As part of its November 15, 2016, Calendar Year 2017 Physician Fee Schedule final rule, the Centers for Medicare and Medicaid Services (CMS) updated and clarified its ban on the use of per-unit of service (i.e., “per-click”) rental charges in office space and equipment leases. Although CMS initially determined that the Physician Self-Referral Law (the “Stark Law”) permitted such charges, the agency effectively reversed its position in a 2008 final rule by revising the regulatory Stark Law exceptions for space and equipment rentals (as well as two other related exceptions). This reversal, however, drew the ire of the D.C. Circuit Court of Appeals, which, in a June 2015 opinion, remanded the per-click rental charge prohibition back to the district court “with instructions to remand to [CMS] for further proceedings consistent with this opinion.” Thus, CMS’s newly promulgated final rule addresses the appellate court’s decision and seeks to reaffirm (with a purportedly stronger rationale) the agency’s ban on per-click rental charges in space and equipment leases.

The Stark Law and Its Rental Exceptions

Absent an exception, the Stark Law prohibits a physician (or an immediate family member of the physician) from referring patients for certain designated health services (“DHS”), for which payment may be made under Medicare, to an “entity” with which the physician (or an immediate family member) has a “financial relationship.” Likewise, the statute prohibits the DHS-furnishing entity from filing claims with Medicare for those referred services. The Stark regulations define financial relationship as either a direct or indirect ownership or compensation arrangement between the DHS entity and the referring physician.

However, numerous Stark Law exceptions exist in both statute and regulation, including protections for physician leases of office space or medical equipment to or from a DHS entity, assuming the lease arrangement satisfies all requirements of the applicable exception. Pertinently, the statutory exceptions for both office space and equipment leases require that “the rental charges over the term of the lease [must be] set in advance, [must be] consistent with fair market value, and [must not be] determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.”

Interpreting the “volume or value” standard for these (as well as other) exceptions, CMS stated in a 1998 proposed rule that compensation could be based on units of service (such as “per-use” medical equipment rentals) so long as the units of service did not include services provided to patients who were referred by the physician receiving payment under the compensation arrangement. Additionally, CMS proposed that:

[A]rrangements in which a physician rents equipment to an entity that furnishes [DHS],

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1 42 U.S.C. § 1395nn.
2 Id.
3 42 C.F.R. § 411.354.
4 See 42 U.S.C. §§ 1395nn(e)(1)(A) and 1395(e)(1)(B) (statutory exceptions for the rental of office space and equipment, respectively); see also, 42 C.F.R. §§ 411.357(a) and 411.357(b) (regulatory exceptions for the rental of office space and equipment, respectively).
such as a hospital that rents an MRI machine, with the physician receiving rental payments on a “per-use” or “per-click” basis (that is, a rental payment is generated each time the machine is used) do not prohibit the physician from otherwise referring to the entity, provided that these kinds of arrangements are typical and comply with the fair market value and other standards that are included under the rental exception.7

Conversely, because a physician’s compensation paid under an equipment lease (or, likewise, an office space lease) can never reflect the volume or value of the physician’s own referrals, CMS proposed in 1998 that rental payments could not be charged on a “per-use” or “per-click” basis when, for example, the MRI machine leased by the hospital is used to treat a patient referred to the hospital for an MRI by the physician lessor.8

Importantly, however, in response to public comments on the 1998 proposed rule, CMS revised the initial proposal and permitted unit-based compensation formulas in its final rule, even in situations where the physician receiving the payment had generated such payment by way of his own referral to the DHS entity. In reversing its position, CMS highlighted a 1993 House Conference Committee report in which the drafters of the Stark statute seemed to suggest that rental charges for office space and equipment leases may be based on daily, monthly, or other time-based usage, “so long as the amount of the time-based or units of service rates does not fluctuate during the contract period based on the volume or value of referrals between the parties to the lease or arrangement.”9

**Council for Urological Interests v. Burwell**

Over a decade later, CMS ultimately finalized a rule effectively prohibiting per-click compensation formulas for determining rental charges in office space and equipment leases.10 In doing so, CMS revised the language of the regulatory exceptions for office space and equipment leases to prohibit the calculation of rental charges “[u]sing a formula based on . . . [p]er-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.”11

Shortly thereafter, an association of physicians (the Council for Urological Interests) who participated in leasing agreements with hospitals (under which they charged the hospitals for the equipment on a per-use basis and performed procedures using the equipment) filed suit to challenge CMS’s authority to ban per-click leases under the Administrative Procedures Act.12 The case ultimately reached the D.C. Circuit Court of Appeals, which ruled in favor of the Council.

The court initially agreed that CMS did have the authority to promulgate regulations in the interest of protecting the Medicare program, and that the Stark statute did not preclude the agency from banning the use of per-click rental charges.13 Indeed, “[t]o the contrary, the statutory text of the [equipment rental] exception clearly provides the [government] with the discretion to impose any additional requirements that [it] deems necessary ‘to protect against program or patient abuse.’”14 Nevertheless, the court took issue with CMS’s statutory interpretation with respect to the per-click ban. Specifically, the court emphasized CMS’s reversal in its interpretation of the 1993 Conference Report from Congress; although CMS had initially (in its 1998 final rule) determined that the Conference Report authorized per-click rental charges, CMS had reinterpreted the same Conference Report in its 2008 final rule to ultimately justify the per-click ban.15 CMS’s rationale for this reversal, said the court, “is plainly not a reasonable attempt to grapple with the Conference Report; it belongs instead to the cross-your-fingers-and-hope-it-goes-away school of statutory interpretation.”16

For this reason, the appellate court remanded the case back to the district court, instructing the lower court to

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13 Id. at 219
14 Id.
15 Id. at 223
16 Id.
subsequently remand per-click prohibition back to CMS for reconsideration. Specifically, the court stated that CMS should consider whether a ban on per-click rental charges comports with the 1993 Conference Report.

Reestablishing the Per-Click Ban

In response to the D.C. Circuit’s ruling in *Council for Urological Interests*, on November 15, 2016, CMS reissued its ban on per-click rental charges in both office space and equipment lease arrangements. However, CMS emphasizes that it “did not propose and [is] not finalizing an absolute prohibition on rental charges based on units of service furnished” and that “[i]n general, per-unit of service rental charges for the rental of office space or equipment are permissible.” As CMS had previously stated, the per-click ban applies only “to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.”

In a second effort to reconcile the 1993 Conference Report with the per-click prohibition, the final rule argues that “the physician self-referral statute responds to the context of the times in which it was enacted . . . [and] incorporates sufficient flexibility to adapt to changing circumstances and developments in the health care industry.” To that end, CMS reiterated its primary concerns with permitting physician lessors to charge rent to lessees for each patient referred to the leasing entity – namely, overutilization of services, patient steering, reduction in the quality of care and patient outcomes, and increased costs to the Medicare program. However, many commentators took issue with the re-proposed (and now final) rule, arguing that CMS had simply restated its rationales from its 2008 final rule and had not even attempted to reconcile the Conference Report with the per-click ban.

Conclusion

Despite its tortured procedural history, the ban on per-click rental charges in office space and equipment lease agreements has been re-finalized by CMS. Although CMS’s clarifications and purportedly new rationales for implementing this rule may again come under fire from the health care industry, as it stands, providers should remain wary of this prohibition and ensure that all lease agreements entered into with a referral source (or an entity to which the provider sends referrals) meet the applicable requirements for the Stark exceptions for office space or equipment leases.

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17 Id. at 214
19 Id. at 80526.
20 Id.
21 Id. at 80527.
22 Id. at 80528.
23 Id. at 80530.
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