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Navigating CMS' Tangled Web Of Stark Law Interpretation

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On June 12, 2015, the D.C. Circuit decided Council for Urological Interests v. Burwell,[2] issuing several opinions with significant implications for the interpretation and implementation of the federal physician self-referral statute[3] and its implementing regulations[4] (collectively, the "Stark Law").

Specifically, the D.C. Circuit upheld a 2008 regulation expanding the definition of the phrase "entity furnishing designated health services" but cast into serious doubt the continuing viability of another 2008 regulation, which bans unit-based (or "per-click") equipment leases where the landlord is in a position to influence the amount of total rental charges through its own referrals.

The case itself, the Stark Law rules it addresses and the potential domino effect of the decision are analyzed in Sections II and III of this article. Before turning to that analysis, Section I provides a brief overview and summary of the pertinent Stark Law provisions.

I. Stark Law Background

Basic Elements

The Stark Law has two separate prohibitions: a referral prohibition and a billing prohibition. Pursuant to the referral prohibition, in the absence of an applicable exception, if a physician (or his or her immediate family member) has a “financial relationship” with an “entity,” that physician may not refer a patient to the entity for the furnishing of designated health services ("DHS") that may be paid for by Medicare.[5] (In Stark Law parlance, a referral that violates the referral prohibition commonly is referred to as a "tainted" referral.) The billing prohibition, in turn, prohibits billing Medicare (or any other person or entity) for DHS furnished pursuant to a tainted referral.[6] Unpacking these prohibitions a bit:

- A “financial relationship” may take one of four forms: a direct or indirect "ownership or investment interest" by the referring physician in the furnishing entity, or a direct or indirect "compensation arrangement" between the referring physician and the furnishing entity.[7]

- DHS covers a wide range of items or services, including inpatient and outpatient hospital services — whether furnished directly or under arrangements — other than lithotripsy.[8]

- Congress has enacted and the Centers for Medicare and Medicaid Services has promulgated a large number of statutory[9] and regulatory[10] exceptions, including several that deal with fairly common arrangements, such as the furnishing of personal services and the rental of space and equipment.

In terms of sanctions, if tainted claims are presented for payment to Medicare, such claims should be denied.[11] In the event that such claims are paid, however, the Stark Law regulations impose an affirmative refund obligation on the part of the entity that collected the payments.[12] In addition, violation of the referral and/or billing prohibitions may trigger various administrative sanctions[13] and, with increasing frequency, may serve as the basis for federal civil False Claims Act liability on the ground that a claim for items and services furnished pursuant to a tainted referral is a "false" claim.

Furnishing Entity Definition

As noted above, the Stark Law is triggered by physician referrals to an "entity for the furnishing of designated health services" (or "furnishing entity" for short).[14] Over the years, questions have arisen over what it means to be a "furnishing entity." For example, is it the entity that actually provides the DHS at issue, the entity that bills for the DHS, both entities, or something else? A hypothetical helps to demonstrate the point. Consider the following, which we will refer to as Hypothetical 1:

- Three physicians (P1, P2 and P3) form a company (RadCo) that operates a free-standing facility that furnishes a wide variety of radiology and other imaging services to patients in the community.

- RadCo owns all of the facility's MRI, CT, ultrasound and other radiology equipment and employs all of the clinical and nonclinical personnel necessary to provide these services at its facility. RadCo has one MRI machine and an MRI technician that are not fully utilized.

- A hospital in the community ("hospital") also furnishes radiology and other imaging services to patients in the community. Hospital has a need for an MRI machine and the services of an MRI technician.

- Hospital and RadCo enter into an arrangement pursuant to which RadCo agrees to lease an MRI machine and provide the services of one of RadCo's MRI technicians to hospital.

- Under the arrangement: (1) the MRI machine is located at hospital, which pays RadCo a predetermined "per-click" amount each time the leased MRI is used for a hospital patient, (2) the MRI technician works at hospital, which pays RadCo an hourly rate for the technician, and (3) hospital bills patients and payers for all MRI services furnished to hospital patients.

In Hypothetical 1, if a physician in the community refers a Medicare patient to hospital for an MRI:

- Is hospital the "furnishing entity" on the grounds that it is the entity that is providing a portion of the items and services necessary to provide the MRI and/or billing for it;,

- is RadCo the "furnishing entity" on the ground that it owns the MRI and employs the MRI technician used in connection with the MRI;, or

- are both hospital and RadoCo "furnishing entities" with respect to the MRI?

The answer to this question has largely depended on when it was asked. In a proposed rule-making in 1998,[15] CMS' predecessor, the Health Care Financing Administration ("HCFA"), first took up the question in earnest:

The health care community has expressed some confusion about when an entity is one involved in the "furnishing of" designated health services. We have, for example, received questions about which entities are the relevant ones when some entities only bill for services, while others actually directly ‘‘furnish’’ the services.[16]

For example, the HCFA noted, in an "under arrangements" situation, a hospital "contracts with a separate provider to furnish services to the hospital’s ... patients, for which the hospital ... ultimately bills."[17]

We believe that, absent an exception, the referral prohibition applies to a physician’s referrals to any entity that directly furnishes designated health services to Medicare ... patients. We believe the prohibition also applies to referrals to any entities that arrange ‘‘for the furnishing of’’ these services to Medicare [beneficiaries] ... by contracting with other providers, whenever it is the arranging entity that bills for the services.[18]

Thus, as of 1998, the HCFA was proposing that an entity should be considered a "furnishing entity" if it was: (1) the entity that actually performed the DHS at issue and/or (2) the entity that billed Medicare for that DHS.

Three years later, however, when the HCFA finalized its definition of "furnishing entity," the agency — largely without explanation — adopted a much narrower rule.[19] Under the 2001 final rule, only the entity that billed Medicare for the DHS at issue was deemed to be the furnishing entity of that DHS.[20] Specifically, the 2001 final rule provides that a "person or entity is considered to be furnishing DHS if it is the person or entity to which HCFA makes payment for the DHS," whether directly or upon assignment or reassignment.[21] In Hypothetical 1, then, as of 2001, where a physician referred a Medicare patient to hospital for an MRI, only hospital (and not RadCo) would be considered the "furnishing entity" of the MRI, as hospital was the only entity that billed Medicare for the MRI.

Six years later, in a 2007 proposed rule-making,[22] CMS revisited its definition of "furnishing entity." CMS began by noting its concerns "with services provided under arrangements to hospitals and other providers," particularly "hospital outpatient services for which Medicare pays on a per-service basis."[23] "We have received anecdotal reports," CMS continued, of "hospital and physician joint ventures that provide hospital imaging services formerly provided by the hospital directly."[24] According to CMS:

> We believe that more and more procedures are being performed as arranged for hospital services.

> There appears to be no legitimate reason for these arranged for services other than to allow referring physicians an opportunity to make money on referrals for separately payable services. Many of the services furnished ... were previously furnished directly by the hospitals, and in most cases, could continue to be furnished directly by hospitals…
>
> Arrangements so structured are particularly problematic because referrals of physician-owners of leasing, staffing and similar entities to a contracting DHS entity can significantly increase the physician-owned entity's profits and investor returns, creating incentives for overutilization and corrupting medical decision-making.
>
> [S]ervices furnished under arrangements to a hospital are furnished in a less medically intensive setting than the hospital, but billed at higher hospital outpatient [prospective payment system] rates, which not only costs the Medicare program more, but also costs Medicare beneficiaries more in the form of higher deductibles and coinsurance.[25]

In light of these considerations, CMS once again proposed modifying the definition of furnishing entity to include "both the person or entity that performs the DHS, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS."[26]

In 2008, the agency adopted its proposed rule, effective Oct. 1, 2009.[27] Since then, the rule has been as follows: A person or entity is considered to be "furnishing DHS" if the person or entity (1) has "performed" services that are billed as DHS or (2) has presented a claim to Medicare for the DHS.[28] CMS justified its final decision on the following grounds:

- The Stark Law's billing prohibition states that an entity that furnishes DHS may not "present" or "cause to be presented" a tainted claim. CMS posited that if the "furnishing" entity means only the entity that bills for DHS, then there would be no need to include the language "cause to be presented" in the billing prohibition.[29]

- The agency further reasoned that the revised definition is consistent with the Stark Law's underlying policy, which is to "disallow self-referrals involving an ownership or investment interest except in a few specified instances."[30] It would be illogical, CMS suggested, for "Congress ... to prohibit a physician from referring patients to a freestanding laboratory or imaging facility that he or she owns, but ... to permit the physician to make such a referral simply because the laboratory or imaging service is sold to another entity that does the billing for it."[31]

- Finally, CMS noted that the change would preclude parties from circumventing the Stark Law's prohibitions "merely by arranging for the service provider to reassign to another, for a fee, the right to receive Medicare payment."[32]

One critical question left open by the 2008 rule-making is what it means for an entity to "perform" services billed as DHS. CMS declined to "provide a specific definition of the term 'perform'" on the ground that the agency wanted the term to have its common meaning.[33] In the view of CMS,

providers, suppliers and practitioners "generally know when they have performed a service and when they are entitled to bill for it."[34] Nonetheless, CMS did clarify that an entity that merely sells or leases space or equipment that is used for medical purposes does not, without more, "perform" DHS.[35] Similarly, CMS noted that an entity that furnishes only staffing, management or billing services is not a performing entity.[36]

Given these clarifications, the 2008 rule change arguably would not have any impact on Hypothetical 1. As noted above, pursuant to the rule in place prior to Oct. 1, 2009, where a physician referred a Medicare patient to hospital for an MRI, only hospital, and not RadCo, would be deemed the furnishing entity, as hospital was the only entity billing Medicare for the MRI. As of Oct. 1, 2009, the result would not be different unless it could be said that RadCo (and not hospital) "performed" the MRI. CMS' clarifications indicate this should not be the case. That is, simply by leasing equipment to hospital, and providing certain staffing services to hospital, RadCo does not become the entity that has "performed" an MRI that is: (1) furnished in hospital space and (2) involves the utilization of hospital supplies and clinical and nonclinical staff other than those supplied by RadCo.

Other arrangements, however, pose closer calls. (This issue is discussed further in Section IV below.) At a minimum, the expanded definition of "furnishing entity" has made it more difficult to analyze and comply with the Stark Law. Simply put, the chances of finding applicable exceptions that cover a physician's referrals to two DHS entities — the entity that performed the DHS and the entity that billed for it — are slimmer than if there is only one DHS entity.

Equipment Rental Exception

As mentioned earlier, Congress and CMS have created a large number of Stark Law exceptions, including an exception expressly designed to protect arrangements pursuant to which a physician leases medical equipment to or from a DHS entity. The statutory equipment rental exception protects "[p]ayments made by a lessee of equipment to the lessor of the equipment for the use of the equipment," provided a number of requirements are met (e.g., the lease must be set out in writing, signed by the parties and specify the equipment covered by the lease).[37] For purposes of this article, we will focus on two of the statutory exception's requirements:

- "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" ("rental charge requirement"); and

- "the lease [must meet] such other requirements as [CMS] may impose by regulation as needed to protect against program or patient abuse" ("other regulatory requirements").[38]

Prior to 1998, the regulatory equipment lease exception largely tracked the statutory exception with respect to the rental charge requirement.[39] In its 1998 proposed rule-making, however, the HFCA noted that it had been "asked about situations in which a physician rents equipment to an entity that furnishes a DHS, such as a hospital that rents an MRI machine, with the physician receiving rental payments on a 'per-click' basis (i.e., rental payments go up each time the machine is used)."[40] The HCFA's response reflected its discomfort with "per-click" rental payments in certain circumstances:

We believe that this arrangement will 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. However, because a physician's compensation under this exception cannot reflect the volume or value of the physician's own referrals, the rental payments cannot reflect ''per click'' payments for patients who are referred for the service by the lessor physician.[41]

Again, a hypothetical may be instructive. Assume the following:

- Physician A owns an MRI machine that she leases to hospital;
- Hospital places the MRI in its radiology department and it is used to provide radiology services to hospital outpatients and inpatients; and
- Physicians A, B and C have occasion to refer Medicare beneficiaries (and other patients) to hospital for MRI procedures.

Under the HCFA's 1998 proposed rule, the hospital-physician A equipment lease could provide for hospital to pay physician A on a per-click basis for MRIs furnished to Medicare patients referred to hospital by physician B and C but not for Medicare patients referred to hospital by physician A because, in the latter case, such compensation would plainly reflect the volume or value of physician A's own referrals.

In 2001, however, when it came time to finalize the regulatory equipment rental exception, the HCFA's position with respect to the rental charge requirement changed. This was due in part to the agency's review of the legislative history of the statutory equipment rental exception and, more specifically, the relevant conference committee report, H.R. Rep. No. 103-213 (1993). The 1993 Conference Report provides that:

[t]he conferees intend that charges for space and equipment leases may be based on daily, monthly, or other time-based rates, or rates based on units of service furnished, 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.[42]

In the face of this legislative history, CMS retreated, if only grudgingly. "Despite the obvious potential for abuse," the agency noted, "given the clearly expressed congressional intent in the legislative history, we are permitting 'per use' payments even when the physician is generating the referrals."[43]

Six years later, however, CMS took another run at the issue.[44] In a proposed Stark Law rule-making in 2007, the agency — without even mentioning the 1993 conference report — stated that, upon reconsideration,

we are proposing that space and equipment leases may not include unit-of-service based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by a physician lessor to the entity. We believe that such arrangements are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee ...[45]

When commenters on CMS' proposed rule reminded the agency of the 1993 conference report — and CMS' 2001 interpretation thereof — the agency, in effect, decided to reinterpret the conference report. More specifically, when it finalized its proposed rule in 2008, CMS stated that "[a]lthough we agree that Congress specifically intended to permit certain per-click leases, we disagree that Congress intended an unqualified exception for per-click leases under the physician self-referral statute."[46] That is:

We recognize that in the [2001] final rule, we stated that the legislative history of the space and equipment lease exceptions led us to the conclusion that Congress clearly intended to permit leases that included per-click payments even for services provided to patients referred by the physician lessor. However, upon further analysis of the legislative history, we no longer believe that the interpretation we adopted in [2001] is the only reasonable interpretation of the statute and legislative history.[47]

As noted above, the 1993 conference report provides that charges for space and equipment leases may be based on time-based or units of service rates, provided those rates do not fluctuate based on the volume or value of referrals between the parties. According to CMS (in 2008):

Where the total amount of rent (that is, the rental charges) over the term of the lease is directly affected by the number of patients referred by one party to the other, those rental charges can arguably be said to ‘‘take into account’’ or ‘‘fluctuate during the contract period based on’’ the volume or value of referrals between the parties. Thus, both the statutory language and the conference report can reasonably be interpreted to exclude from the space and lease exceptions leases that include per-click payments for services provided to patients referred from one party to the other.

Accordingly, in its final rule in 2008, CMS revised the regulatory equipment and space rental exceptions, as well as two other exceptions that could potentially protect such rental arrangements — the exceptions for fair market value compensation and indirect compensation arrangements — to prohibit per-click compensation.[48]

II. Council for Urological Interests v. Burwell

Background

On June 12, 2015, the D.C. Circuit decided Council for Urological Interests v. Burwell.[49] The appellant, "a group of joint ventures principally owned by urologists" that "lease laser technology to hospitals," filed the underlying lawsuit in 2009. The suit alleged that the two CMS rules discussed above — those (1) defining a furnishing entity to include both performing and billing entities ("furnishing entity rule") and (2) banning per-click compensation in equipment rental arrangements ("equipment per-click rule") — exceeded the agency's authority under the Administrative Procedures Act.

The case initially was dismissed by the district court for lack of subject matter jurisdiction but, on appeal, that decision was reversed.[50] On remand, the district court granted the government’s motion for summary judgment, concluding that the two rules were entitled to Chevron deference and that CMS' interpretation of the statute was reasonable.[51] On appeal, the D.C. Circuit, following a "sometimes arduous journey through the tangled [Stark Law] regime," affirmed in part and reversed in part, holding that while CMS was authorized to promulgate the furnishing entity rule, it was not authorized to

promulgate the equipment per-click rule.[52]

Chevron Standard

The D.C. Circuit began its analysis by noting that "[w]hen Congress gives an agency authority to interpret a statute" — such as CMS' authority to interpret the Stark Law — federal courts "review the agency's interpretation [of that statute] under the deferential two-step test" set forth in Chevron USA Inc. v. Natural Resources Defense Council Inc., 467 U.S. 837 (1984).[53] The first step requires determining "whether Congress has directly spoken to the precise question at issue"; if so, the court "give[s] effect to congressional intent."[54] If, on the other hand, the statute is "silent or ambiguous" on the matter, the court moves to step two, and asks whether the agency's interpretation is "based on a permissible construction of the statute"; if so, the court defers to the agency's interpretation.[55]

Furnishing Entity Rule

With respect to the furnishing entity rule, the Council for Urological Interests conceded that the Stark Law was sufficiently ambiguous on the definition of "furnishing entity" to move directly to Chevron step two (i.e., is the rule rationally related to the goals of the Stark Law).[56] The D.C. Circuit concluded yes, "defining the 'entity furnishing designated health services' to include the entity providing the services is a permissible construction of the statute."[57] According to the court, "this is apparent from a simple reading of the statute itself," throughout which "the terms 'provide' and 'furnish' are used interchangeably."[58] "Moreover," the court continued, "this definition furthers the purpose of the statute by closing a loophole otherwise available to physician-owned entities that would allow circumvention of the purpose of the Stark Law merely by having [another entity] bill Medicare for the services."[59] In sum, the court concluded, the furnishing entity rule "is a reasonable construction of the statute that is entitled to deference."[60]

Equipment Per-Click Rule

With respect to the equipment per-click rule, a majority of the three-judge panel rejected the Council for Urological Interests' argument that the Stark Law and its legislative history "make[ ] it plain that [CMS] must allow per-click leases."[61] With respect to the statutory text, the majority noted that the Stark Law's statutory equipment rental exception not only "is silent regarding the permissibility of per-click leases,"[62] but "explicitly permits [CMS] to impose additional conditions on equipment rental agreements"[63] "as needed to protect against program or patient abuse."[64] With respect to the legislative history, the majority concluded that the use of the word "may" in the 1993 conference suggested that, while per-click leases are not precluded, they could be prohibited nonetheless.[65]

Turning to Chevron step two, the majority first clarified that in assessing whether an agency's statutory interpretation is "permissible" and "reasonable," the court "look[s] to what the agency said at the time of the rule-making — not to its lawyers' post-hoc rationalizations."[66] In 2001, when CMS rejected the equipment per-click rule, it "identified the 1993 conference report as an important locus of statutory interpretation."[67] "[G]iven the clearly expressed congressional intent in the legislative history," the agency stated, "we are permitting 'per use' payments."[68] In 2008, however, when CMS adopted the equipment per-click rule, the agency asserted that the conference report was ambiguous. Specifically, CMS' rationale (as noted above) was that "[w]here the total amount of rent (i.e., the rental charges) over the term of the lease is directly affected by the number of patients referred by one party to the other, those rental charges can arguably be said to 'take into account' or 'fluctuate during the contract period based on' the volume or value of referrals between the parties."[69]

The D.C. Circuit dismissed CMS' 2008 explanation as "border[ing] on the incomprehensible."[70] "[P]lainly," the court stated, the agency's "attempt to grapple with the conference report" was not "reasonable" and "belongs instead to the cross-your-fingers-and-hope-it-goes-away school of statutory interpretation."[71] Indeed, the court continued, the 1993 conference report "makes clear that the 'units of service rates' are what cannot 'fluctuate during the contract period,' not the lessor's total rental income."[72] According to the court, CMS' 2008 "interpretation reads the word 'rates' out of the conference report entirely" and thus "if a reasonable explanation is the stuff of which a permissible construction is made," CMS' "tortured reading of the conference report is the stuff of caprice."[73] On this record, the court concluded, the equipment per-click rule failed Chevron step two, and the court remanded the rule to the district court "with instructions to remand to [CMS] for further proceedings consistent with this opinion."[74] On remand, the court stated, CMS "should consider — with more care than [it] exercised here — whether a per-click ban on equipment leases is consistent with the 1993 conference report."[75]

III. Beyond Council for Urological Interests

The D.C. Circuit's decision in Council for Urological Interests raises a series of interesting Stark Law issues, several of which are discussed below.

Current Status of Equipment Per-Click Rule

The equipment per-click rule, as currently codified in 42 C.F.R. §411.357(b)(4)(ii)(B), provides that "[p]ayments made by a lessee to a lessor for the use of equipment" may not be determined "[u]sing a formula based on ... per unit of service rental charges to the extent such charges reflect services provided to patients referred by the lessor to the lessee." As noted in Section II above, the D.C. Circuit, in Council for Urological Interests, concluded that this rule "fails Chevron step two" and remanded the rule to the district court with instructions that it, in turn, remand the rule to CMS for "further proceedings consistent with this opinion." [76] The court further instructed CMS to consider — "with more care than [CMS] exercised [in 2008]" — whether the rule is, in fact, "consistent with the 1993 conference report."[77]

This disposition — a remand to CMS for "further proceedings" — raises an obvious question: Is the equipment per-click rule effectively dead or merely on life support? That is, assuming the district court remands the case to CMS, which then undertakes "further proceedings" consistent with the court's opinion, will the rule be valid or invalid during the pendency of these proceedings?

While much uncertainty remains, it might be argued that the rule no longer has the force of law. That is, while the D.C. Circuit has the authority to mandate that the district court remand a regulation to the relevant regulatory agency, it is less clear that either court is empowered to require that the agency engage in further rule-making. If this is correct — that is, CMS may or may not engage in "further proceedings" — then, logically, the default position should be that the equipment per-click rule does not have the force of law until and unless CMS, in fact, initiates proceedings to repromulgate the rule (with a different statutory rationale[78]) in accordance with the APA.

Impact on Other Per-Click Bans in Stark Regulation Exceptions

As noted in Section I, when CMS promulgated the equipment rental per-click rule in 2008, it instituted virtually identical bans using precisely the same rationale in three other regulatory exceptions: the space

lease exception,[79] the fair market value compensation exception ("FMV exception")[80] and the indirect compensation arrangements ("ICA") exception.[81] What about these other "per-click" bans? Will they rise or fall depending on the final disposition of the equipment per-click rule?

Space Lease Exception

The statutory equipment rental exception and the statutory space rental exception are virtually identical. Both, for example, require that: (1) "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,"[82] and (2) "the lease [must] meet[] such other requirements as [CMS] may impose by regulation as needed to protect against program or patient abuse."[83]

Not surprisingly, then, when CMS instituted the equipment rental per-click rule in 2008, it also made corresponding changes to the regulatory space rental exception. The regulatory space rental exception, as amended in 2008, provides that "[p]ayments for the use of office space made by a lessee to a lessor" may not be determined "[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."[84] As detailed in Section I, CMS used the precise same rationale for implementing the per-click ban in both the equipment and space rental exceptions, and in the 1993 conference report, the conferees treated equipment and space interchangeably. Under these circumstances, one would expect the per-click bans in the regulatory space and equipment exceptions to stand or fall together.

Fair Market Value Compensation Exception

The FMV exception, which has no statutory counterpart, is something of an all-purpose exception intended to protect a wide variety of arrangements pursuant to which a physician provides "items" or "services" to a DHS entity in exchange for fair market value compensation.[85] (In contrast to its close cousin, the personal service arrangements exception, the FMV exception is not available where the DHS entity provides the items/services to the physician.[86]) CMS has made it clear that where a physician leases equipment (i.e., an "item") to a DHS entity, that arrangement may be protected by either the equipment rental exception or the FMV exception.[87] (Note, however, that the FMV exception is not available for arrangements involving the rental of space, which the agency does not consider an "item" or "service."[88])

Because the FMV exception may be used to protect arrangements pursuant to which a physician leases equipment to a DHS entity — and in order to prevent parties doing something under the FMV exception that they could not do under the equipment rental exception — CMS, at the time it instituted the equipment per-click rule, also modified the FMV exception to provide that "[c]ompensation for the rental of equipment may not be determined using 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."[89]

It is less obvious what impact, if any, the final disposition of Council for Urological Interests will have on the per-click ban in the FMV exception. On the one hand, the ban certainly does not appear consistent with the spirit of the 1993 conference report. On the other hand, the conference report speaks only to the equipment and space rental exceptions and not to the FMV exception, which was created by CMS from whole cloth. Further, of course, should the equipment per-click rule ultimately be struck down, maintaining the per-click ban in the FMV exception will not preclude equipment rental arrangements

providing for per-click compensation from qualifying for Stark Law protection; it simply will reduce the number of exceptions for which such arrangements may qualify.

Indirect Compensation Arrangements Exception

As noted at the outset, there are four types of "financial relationships" under the Stark Law: (1) direct and (2) indirect ownership interests and (3) direct and (4) indirect compensation arrangements. Although the actual analysis can get quite complicated, as a general proposition, a physician can have an indirect compensation arrangement with a DHS entity whenever there is an "unbroken chain" of financial relationships between the physician and the DHS entity that involves at least one "intervening person or entity."[90] For example, if physician owns equipment company and equipment company leases equipment to hospital (Hypothetical 2), physician and hospital do not have a direct compensation arrangement, but they may have an indirect compensation arrangement.

CMS has created an exception for indirect compensation arrangements.[91] Like the FMV exception, the ICA exception may be used to protect indirect compensation arrangements where one of the "links" in the "chain" of financial relationships between a physician and DHS entity is a lease arrangement. In Hypothetical 2, for example, the ICA exception could be used to protect an indirect compensation arrangement between physician and hospital. (Indeed, the ICA exception is much broader in this respect than the FMV exception, as it is available: (1) for both equipment and space rental arrangements and (2) irrespective of whether it is the physician or DHS entity that is the lessor of the equipment or space.)

Because the ICA exception may be used to protect equipment and space lease arrangements — and in order to avoid disparate treatment of such arrangements under the equipment, space, and FMV exceptions, on the one hand, and the ICA exception, on the other — CMS, at the time it instituted the equipment per-click rule, also modified the ICA exception to provide that where the focus of the analysis is on a link in the chain that is an equipment or space lease, "[c]ompensation for the rental of office space or equipment may not be determined using 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."[92]

As with the FMV exception, it is not obvious what impact, if any, the final disposition of Council for Urological Interests will have on the per-click ban in the ICA exception. There is one important distinction between the FMV and ICA exceptions, however, that may influence CMS. CMS has developed a rule, commonly referred to as the physician "stand in the shoes" (or "SITS") rule, which provides that where a physician has a (genuine, and not just titular) ownership interest in a "physician organization," that owner stands in the shoes of the physician organization with respect to the organization's compensation arrangements as if he or she were in direct privity with the other (nonphysician organization) parties to those compensation arrangements.[93]

For example, if we replace equipment company with physician organization in Hypothetical 2 — so that physician is an owner of physician organization and physician organization leases equipment to hospital — physician will stand in the shoes of physician organization and, as such, have a direct compensation arrangement with hospital and not an indirect compensation arrangement. Under these circumstances, if the equipment per-click rule is void (or if and when the equipment per-click rule is voided), the equipment lease between physician organization and hospital may provide for per-click compensation.

If the equipment per-click rule is void (or voided), but the same ban is not removed from the ICA exception, physicians who lease equipment to hospitals directly or through a physician organization will

be able to take advantage of the equipment rental exception in a way that physicians having a more distant and tenuous relationship with the DHS entity will not. Indeed, and ironically, whereas CMS added the per-click ban to the ICA exception in 2008 in order to prevent parties from doing indirectly what they could not do directly, if the equipment per-click rule is void (or voided), but the same ban is not also removed from the ICA exception, CMS will effectively be permitting parties to do directly what they cannot do indirectly.

Furnishing Entity

As discussed in Section I, when CMS amended the definition of furnishing entity to include both "performing" and "billing" entities, the agency declined to define the term "perform," contending that providers, suppliers and practitioners "generally know" when they have performed a service. In fact, it is far from clear when an entity is "performing" DHS for purposes of the furnishing entity definition, and now that the D.C. Circuit has upheld this definition, the time has come for CMS to promulgate a proper definition of "perform." To date, this is the entirety of what CMS has said on the topic:

Physicians and other suppliers and providers generally know when they have performed a service and when they are entitled to bill for it. By way of example only, we consider a service to have been ''performed'' by a physician or physician organization service if the physician or physician organization does the medical work for the service and could bill for the service, but the physician or physician organization has contracted with a hospital and the hospital bills for the service instead. We do not mean to imply that a physician service provider can escape the reach of the physician self-referral statute by doing substantially all of the necessary medical work for a service, and arranging for the billing entity or some other entity to complete the service. We do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services or personnel to the entity performing the service, to perform DHS.[94]

In addition to the fact that it has not been codified as part of any regulatory definition, this preamble is confusing, contradictory and incomplete. For example, the preamble states that suppliers and providers generally know "when they have performed a service and when they are entitled to bill for it." So is that the test? In other words, if a physician has not furnished all of the items and services necessary for the physician to be entitled to bill for the DHS then the physician has not "performed" the DHS? But if that is correct — and it certainly is a reasonable reading of the preamble — why does CMS go on to say that a physician cannot escape the reach of the physician self-referral statute by "doing substantially all of the necessary medical work for a service, and arranging for the billing entity or some other entity to complete the service"?

In Hypothetical 1 above, where hospital provides MRIs to inpatients and outpatients using its own space, supplies and nonclinical personnel, and RadCo provides the MRI machine and MRI technician, at what point would RadCo be deemed to be providing "substantially all of the necessary medical work" for the MRI service and hospital merely "completing the service"? This is critically important, because if RadCo is going to be deemed a furnishing entity (along with hospital, which is billing for the DHS and therefore most certainly a furnishing entity), the physician owners of RadCo (P1, P2 and P3), along with any physicians who are employed or under contract with RadCo, will now have a financial relationship with a (second) DHS entity (RadCo) and, as such, will be precluded from referring Medicare patients to RadCo in the absence of an applicable exception.

Relatedly, while it is helpful to know that CMS does "not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services or personnel to the entity performing the service, to perform DHS," what about an entity that does all of these things? For example, if a physician organization leases the space and equipment, and provides the supplies, personnel and billing and management services, that are used by a hospital to furnish an outpatient service, is the physician organization "performing" the outpatient service or not? Moreover, does it make a difference if the amount that the Medicare program would reimburse the performing entity and the billing entity ends up being precisely the same. In other words, does the agency's concern with "under arrangements" fade if the separation of the billing function does not cause the Medicare program to pay any more for the service?

Conclusion

With the possible exception of the federal health care program anti-kickback statute, the Stark Law poses the greatest compliance challenge to hospital-physician integration in the United States. Simply put, almost every arrangement between a hospital and a physician (or a physician medical practice) risks violating the Stark Law. As the rule-makings addressed in Council for Urological Interests attest, CMS interpretations of the Stark Law have vacillated over the years between the unforgiving and forgiving, and back again. As the D.C. Circuit has made clear, CMS' flexibility in this regard is not unlimited, particularly where, as with respect to the issue of per-click equipment leases, Congress plainly has spoken, either in the statutory text or in the congressional record.

The ball is now back in CMS' court. The authors hope that in addition to addressing the issue presented — the continued viability of the equipment per-click rule — the agency will address the same bans in the space, FMV and ICA exceptions, and provide further (and much needed) guidance on the meaning of "performing" entity. If CMS' most recent proposed Stark Law rule-making on July 15 is any indication, the agency appears to be in a forgiving mood. But only time will tell.

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[2] Council for Urological Interests v. Burwell, No. 13-5235 (D.C. Cir. Jun. 12, 2015).

[3] 42 U.S.C. §§ 1395nn, 1396(b)-(s).

[4] 42 C.F.R. § 411.350 et seq.

[5] 42 U.S.C. § 1395nn(a)(1)(A).

[6] Id. § (a)(1)(B)

[7] Id. § (a)(2)(B).

[8] 42 C.F.R. § 411.351; CMS, FAQ 9780, available at https://questions.cms.gov/faq.php?id=5005&faqid=9780 (last accessed July 15, 2015) ("Currently, lithotripsy is not considered a designated health services for purposes of the physician self-referral law.").

[9] 42 U.S.C. §§ 1395nn(b)-(e).

[10] 42 C.F.R. §§ 411.355-357.

[11] 42 U.S.C. § 1395nn(g)(1); 42 C.F.R. § 411.353(c)(1).

[12] 42 C.F.R. § 411.353(d), referencing 42 C.F.R. § 1003.101. The regulation contemplates a refund to the Medicare program. The Stark Law statute speaks of a refund to "the "individual" (ostensibly, the patient) only. 42 U.S.C. § 1395nn(g)(2).

[13] 42 U.S.C. §§ 1395nn(g)(3)-(4); 42 C.F.R. §§ 1003.102(a)(5), 1003.102(b)(9), 1003.105.

[14] 42 U.S.C. § 1395nn(a)(1)(A).

[15] 63 Fed. Reg. 1659 (Jan. 9, 1998).

[16] Id. at 1706.

[17] Id.

[18] Id.

[19] 66 Fed. Reg. 856, 856 (Jan. 4, 2001).

[20] Id. at 913-14.

[21] Id. at 953.

[22] 72 Fed. Reg. 38122, 38187 (Jul. 12, 2007).

[23] Id. at 38186.

[24] Id.

[25] Id. at 38186-87.

[26] Id. at 38187.

[27] 73 Fed. Reg. 48434, 48434 (Aug. 19, 2008).

[28] Id. at 48721.

[29] Id. at 48723. CMS' reasoning does not contend with the fact that the statute repeatedly refers to "entity" in the singular, and never in the plural. Thus, although the text cited by CMS suggests that the furnishing entity may on occasion be the "performing" entity, as opposed to the billing entity, it does not support the proposition that there may be two DHS entities with respect to the same service.

[30] Id. at 48723-24.

[31] Id. at 48724.

[32] 73 Fed. Reg. 48434, 48724 (Aug. 19, 2008).

[33] Id. at 48726.

[34] Id.

[35] Id.

[36] Id.

[37] 42 U.S.C. § 1395nn(e)(1)(B).

[38] Id.

[39] 60 Fed. Reg. 41914, 41919 (Aug. 14, 1995).

[40] 63 Fed. Reg. 1659, 1714 (Jan. 9, 1998).

[41] Id.

[42] H.R. Rep. No. 103-213, at 814 (1993) (emphasis added).

[43] 66 Fed. Reg. 856, 878 (Jan. 4, 2001).

[44] 72 Fed. Reg. 38122, 38183 (Jul. 12, 2007).

[45] Id.

[46] 73 Fed. Reg. 48434, 48715 (Aug. 19, 2008).

[47] Id.

[48] The four exceptions also were amended to prohibit percentage-based compensation methodologies. Id. at 48713; see 42 C.F.R. §§ 411.357(a), 411.357(b), 411.357(l), 411.357(p).

[49] No. 13-5235 (D.C. Cir. Jun. 12, 2015).

[50] Id., slip op. at 10.

[51] Id., slip op. at 2-3.

[52] Id., slip op. at 3.

[53] Id., slip op. at 11.

[54] Council for Urological Interests v. Burwell, No. 13-5235, slip op. at 12 (D.C. Cir. Jun. 12, 2015).

[55] Id.

[56] Id., slip op. at 22.

[57] Id.

[58] Id., slip op. at 22-23.

[59] Council for Urological Interests v. Burwell, No. 13-5235, slip op. at 23 (D.C. Cir. Jun. 12, 2015).

[60] Id. at 26.

[61] Id., slip op. at 17-18.

[62] Id., slip op. at 16.

[63] Id., slip op. at 15.

[64] Council for Urological Interests v. Burwell, No. 13-5235, slip op. at 14 (D.C. Cir. Jun. 12, 2015).

[65] Id., slip op. at 18. Judge Karen LeCraft Henderson dissented from this part of the opinion on the ground that, in her view, "Congress unambiguously intended to authorize per-click equipment leases[,]" causing CMS' per-click ban to falter under the first step of Chevron. Id., slip op. at 30.

[66] Id., slip op. at 19, citing U.S. Securites and Exchange Commission v. Chenery Corp., 332 U.S. 194, 196 (1947).

[67] Id., slip op. at 19.

[68] 66 Fed. Reg. 856, 878 (Jan. 4, 2001).

[69] 73 Fed. Reg. 48434, 48716 (Aug. 19, 2008).

[70] Council for Urological Interests v. Burwell, slip op. at 19 (Jun. 12, 2015).

[71] Id., slip op. at 20.

[72] Id.

[73] Id. (internal quotations omitted).

[74] Id., slip op. at 21.

[75] Council for Urological Interests v. Burwell, slip op. at 21 (Jun. 12, 2015).

[76] Id.

[77] Id.

[78] Id. For example, the D.C. Circuit suggested in its Chevron step 1 analysis that a per-click ban might be authorized by the "Other Regulatory Requirements" provision of the statutory exception. Id., slip op. at 12-18.

[79] 42 C.F.R. § 411.357(a).

[80] Id. § 411.357(l).

[81] Id. § 411.357(p).

[82] 42 U.S.C. § 1395nn(e)(1)(A)(iv).

[83] Id. § 1395nn(e)(1)(A)(vi).

[84] 42 C.F.R. § 411.357(a)(5).

[85] Id. § 411.357(I).

[86] Id.

[87] Id. §§ 411.357(b), 411.357(l).

[88] Id. § 411.357(I).

[89] 73 Fed. Reg. 48434, 48720 (Aug. 19, 2008).

[90] 42 C.F.R. § 411.354(c)(1)-(2).

[91] Id. § 411.357(p).

[92] 73 Fed. Reg. 48434, 48713-14 (Aug. 19, 2008).

[93] 42 C.F.R. § 411.354(c).

[94] 73 Fed. Reg. 48434, 48726 (Aug. 19, 2008).
