaps implementing a ban on per-click leases, the reasoning provided by CMS in the FY 2009 IPPS final rule was insufficient. The Court felt that the rule contained “an unreasonable interpretation of the conferees' statements” in the Conference Committee Report. As a result, the Court remanded the case to CMS for a fuller consideration of the legislative history. The CY 2017 MPFS proposal is intended to address that instruction from the Court.

CMS proposes to include at “§§ 411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B) the requirement that rental charges for the office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.” CMS is relying on the authority granted to the Secretary in sections 1877(e)(1)(A)(vi) and (B)(vi) of the Act to re-propose the requirement in the exceptions at § 411.357(a) and (b) for the rental of office space and equipment, respectively. CMS references the authority granted to the Secretary in section 1877(b)(4) of the Act to re-propose the requirement in the exceptions at § 411.357(l) and (p) for fair market value compensation and indirect compensation arrangements, respectively.

In the current proposal, CMS reiterates that the authority granted to the Secretary was intended to permit CMS to identify actual or potential program or patient abuse and address those concerns with revisions to the Stark law regulations. The Agency notes that although Congress did not outright prohibit per-click lease arrangements, neither the statute nor the Conference Report requires that per-click arrangements must be permissible. CMS believes that there is sufficient concern of abusive arrangements that the proposed per-click prohibition is necessary to protect beneficiaries and the Medicare program.

The concerns identified by CMS reflect those that the Agency included in prior rulemakings as well as additional concerns raised previously by commenters in response to those rulemakings. CMS notes studies that have found that physicians with financial relationships with entities to which they refer ordered more services than physicians without those same relationships.³ CMS also cites recent studies by GAO that reached the same conclusions, including the risk of patient-steering, reductions in quality of care and patient outcomes, as well as possible increased costs to the Medicare program. CMS specifically references concerns that physicians might limit treatment choices for patients to those for which the physician will realize a profit even if the more appropriate choice for the patient is no treatment; refer to the lessee rather than an entity that may use equipment better suited for the particular patient; and inconvenience patients by referring to the location that will financially benefit the physician even if not the patient's preferred site.

Based on these concerns, CMS believes that the proposed restriction on the specified per-click lease arrangements is necessary to protect against program or patient abuse. CMS does note, however, that this is not intended to be an absolute ban on per-click compensation arrangements. The revisions proposed in this rulemaking are targeted only at those lease arrangements under which the lessor generates the payment from the lessee through a referral to the lessee for a service to be provided in the rented office space or using the rented equipment. CMS makes clear that in general, per-unit of service rental charges for the rental of office space or equipment would be permissible. However, if the referral for the services provided in the office were generated by the lessor, the prohibition would apply and the compensation for the space or equipment in those instances would have to be calculated in a manner that did not reflect the unit of services being ordered by the lessor.

For further support of CMS's concerns related to per-click lease arrangements under which the per-unit rate reflects referrals from the physician-lessor, the Agency turned to the OIG. CMS makes brief note of two advisory opinions published by the OIG in 2003 and 2010 that express the OIG's concerns with per-unit of service compensation arrangements. The OIG's opinions were based upon concerns of overutilization and per-click fee arrangements that are "inherently reflective of the volume or value of services ordered and provided." Although they express some of the same concerns, it is interesting that both advisory opinion address service arrangements and not lease of space or equipment as is CMS's focus in the proposal at issue.

Comments

The fact that CMS is re-proposing its prohibition on per-click payments for certain leases of space and equipment raises questions about the current status of the prohibition. The Court's decision asserts that CMS overreached its authority in issuing its prior prohibition. This raises the question of whether the prohibition is currently effective. Does the rule have the force of law while these further proceedings are pending? How should a provider respond if it identifies an otherwise prohibited per-click arrangement prior to the current proposal being finalized? Should a provider's approach differ based on whether it is structuring an arrangement going forward or determining whether there is an affirmative disclosure obligation for past conduct? These are difficult and complicated questions that should be discussed with experienced Stark law counsel.

Comments on the proposal are due by September 6, 2016.

¹ *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. June 12, 2015).

² *Council for Urological Interests*, 790 F.3d at 219.

³ 63 Fed. Reg. 1661.