

# RADIOLOGY

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## MANAGEMENT

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### Labor Transformations and the Challenges of a Multigenerational Workforce



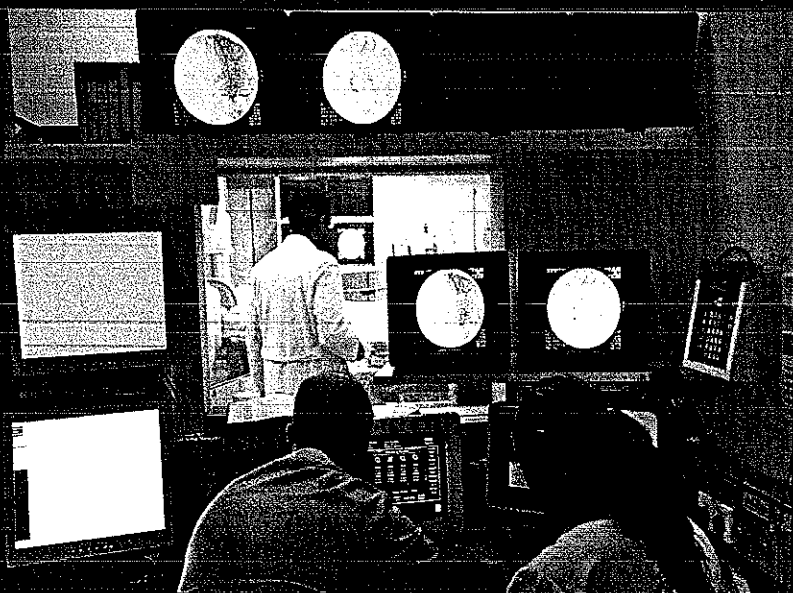
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### Recent Developments and Key Legal Issues Impacting Diagnostic Imaging Services, Part 1



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# Recent Developments and Key Legal Issues Impacting Diagnostic Imaging Services, Part 1

By Adrienne Dresevic, Esq and Carey F. Kalmowitz, Esq

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## EXECUTIVE SUMMARY

- The Stark Law prohibits physician referrals of Medicare beneficiaries to entities with which they, or members of their immediate family, have a financial relationship for "designated health services," including imaging services, unless an exception applies.
- The Final Stark Rule expands the definition of "entity" to include persons or organizations that bill for and/or perform designated health services, which expanded definition will prohibit referring physicians from having an ownership or investment interest in "under arrangements" imaging and other service providers.
- The Final Stark Rule prohibits the use of formulae for space and equipment leases based on a percentage of revenue generated by the use of the space or equipment.
- The Final Stark Rule expands the definition and prohibition of per-click arrangements, which in effect, prohibits such arrangements when the physician or physician organization is either the lessor or lessee.

In recent years, the diagnostic imaging services industry has been intensely scrutinized by the federal government, as evidenced by heightened regulatory action targeting certain diagnostic imaging arrangements, such as changes to the federal Stark Law (that restrict the flexibility of structuring diagnostic imaging arrangements), expansion of the federal anti-markup prohibition, changes to the independent diagnostic testing facility (IDTF) performance standards, and implementation of payment changes related to the way imaging services are paid under the physician fee schedule.\* Industry stakeholders should anticipate, and be attentive to, future regulatory changes, as the Centers for Medicare and Medicaid Services (CMS)

\*See, for example: (1) 73 Fed. Reg. 48688 (2008) for the 2009 Final Stark Rules, which were contained in the 2009 Final Hospital Inpatient Payment Systems Rule; (2) 42 CFR Section 410.33, which contains the quality and performance standards applicable to IDTFs; (3) 42 CFR Section 414.50, 72 Fed. Reg. 66222 (2007), 73 Fed. Reg. 404 (2008), and 73 Fed. Reg. 38544-38548, 38606 (2008), all of which address the amended anti-markup provisions applicable to diagnostic imaging tests; and (4) Section 5102 of the Deficit Reduction Act of 2005 (DRA).

is expected to continue to focus on areas such as diagnostic imaging, which it believes are vulnerable to patient and program abuse, and which is among the fastest growing set of services paid for under Medicare Part B physician fee schedule<sup>1</sup>

This article will be published in 2 parts. Part 1 will summarize some of the more significant recent federal Stark regulatory changes and their impact on diagnostic imaging arrangements. Part 2, which will be published in the next issue, will address recent federal regulatory changes relative to the 2009 Final Medicare Physician Fee Schedule provisions addressing the anti-markup provisions and IDTF enrollment and billing requirements. It will also address Medicare's Recovery Audit Contractor Program.

## An Overview of Stark's General Application to Diagnostic Imaging Services

Section 1877 of the Social Security Act ("Stark" or the "Stark Law") is a broad statutory prohibition that bans physician referrals of Medicare beneficiaries to entities with which they or members of their

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immediate family, have a financial relationship for certain services itemized in the statute, referred to as "designated health services" (DHS)<sup>2</sup> DHS include, among others, inpatient and outpatient hospital services and radiology and certain other imaging services. The Stark regulations define radiology and certain other imaging services by reference to a list of CPT/HCPCS codes. The list of codes identifying these services includes both the professional and technical component of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resource imaging, nuclear medicine, or other imaging services. The list, however, does not include invasive radiology procedures such as certain x-ray fluoroscopy or ultrasound procedures that require insertion of a needle, catheter, tube, or probe and are integral to the performance of non-radiological medical procedures during or immediately following the non radiological procedure.<sup>3</sup> Accordingly, because invasive radiology services are not considered DHS, joint ventures where participants include physicians who refer for these types of invasive imaging services do not fall directly within the ambit of Stark.\*

In addition to invasive imaging services, there is also a provision within the Stark Law that effectively operates as an exception for certain referrals by diagnostic radiologists. Specifically, a referral by a radiologist for diagnostic radiology services pursuant to a consultation requested by another physician is not considered a referral under

the Stark Law, so long as the referring radiologist (or a radiologist in the same group practice) supervises or furnishes the service.<sup>3</sup> This so-called "radiologist exception" permits certain joint venture arrangements that involve ownership by diagnostic radiologists, as opposed to other referring physician specialists.

The in-office ancillary services (IOAS) exception has arguably been the single most important exception to the Stark Law for physicians in a variety of different specialties (eg, cardiologists and internists) that furnish imaging services within their practices to their patients. Without this exception, a substantial number of common in-office imaging services arrangements would not be possible. The IOAS exception is designed to protect the in-office provision of certain DHS, including diagnostic imaging services.<sup>4</sup> The IOAS exception comprises a supervision, location, and billing requirement. Shared imaging facilities customarily rely upon this exception, as CMS has recognized that shared facilities can meet this exception, provided that each participating physician practice satisfies the requirements of the IOAS exception.<sup>4</sup>

Additionally, the physician services exception under Stark enables group practices to make referrals within their practices for physician services that are DHS (eg, the professional interpretation of an imaging service).<sup>5</sup> For example, this exception is applicable to professional interpretations ordered by a group practice physician and subsequently furnished by an independent contractor radiologist. For purposes of this exception, however, independent contractors must provide the services in the group practice's facilities. Otherwise, a violation of Stark can be established. That is, under Stark, in order for a group practice to bill Medicare for

the professional component of imaging services provided by an independent contractor radiologist, the interpretation must be furnished on-site in the group practice's facility. The provision of off-site interpretations by an independent contractor radiologist is not permitted under Stark if the group practice intends to bill Medicare for that component of the service.\*\*

The Stark Law contains a number of other exceptions applicable to the provision of various imaging services arrangements, which protect ownership and compensation relationships between referring physicians (or their immediate family members) and DHS entities, including hospitals, physician practices, and other imaging services providers. For example, a common imaging arrangement involves lease agreements between a radiologist (who owns space and imaging equipment) and a physician practice that refers patients to the radiologist for the professional component of the service. In a substantial majority of these arrangements, the agreements for the lease of space and equipment must be structured to comply with the requirements of the rental of space and rental of equipment exceptions under the Stark Law (see 42 CFR Section 411.357[a] and [b] for these requirements). To comply with these exceptions, the rental charges over the term of the lease must be set in advance, consistent with fair market value, and must not be determined in any manner that takes into account the volume or

\*Please note, however, that the 2009 IPPS Final Stark Rules revise the definition of "entity" for purposes of the Stark Law, and certain joint venture arrangements between referring physicians and hospitals may implicate the Stark Law, effective October 1, 2009.

\*\*Effective January 1, 2009, the group may bill for such off-site services provided that it complies with the harsh payment limitations of the Medicare final anti-markup provisions.

*The Final Rule contains several significant modifications to the Stark regulations, some of which will require physicians, hospitals, and other imaging providers to unwind or restructure their arrangements.*

value of referrals, or other business generated between the parties.

### Major Stark Changes Finalized

In 2007, CMS published the third phase (and, according to the prevailing thinking in the industry, the final phase) of the Stark regulations (Phase III).<sup>6</sup> Despite the publication of Phase III, however, CMS has continued to identify issues for further study, potential change, and future rulemakings. On August 19, 2008, CMS published yet another installment of final Stark rules in its 2009 Final Hospital Inpatient Prospective Payment Systems Rule (Final Rule).<sup>7</sup> The Final Rule contains several significant modifications to the Stark regulations, some of which will require physicians, hospitals, and other imaging providers to unwind or restructure their arrangements. Several of the new Stark regulations included in the Final Rule are not effective until October 1, 2009, in order to give parties time to unwind or restructure arrangements which are covered by the changes, but other provisions went into effect on October 1, 2008.\* Although there were several significant changes in the Final Rule, this article will focus solely on a few key changes likely to have a significant impact on common diagnostic imaging services arrangements.

### Services Provided "Under Arrangements"

Under current Stark I law, only those entities to which CMS makes payment for the

DHS are considered to be furnishing DHS.<sup>3</sup> Prior to the changes contained in the Final Rule, Stark generally permitted physicians to invest in entities which provided services "under arrangements" (eg, a hospital can bill for a service line that is furnished by another entity pursuant to a contract under the hospital's oversight) to hospitals because the physician did not have an ownership interest in the hospital (ie, the entity furnishing DHS). In recent years, for example, "under arrangements" joint ventures between hospitals and referring physicians have been used to furnish imaging and cardiac catheterization services to hospitals. The Final Rule significantly expands the definition of "entity" to include entities that perform services that are, in turn, billed as DHS by another entity.<sup>3,8</sup> As a practical matter, this change means that referring physicians likely will not be able to have an ownership or investment interest in "under arrangements" imaging and other service providers.

Specifically, under the Final Rule, effective October 1, 2009, an "entity" for purposes of Stark will now include the person or organization that has: (1) billed for the DHS; or (2) performed the DHS.<sup>8</sup> Under these new rules, where one entity performs a service that is billed by another entity, both entities are considered DHS entities with respect to that service.<sup>9</sup> Accordingly, pursuant to the Final Rule, any financial relationship between the service provider and the physicians who refer to it for services that

the hospital bills "under arrangements" will need to comply with an applicable Stark exception.

CMS does not define what it means to "perform" a service, but does indicate that an organization is not performing DHS if it only leases or sells space or equipment, furnishes supplies that are not separately billable, or provides management, billing services, or personnel to the entity performing the service.<sup>10</sup> CMS does state that the common meaning of the term "perform" applies and it considers a physician or physician organization to have performed DHS if the physician or physician organization furnishes the medical work for the service and could bill for the service, even in cases where the physician or organization has contracted with a hospital and the hospital bills for the service instead.<sup>10</sup>

In the preamble commentary, many stakeholders expressed concern that the proposals would disrupt access to care, particularly in underserved or rural areas.<sup>11,12</sup> In response, CMS notes that it is not prohibiting services to be furnished "under arrangements." For example, with respect to service providers that furnish services to rural patients, CMS states that the new rules will not alter the availability of the exception for an ownership interest in a rural provider, but as a DHS entity, a physician owner/investor in such a service provider would need to meet an ownership exception (such as the rural provider exception) in order to protect his or her referrals to the service provider.<sup>12,13</sup>

*With respect to service providers that furnish services to rural patients, CMS states that the new rules will not alter the availability of the exception for an ownership interest in a rural provider.*

\*Final Stark Rules addressing percentage-based compensation formulae, unit-of-service ("per-click") leasing arrangements, and services provided "under arrangements" are effective October 1, 2009. Final Stark Rules addressing "stand in the shoes" (SITS), period of disallowance, alternative method for compliance with certain exceptions, obstetrical malpractice insurance subsidies, ownership or investment in retirement plans, and burden of proof were effective October 1, 2008.

With respect to ownership or investment interests that will not qualify for the rural provider exception, CMS believes access will not be significantly disrupted for several reasons. First, CMS states that the final rules do not prohibit physician group practices or other physician organizations from contracting with a hospital for the provision of services "under arrangements." CMS points out that any physician that has a compensation arrangement (as distinguished from an ownership or investment interest) with the physician group practice or other physician organization may refer patients for services that are provided by the hospital "under arrangements" so long as one of the compensation exceptions is met. Moreover, CMS notes that to the extent that an owner/investor in the physician service provider has referred the patient for a service, but then personally performs the service, there is no referral, and Stark is not implicated. CMS does caution, however, that despite the personal performance of the professional component, the technical component to any service or a facility fee that is billed by any provider "under arrangements" is considered a referral. CMS also believes that, in many cases, physician groups could provide the services and bill for them directly (without the need to contract with a hospital to provide them "under arrangements"), and that to the extent that the services would be DHS when performed and billed by the physician group directly, referrals to the physician entity could be protected by the IOAS exception.<sup>13</sup> CMS also notes that to the extent that the physician service providers are furnishing lithotripsy, it presently does not consider lithotripsy to be DHS.

It is expected that there are a substantial number of existing "under arrangements" transactions involving physician owned entities (including imaging services providers) that will have to be unwound or restructured before the October 1, 2009 effective date. For example, in the case of an imaging center joint venture between a hospital and referring physician

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investors that involves an “under arrangements” contract with the hospital pursuant to which the joint venture entity performs imaging services that are billed under the hospital’s name and billing number, the referring physicians who have an investment interest in the imaging center joint venture will most likely need to unwind or restructure the venture before October 1, 2009. One issue that was not definitively addressed is whether an entity that performs some, but not substantially all, of the medical work for the service (eg, turnkey management service provider) will be considered to be performing DHS.

Radiologists, however, may be able to benefit significantly from the Final Rule’s impact on many current “under arrangements” providers. As previously discussed, the Stark Law excludes from the definition of “referral” certain requests by radiologists (eg, “radiologist referral exception”), which means that radiologists, in many circumstances, may continue to own an

entity that performs services “under arrangements”

### The Demise of Percentage-Based Compensation for Space and Equipment Leases

In an earlier proposal, due to its concerns regarding heightened risk of program and patient abuse, CMS planned on eliminating percentage-based compensation arrangements, except in the context of service agreements governing services personally performed by physicians.<sup>14</sup> In the Final Rule, CMS adopts a more streamlined approach and targets percentage-based compensation only in the context of space and equipment leases.<sup>15-17</sup>

Specifically, the Final Rule amends the current Stark exceptions for rental of office space, rental of equipment, fair market value compensation arrangements, and indirect compensation arrangements to prohibit the use of compensation formulae for space and equipment leases based

upon a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space lease or to the services performed on or business generated by the use of leased equipment.<sup>15-17</sup>

Effectively, by implementing these changes, CMS precludes most percentage-based arrangements for the lease of space or equipment (direct or indirect) between DHS entities and referring physicians. Current percentage-based leasing arrangements for office space or equipment that violate these new rules will need to be restructured prior to October 1, 2009, the effective date. Percentage-based compensation formulae prohibitions applicable to office space and equipment leases have a delayed effective date of October 1, 2009.<sup>18</sup>

Further, although CMS did not extend this new percentage-based prohibition outside of the space and equipment lease

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*The per-click prohibition applies whether the lessor is the referring physician or an entity in which the referring physician has an ownership interest.*

context (eg, management services), CMS cautions that it intends to “continue to monitor compensation formulae in arrangements between DHS entities and referring physicians and, if appropriate, may further restrict percentage-based formulae in a future rulemaking”<sup>19</sup> Thus, parties involved in management services arrangements that are based upon percentage-based formulae should stay tuned for future regulation in this area.

**“Per-Click” Leasing Arrangements Prohibited—For Now, Block Time Leases Survive**

Although unit-of-service (“per-click”) payments were generally permitted under the Stark Law, due to concerns that this type of compensation methodology was inherently susceptible to abuse, earlier CMS introduced a proposal which prohibited the use of per-click payments involving space and/or equipment leases in those situations where a physician (or entity owned by a physician) leases space and/or equipment to another entity and the physician subsequently refers patients to that other entity for services. For example, this would prohibit a cardiologist from leasing a CT scanner to a hospital on a per-click basis if that cardiologist refers patients to the hospital for CI services.<sup>20</sup> While the original proposal only restricted per-click payments when the physician was a lessor, CMS also solicited comments on whether it should prohibit per-click payments in situations in which the physician is the lessee and a DHS entity is the lessor.<sup>20</sup>

Under the Final Rule, CMS prohibits the use of per-click payment methodologies

for leasing arrangements under the space and equipment lease exceptions, fair market value exception, and the exception for indirect compensation arrangements to the extent that these charges reflect services provided to patients referred between the parties.<sup>16,21</sup> Notably, the per-click prohibition applies whether the lessor is the referring physician or an entity in which the referring physician has an ownership interest. The Final Rule is also broader than the original proposal and applies if the lessor is a DHS entity that refers patients to a physician or physician organization lessee.<sup>22</sup>

CMS notes that it is not prohibiting per-click compensation arrangements involving non-physician owned lessors to the extent that such lessors are not referring patients for DHS, nor are they prohibiting per-click payments to physician lessors for services rendered to patients who were not referred to the lessee by the physician lessors. However, CMS reminds stakeholders that all such arrangements must still satisfy all of the requirements of the lease exceptions, including the requirements that they be fair market value and commercially reasonable.<sup>23</sup>

Notably, in addition to the per-click restrictions, CMS also states that “on demand” rental agreements are effectively per-click or per-use arrangements, and that it considers these types of agreements to be covered by the Final Rule. Accordingly, “on demand” rental payments are also now prohibited for leases of space and equipment to the extent that these charges reflect services provided to patients referred between the parties.<sup>23</sup> However, CMS declined to prohibit all time-based

leasing arrangements (eg, block time leases), as CMS believes that they may meet the requirements of the space and equipment lease exceptions. CMS cautions, however, that the same concerns that arise with respect to per-click payments potentially may exist with certain time-based leasing, such as leasing the space or equipment in limited blocks of time (eg, once a week for 4 hours), and parties entering into block leases should carefully structure them in accordance with the strictures of the anti-kickback statute.<sup>23,24</sup>

The final per-click prohibitions are effective for lease payments made on or after October 1, 2009.<sup>9</sup>

## Conclusion

Through a series of regulatory actions, CMS has been targeting diagnostic imaging services arrangements. Although Part 1 of this article focused solely on the recent Stark regulatory changes, further federal regulatory changes that may significantly affect the structure of many current imaging arrangements will be discussed in Part 2. As a result, we advise providers to incorporate mechanisms into their current contractual arrangements that will permit these arrangements to adopt a more stringent regulatory framework. Finally, the regulatory changes discussed in this article (and in Part 2) likely will not be CMS’ final word on diagnostic imaging. Providers should be mindful of this before entering into structures that cannot be unwound or modified. ❖

## References

<sup>1</sup>GAO Report to Congressional Requesters GAO-08-452 “Medicare Part B Imaging Services Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices” (June 2008)

<sup>2</sup>42 U.S.C. Sect. 1395nn (2006).

<sup>3</sup>Definitions, 42 C.F.R. Sect. 411.351 (2007).

*We advise providers to incorporate mechanisms into their current contractual arrangements that will permit these arrangements to adopt a more stringent regulatory framework.*

<sup>4</sup>General exceptions to the referral prohibition to both ownership/investment and compensation, 42 C.F.R. Sect. 411.355(b) (2007).

<sup>5</sup>General exceptions to the referral prohibition to both ownership/investment and compensation, 42 C.F.R. Sect. § 411.355 (a) (2007).

<sup>6</sup>72 *Federal Register* 51012 (September 5, 2007).

<sup>7</sup>73 *Federal Register* 48688 (August 19, 2008).

<sup>8</sup>73 *Federal Register* 48751 (August 19, 2008).

<sup>9</sup>73 *Federal Register* 48721 (August 19, 2008).

<sup>10</sup>73 *Federal Register* 48726 (August 19, 2008).

<sup>11</sup>73 *Federal Register* 48727 (August 19, 2008).

<sup>12</sup>73 *Federal Register* 48728 (August 19, 2008).

<sup>13</sup>73 *Federal Register* 48729 (August 19, 2008).

<sup>14</sup>72 *Federal Register* 38184 (July 12, 2007).

<sup>15</sup>73 *Federal Register* 48709–48713 (August 19, 2008).

<sup>16</sup>73 *Federal Register* 48752–48753 (August 19, 2008).

<sup>17</sup>Exceptions to the referral prohibition related to compensation arrangements, 42 CFR Section 411.357 (2007).

<sup>18</sup>73 *Federal Register* 48690 (August 19, 2008).

<sup>19</sup>73 *Federal Register* 48710 (August 19, 2008).

<sup>20</sup>72 *Federal Register* 38182–38183 (July 12, 2007).

<sup>21</sup>Exceptions to the referral prohibition related to compensation arrangements, 42 CFR Section 411.357 (2007).

<sup>22</sup>73 *Federal Register* 48714 (August 19, 2008).

<sup>23</sup>73 *Federal Register* 48719 (August 19, 2008).

<sup>24</sup>73 *Federal Register* 48720 (August 19, 2008).

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