Stark Law–Frequently Asked Questions
Updated January, 2011

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Stark Law Overview

1. What is the Stark Law?

In 1989, Congress adopted a physician self-referral proscription applicable to entities providing Medicare-covered clinical laboratory services. In 1993, Congress expanded the physician self-referral proscription beyond clinical laboratory services to a host of "designated health services." This law is often referred to as the "**Stark Law**" after Pete Stark (D-CA), the Congressman who introduced and strongly supported the statute.

In summary, the Stark Law prohibits a ***physician*** (or an immediate family member of such physician) who has a "***financial relationship***" (including compensation and investment / ownership interests) with an entity from ***referring*** (broadly defined) patients to the entity for "designated health services" covered by the Medicare program, unless an exception is available. In the event a proscribed referral is made and no exception is available, the entity performing the services is prohibited from submitting a claim for the services to the Medicare program or billing any individual, third-party payor or other entity for the services. In addition, certain aspects of the Stark Law apply to the state Medicaid programs.

The Stark Law provides significant civil (but not criminal) sanctions for violations including denial of payment; refunds of amounts collected in violation; a civil money penalty (CMP) of up to $15,000 for each bill or claim for a service a person knows (or should know) is a service for which payment may not be made; the imposition of up to three times the amounts for each item or service wrongfully claimed; potential exclusion from Federal health care programs; and a CMP of up to $100,000 for each arrangement or scheme which the physician or entity knows (or should know) has a principal purpose of assuring referrals which, if directly made, would be in violation of the proscription.

2. Who regulates the Stark Law?

Congress enacted the Stark Law and has made changes to the law over the years. In addition, the Centers for Medicare & Medicaid Services ("**CMS**") regulate the Stark Law and issue regulations, guidance and advisory opinions. Other parties (e.g., whistleblowers) and government agencies such as the Office of Inspector General ("**OIG**") of the U.S. Department of Health & Human Services and the U.S. Department of Justice ("**DOJ**") have asserted jurisdiction over the enforcement of the Stark Law through various legal theories.

3. What are the "designated health services"?

There are currently ten (10) categories of "designated health services:" (1) clinical laboratory services, (2) physical therapy, occupational therapy, and speech language pathology services, (3) radiology and certain other imaging services, (4) radiation therapy services and supplies, (5) durable medical equipment (DME) and supplies, (6) parenteral and enteral nutrients, equipment and supplies, (7) prosthetics, orthotics and prosthetic devices and supplies, (8) home health services, (9) outpatient prescription drugs, and (10) inpatient and outpatient hospital services. (For more information on radiology and imaging services, please see: ***What radiology and imaging services are "designated health services"?)***

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4. ***What is the current status of the Stark Law? Are there any changes on the horizon? What additional risks might I face? What action is being considered that could further change the Stark Law? How does the Medicare Anti-Markup Rule relate to the Stark Law and how might this impact my arrangement?***

The Stark Law is currently in flux. A number of arrangements that were permitted prior to recent Stark Law changes will now need to be reviewed and practices adjusted accordingly.

Significantly, in March 2010, as part of the comprehensive health reform package, the in-office ancillary services exception was amended to include a new disclosure requirement. Significantly, Section 6003 of the Patient Protection and Affordable Care Act of 2010 ("**PPACA**") requires that with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and other designated health services that the Secretary of the U.S. Department of Health and Human Services through CMS determines appropriate, the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from another person (e.g., not the physician or the physician's immediate family member) and provide such individual with a written list of suppliers who furnish such services in the area in which such individual resides. In November of 2010, CMS published a final rule interpreting the new disclosure requirement, effective January 1, 2011. (For more information on the in-office ancillary services exception, including the new disclosure requirement, please see: ***Can a physician practice furnish "designated health services" to its own patients in its own office? What is the in-office ancillary services exception and what are the general requirements?***)

In addition, in August of 2008 CMS finalized a number of Stark Law changes in the final 2009 Hospital Inpatient Prospective Payment System rule (the "**August 2009 Final Rule**"). The August 2009 Final Rule incorporates a number of changes into the Stark Law including:

(i) Prohibitions on a number of hospital / physician joint ventures (e.g., certain "under arrangements" transactions),

(ii) Prohibitions on per click / per unit payments for space and equipment, and

(iii) Prohibitions on percentage-based space and equipment leasing transactions.

Each of the three (3) above changes became effective on October 1, 2009. The August 2009 Final Rule included a host of other Stark Law changes some of which were effective October 1, 2008 and others of which became effective October 1, 2009. In addition, CMS has proposed a number of other Stark Law changes, including a Stark Law exception for incentive payments and shared savings programs (e.g., gainsharing arrangements). ***In light of the breadth of these Stark Law changes, the health care industry must continue to closely monitor fluctuations in the Stark Law.***

The Stark Law is not the only law that CMS is using to regulate physician arrangements. Most notably, effective January 1, 2009, the anti-markup rule was broadened to the extent that certain physician and supplier practice models became impractical (the "**Broadened Anti-Markup Rule**"). In brief, the anti-markup rule historically prohibited physicians from marking up the technical component of diagnostic tests (including diagnostic imaging). The Broadened Anti-Markup Rule now prevents billing physicians (and other suppliers) from marking up either the technical or professional

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component (e.g., interpretations) of certain diagnostic tests, and includes a new, and more restrictive, site-of-service limitation. The Broadened Anti-Markup Rule upsets the practicality of a subset of otherwise permissible arrangements under the Stark Law's in-office ancillary services exception. As a result, certain models, especially models in which diagnostic services (e.g., imaging services) are rendered in a centralized building, that are permissible under the Stark Law, became impractical because these models became subject to the anti-markup payment limitations which, in brief, prevent the billing physicians and suppliers from marking-up or profiting from the impacted services. As a result, physicians and other suppliers should have restructured or unwound these arrangements or appropriately modified their charges under the Broadened Anti-Markup Rule. ***Consequently, the health care industry must continue to closely monitor the fluctuations in technical payment rules and not just the Stark Law.***

5. What types of arrangements and joint ventures are permitted? What are the Stark Law exceptions?

There are a number of permitted arrangements and joint ventures. For example, a physician's group practice may provide imaging services in the group practice's offices or may be able to engage in a joint venture with a hospital to provide certain imaging equipment or services to the hospital. Although potentially permissible, these ventures must be carefully reviewed for compliance with the Stark Law. Significantly, these arrangements must be structured to comply with one of the Stark Law exceptions. The Stark Law contains several exceptions, some applying to ownership arrangements, some applying to both ownership and compensation arrangements, and the remainder applying only to compensation arrangements. Some of the relevant exceptions include:

- The in-office ancillary services exception (an exception that applies to both ownership / investment interests and compensation),
- The ***physician services*** exception (an exception that applies to both ownership / investment interests and compensation),
- The ***rural provider*** exception (an exception that applies to only ownership / investment interests),
- The ***rental of office space and equipment*** exception (a compensation only exception),
- The ***personal services arrangements*** exception (a compensation only exception),
- The exception for electronic health records (a compensation only exception),
- The exception for electronic prescribing (a compensation only exception), and
- The exception for technology provided as part of a community-wide information system (a compensation only exception).

There are also a number of other Stark Law exceptions. Each of the Stark Law exceptions has specific and technical requirements that must be met. For example, the in-office ancillary services

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exception has requirements relating to (i) the supervision of services, (ii) the location of services, (iii) the billing of services, (iv) the structure of group practices, and (v) patient disclosures.

6. ***Can a physician practice furnish "designated health services" to its own patients in its own office? What is the in-office ancillary services exception and what are the general requirements?***

The in-office ancillary services exception protects physicians' referrals for most, but not all, designated health services furnished in the physicians' offices. Congress' main objective in adopting this exception included "permitting the provision of in-office ancillary services for the convenience of patients during their patient visits" and "permitting the provision of in-office ancillary services in a dedicated building used for these services." The in-office ancillary services exception has requirements relating to (i) the supervision of services, (ii) the location of services, (iii) the billing of services, (iv) the structure of group practices, and (v) patient disclosures.

Summary of the Supervision of Services Requirements

In order to qualify for the in-office ancillary services exception, the referring physician (or another physician who is a member of the same group practice) must personally furnish the services. If other individuals (*e.g.,* technicians) perform the services, those individuals must be directly supervised by the referring physician or another physician in the same group practice in order for those services to qualify. Although the Stark Law uses the phrase "directly supervised," CMS has interpreted this to mean supervised to the extent otherwise required in the Medicare program.

Summary of the Location Requirements

To be exempt, in-office ancillary services also must be furnished either (i) in a "***centralized building***" used by the group practice for the centralized provision of the group's "designated health services" (other than clinical laboratory services); or (ii) in the "***same building***" in which:

- The referring physician or group practice has an office that is normally open to their patients at least thirty-five (35) hours per week, and the referring physician or group members regularly practice medicine and furnish physician services to patients in that office at least thirty (30) hours per week;

- The patient usually receives physician services from the referring physician or a member of the group practice, the group practice has an office that is normally open to patients at least eight hours per week, and the referring physician regularly practices medicine and furnishes physician services to patients in that office at least six hours per week; or

- The referring physician must be present and order the designated health service in connection with a patient visit during the time the office is open or the referring physician or a group practice member is present while the "designated health service" is furnished during the time the office is open, the referring physician or group practice has an office that is normally open eight hours per week, and the referring physician or group member regularly practices medicine and furnishes physician services to patients at least six hours per week in that office (including "some" services that are unrelated to "designated health services").

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The regulations define the term "***same building***" as a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (*e.g.,* lawns, courtyards, driveways, parking lots) and interior parking garages. However, the "same building" does not include a mobile vehicle, van or trailer. Separate physician office suites within the same medical office building could fall within the "***same building***" requirement if the street address for all of the suites were the same, although the suite numbers could be different or located on different floors. In addition, the "***same building***" test does not require that the physician or group practice have exclusive use and control over the space. Therefore, multiple groups that are in the "***same building***" may share the space so long as the shared space is properly structured.

A "***centralized building***" means: all or part of a building, including … a mobile vehicle, van or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and is used exclusively by the group practice. Therefore and unlike the "***same building***" test, it is important to note that space shared by more than one group practice, by a group practice and more than one solo practitioner, or by a group practice and another provider (e.g., a diagnostic imaging facility) is not considered to be a "***centralized building***." CMS has noted that neither a statutory requirement nor legislative history exists for "one single centralized location for a group to provide designated health services." Thus, there is no requirement that a "***centralized building***" service all of the group's offices or provide the group's entire "designated health services." Although the Stark Law permits designated health services to be provided in a "***centralized building***," as noted above, the Broadened Anti-Markup Rule may upset the practicality of a number of "***centralized building***" models. ***Thus, it is important that these arrangements be carefully reviewed and structured with the assistance of competent legal counsel.***

Summary of the Billing Requirements

Certain billing requirements must be met in order to qualify for this exception. The "designated health services" must be billed by one of the following:

(i) The physician performing or supervising the service;

(ii) The group practice in which that physician is a member;

(iii) The group practice if the supervising physician is a "physician in the group;"

(iv) An entity that is owned by the referring or supervising physician or her group practice; or

(v) An independent third-party billing company.

Summary of Group Practice Requirements

Both structural and operational requirements apply for qualifying as a group practice. In summary, ***the group practice requirements focus upon the nature of a group's integration*** and include detailed rules on: (1) structuring as a single legal entity, (2) the "members" of the group, (3) the range of patient care services, (4) the furnishing and billing of patient care services, (5) the distribution of income and expenses, (6) group decision making, (7) compensation based upon volume or value of referrals, (8) physician / patient encounters, and (9) productivity bonuses and profit shares. These requirements are also important because, for example, group practices have greater flexibility in

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paying physicians incentive-based compensation under the Stark Law than do other physician organizations that fall short of group practice qualification.

Summary of the Disclosure Requirements

As part of a comprehensive health reform package, in March 2010 the in-office ancillary services exception was amended to include a new disclosure requirement. Significantly, Section 6003 of PPACA requires that, with respect to MRI, CT, PET, and other designated health services that the Secretary determines appropriate, the referring physician must provide certain patient disclosures. In November of 2010, CMS issued a final rule implementing Section 6003 of PPACA. Despite CMS' broad authority under PPACA, CMS is thus far only requiring the disclosure obligation for referrals for MRI, CT, and PET services provided under the in-office ancillary services exception. In summary, beginning January 1, 2011, the patient disclosure must:

(i) be in writing;

(ii) be given at the time of the referral;

(iii) notify the patient that the patient may receive the same services from a person other than the physician;

(iv) be written in a manner sufficient to be reasonably understood by all patients; and

(v) include the name, address and telephone number of at least 5 other "suppliers" that provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician's office location "at the time of the referral" (unless less than 5 "suppliers" are within the 25-mile radius, in which case all suppliers in the radius should be listed). If there are no other "suppliers" that provide the services for which the individual is being referred than the "provision of the written list" is not required. However, the general notification is still required.

In the final rule implementing the new disclosure requirement, CMS stated that the intent of the law is to "provide choice for patients, as well as a degree of protection against conflicts of interest." ***In light of the questions and complexities associated with the in-office ancillary services exception, it is important that these arrangements be carefully reviewed and structured with the assistance of competent legal counsel.***

7. Does the Stark Law apply to ambulatory surgery center services? What are the implications of the Stark Law for a practice offering "designated health services" (e.g., imaging services) out of an ambulatory surgical center?

Ambulatory surgery center composite rate services are not "designated health services" covered by the Stark Law. However, if the ambulatory surgery center provides any separately billable "designated health services" that are not included within the ambulatory surgery center's composite rate payment (e.g., separately reimbursable imaging services), the Stark Law and all of its rules and restrictions apply.

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8. Are there other laws that I should be concerned about when structuring my arrangement?

Yes, in addition to considering the Stark Law, there are a host of other Federal and state laws that may impact your proposed arrangement. For example, a number of states have adopted state self-referral and fee-splitting laws, which may be more restrictive than the Stark Law. States also have certain licensing, registration and permitting requirements. In addition, other Federal laws might be applicable to your arrangement including, without limitation, the anti-markup rules, the Federal Anti-Kickback Law and the Federal False Claims Act. Moreover, there are a number of laws and regulations that govern how products and services may properly be rendered and billed to patients, commercial insurers and the state and Federal governments. All of these laws must be read together and considered for your arrangement. ***Therefore, the services of a competent attorney should be sought.***

Radiology & Imaging Specific Questions

1. What radiology and imaging services are "designated health services"?

A large number of radiology and imaging services are included in the definition of "designated health services", including the professional and technical components of x-ray, ultrasound, CT, MRI, nuclear medicine (including PET) and bone densitometry. More specifically, CMS has defined many "designated health services", including radiology and certain other imaging services, by publishing specific lists of the Current Procedural Terminology (CPT®) and CMS Common Procedure Coding System (HCPCS®) codes that physicians and providers most commonly associate with a given service. This list of specific codes can be found at: https://www.cms.gov/PhysicianSelfReferral/40_List_of_Codes.asp#TopOfPage. However, the following are not considered "designated health services" under the Stark Law (1) x-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice; and (2) radiology procedures that are integral to the performance of a nonradiological medical procedure and performed (i) during the nonradiological medical procedure, or (ii) immediately following the nonradiological medical procedure when necessary to confirm placement of an item placed during the nonradiological medical procedure.

2. Does the Stark Law apply to radiologists and radiation oncologists?

Under the Stark Law, certain referral relationships are deemed not to constitute a "referral" if the services are furnished by (or under the supervision of) a specialist pursuant to a consultation. In summary, the Stark Law excludes from the term "referral" a request by a radiologist for diagnostic radiology services and a request by a radiation oncologist for radiation therapy, if such services are pursuant to a consultation requested by another physician and are furnished by or under the supervision of the radiologist or radiation oncologist. By way of example, a referral for imaging by a radiologist pursuant to a consultation requested by another physician is not a "referral" for purposes of the Stark Law, provided the imaging services are supervised by the referring radiologist or another radiologist in the same group practice. However, if the radiologist makes a referral that is not pursuant to a consultation requested by another physician, the referral must qualify for a Stark Law exception. (For more information on the Stark Law exceptions, please see: ***What types of arrangements and joint ventures are permitted? What are the Stark Law exceptions?***)

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Health Information Technology Specific Questions

1. *Why are there Stark Law exceptions for health information technology?*

Hospital inpatient and outpatient services are included in the Stark Law "designated health services." Therefore, if a hospital wishes to, for example, donate or subsidize certain health information technology ("***HIT***") to a referring group practice or physician, the hospital must meet a Stark Law exception. Currently, there are HIT exceptions to the Stark Law for (1) Community-Wide Health Information Systems, (2) electronic health records, and (3) electronic prescribing.

2. *What are the general requirements for the health information technology exceptions?*

Historically, there has been a Stark Law exception for Community-Wide Health Information Systems ("***CWHIS***"). Subject to certain conditions, the CWHIS Stark Law exception addresses the provision of information technology (including hardware and software) and services to community physicians to enable them to participate in a CWHIS designed to enhance the overall health of the community. The CWHIS exception requires that the items or services be principally used by the physician as part of the CWHIS, that these items and services be provided to the physician in a manner that does not take into account the physician's volume or value of referrals, and that the health-information system (including both hardware and software) must be "community-wide" (i.e., it is available to all providers, practitioners and residents of the community who desire to participate).

In 2006, CMS created a new exception for compensation arrangements involving certain electronic health records ("***EHR***") arrangements. This exception established the conditions under which entities furnishing "***designated health services***" (e.g., a hospital) may donate to physicians interoperable electronic health records software, information technology and training services. In summary, the Stark Law EHR Stark exception (the "***EHR Exception***") includes the following requirements:

- ***Necessary and used predominately***. The software and/or information technology and training services donated must be necessary and used predominately to create, maintain, transmit or receive electronic health records.

- ***Interoperability***. The electronic health record software must be interoperable at the time it is provided to the physician. (Please see: ***What is considered "interoperable" software under the Stark Law EHR exception?***)

- ***EHR Limitations & Restrictions***. The donor (e.g., the hospital) or any person on the donor's behalf does not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or EHR systems.

- ***15% of Cost***. Prior to the receipt of the items or services, the physician must pay at least 15% of the donor's costs for the HIT donated to the physician, and the donor cannot finance the recipient's payments. (Please see: ***Has CMS provided any guidance on how "cost" is expected to be calculated?***)

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- ***Not a condition of doing business***. Neither the physician nor the physician's practice makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

- ***Volume or value of referrals / business***. The selection of the recipient and the amount of the donation may not be determined in a manner that directly takes into account the volume or value of referrals or other business generated by the parties. CMS provided a number of situations where the determination is "deemed" not to be "directly related to the volume or value of referrals" or other business generated between the parties. For example, a determination based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program), is deemed not to be directly related to the volume or value of referrals.

- ***Written agreement***. The arrangement is set forth in a written agreement that is signed by the parties, specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contributions and covers all the EHR items and services to be provided by the donor.

- ***Equivalent HIT***. The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items and services equivalent to those provided by the donor.

- ***Use for any patient***. For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

- ***Other uses of HIT***. The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

- ***Electronic prescribing***. The EHR software contains electronic prescribing capability that meets the applicable standards under Medicare Part D at the time the items and services are provided.

- ***Compliance with other laws***. The arrangement does not violate the Anti-Kickback statute or any federal or state law or regulation governing billing or claims submission.

The Stark Law EHR exception is currently set to expire on December 31, 2013. In addition to the CWHIS exception and EHR Exception, there is an exception for electronic prescriptions (the "**E-Prescribing Exception**"). Although not identical to the HER Exception, the E-Prescribing Exception contains a number of similar conditions. Of notable difference, the E-Prescribing Exception does not require the physician to pay at least 15% of the donor's cost. In addition to the Stark Law, a number of other Federal and state laws govern electronic health records and electronic prescribing. For example, some laws limit or prohibit electronic prescribing in certain context while other laws provide incentives for the use and implementation of electronic prescribing.

3. ***What is considered "interoperable" software under the Stark Law EHR exception?***

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Software is considered interoperable if it meets a specific regulatory definition of "interoperable" or is deemed to be interoperable if the software is certified no more than 12 months prior to the date it is provided to the physician by a body recognized by the Secretary of Health and Human Services. Currently, the Certification Commission for Healthcare Information Technology (CCHIT) is the certifying body recognized by the Secretary of Health and Human Services. The regulatory definition of "interoperable" is "able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered."

4. *What HIT is allowed under the EHR Exception? Does the E-Prescribing Exception allow other HIT?*

The Stark Law EHR Exception allows software or information technology and training services necessary and used predominately to create, maintain, transmit or receive electronic health records if the other EHR Exception requirements are met. CMS has included the following HIT by way of example: (i) interface and translation software; (ii) rights, licenses, and intellectual property related to EHR software; (iii) connectivity services, including broadband and wireless Internet services; (iv) clinical support and information services related to patient care (but not separate research or marketing support services); (v) maintenance services; (vi) secure messaging (permitting physicians to communicate with patients through electronic messaging); and (vii) training and support services (such as access to help desk services). CMS has also provided a list of excluded HIT: (i) hardware (and operating software that makes the hardware function), (ii) storage devices, (iii) software with core functionality other than electronic health records (for example, human resources or payroll software); (iv) items or services used by a physician primarily to conduct personal business or business unrelated to the physician's practice, and (v) the provision of staff to physicians or their offices.

The electronic prescription exception protects hardware, software, internet connectivity and training and support services. Therefore, the major distinction between the two exceptions in terms of covered technology is hardware.

5. *Has CMS provided any guidance on how "cost" is expected to be calculated?*

Yes, as noted above, one of the conditions of the EHR Exception is that the physician must pay at least 15% of the donor's costs for the HIT donated to the physician, prior to the receipt of the items or services and the donor cannot finance the recipient's payments. CMS has said that: "With respect to calculation of the costs [ ] parties should use a reasonable and verifiable method for allocating costs and are strongly encouraged to maintain contemporaneous and accurate documentation. Methods of cost allocation will be scrutinized to ensure that they do not inappropriately shift costs in a manner that provides an excess benefit to the physician recipient or results in the physician effectively paying less than 15 percent of the donor's true cost of the technology."

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