

Basic Introduction to the Stark Law



MASSACHUSETTS
MEDICAL SOCIETY

*This Issue Brief is the first in a series addressing the federal prohibition on physician self-referral, commonly referred to as the Stark Law.¹ The goal of this series is to educate physicians on the basics of the law and provide practical guidance on its application to physicians in various practice settings. This first Issue Brief will orient the reader by providing an overview of the Stark Law prohibition and its various component parts. This will be followed by subsequent Issue Briefs that will go into more detail on the Stark Law's most commonly relied upon exceptions, the key elements of the compensation exceptions (e.g., fair market value), the benefits for group practices under the Stark Law, the considerations relevant to physicians in private practice, faculty practice plans and hospital-affiliated group practices, and finally a discussion on the continuing relevance of the Stark Law in today's alternative payment world. As the law is heavily dependent on a series of defined terms, **these terms are indicated in bold and italicized for ease of reference for the reader throughout these Issue Briefs.***

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WHAT IS THE STARK LAW? A BRIEF HISTORY

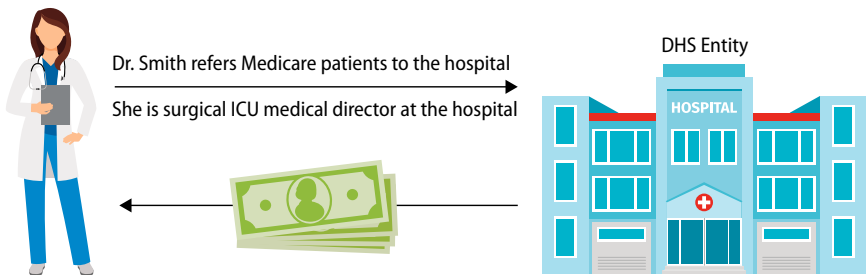
As Judge James A. Wynn of the United States Court of Appeals for the Fourth Circuit opined in a notable 2015 Stark Law case, “even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure — especially when coupled with the False Claims Act.”² However, the original intent of the law was surprisingly simple — to protect patients and the federal government from the effects of the conflict of interest that may arise when a physician refers a patient to an entity from which he or she benefits financially. Prior to the passage of the law, findings from several studies³ supported the idea that physicians with such a relationship tended to make care decisions based on financial reasons and not on what was in the best interest of the patient. These studies tied physician financial relationships to increased utilization of such services and by extension increased costs to the federal Medicare and Medicaid programs.

In response to this identified conflict of interest, Congress passed the Ethics in Patient Referrals Act or “Stark Law” (so named after the bill’s sponsor, Representative Pete Stark) as part of the Omnibus Reconciliation Act of 1989. The original law, known as “Stark I,” barred physicians from referring Medicare or Medicaid⁴ patients to clinical laboratories in which the physician or an immediate family member of the physician had a financial interest (i.e., ownership interest or compensation arrangement). In 1993, the law was significantly expanded (“Stark II”) to include 11 additional kinds of services, which are defined as *designated health services* (or DHS) under the law. To date, the Centers for Medicare and Medicaid Services (CMS), the agency responsible for oversight of the Stark Law, has issued approximately 19 final rules that address the Stark Law. Key among these are the Stark Law Phase I (January 4, 2001), Phase II (March 26, 2004), and Phase III (September 5, 2007) final rules.⁵

The Stark Law is a strict liability statute and violations, even technical ones, can lead to severe penalties and sanctions, including denial of Medicare payment, refund of overpayments,⁶ civil monetary penalties for knowing violations, and potential exclusion from participation in federal health care programs. As such, physicians are strongly encouraged to retain qualified legal counsel if they are contemplating entering into a financial arrangement with an entity that provides DHS (e.g., hospital or clinical laboratory) that may implicate the law or have concerns about compliance with respect to existing arrangements. Parties to an existing or proposed arrangement also may take advantage of CMS’s advisory opinion process, which provides guidance on the application of the Stark Law to specific factual situations.⁷ Finally, physicians and other health care providers can voluntarily self-disclose actual or potential violations of law to CMS through its self-referral disclosure protocol.⁸

WHAT DOES THE STARK LAW PROHIBIT?

The Stark Law prohibits a *physician* from making a *referral* to an *entity* for the furnishing of *designated health services* payable by Medicare if the physician or an *immediate family member* of the physician has a *financial relationship* with the entity. Further, the law prohibits the entity from billing or receiving any payment from Medicare or from any individual or other entity for the DHS furnished pursuant to the prohibited referral.⁹ Thus, the primary penalty under the Stark Law is nonpayment of Medicare claims. Once it has been determined that the law is implicated, parties may protect arrangements under the law by strictly complying with one of the applicable statutory or regulatory exceptions (e.g., bona fide employment relationships, rental of office space).



EXAMPLE Dr. Smith has a private practice and is a member of the medical staff of the hospital and routinely refers patients, including patients covered by Medicare, to the hospital for inpatient and outpatient services. Recently, the hospital asked her to serve as the surgical ICU medical director for which she would be paid \$3,000 per month. This new relationship between Dr. Smith and the hospital implicates the Stark Law because Dr. Smith will now receive compensation from the hospital for her medical director services and will continue to refer Medicare patients there. The compensation arrangement must be structured to meet the terms and conditions of an applicable exception, such as the personal services arrangement exception, to receive protection under the law.

WHICH INDIVIDUALS' FINANCIAL RELATIONSHIPS ARE THE FOCUS UNDER THE LAW?

As a threshold matter, there must be a financial relationship between a physician or his or her immediate family member and a DHS entity in order for the Stark Law to be implicated. *Physician* is defined to include the following:

- Doctor of medicine or osteopathy
- Doctor of dental surgery or dental medicine
- Doctor of podiatric medicine
- Doctor of optometry
- A chiropractor¹⁰

An *immediate family member of a physician* is defined to include the following:

- Husband or wife, including lawfully married same-sex spouses
- Birth or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law
- Grandparent or grandchild
- Spouse of a grandparent or grandchild¹¹

EXAMPLE If Dr. Smith works at a primary care practice located in the same office building as a clinical laboratory owned by her brother-in-law, she would not be able to refer patients or specimens to that laboratory unless his financial relationship with the laboratory complied with the requirements of an applicable Stark Law exception.

WHAT ARE DESIGNATED HEALTH SERVICES (DHS) AND WHY DOES IT MATTER?

Beyond the requirement that an arrangement involve a physician or an immediate family member, the law is implicated only if the arrangement in question has the potential to include referrals for designated health services payable by Medicare. Thus, the DHS list is often a helpful place to start in determining whether an arrangement may implicate the Stark Law. Below is a table of the DHS categories and the associated limitations for each category:¹²

DHS CATEGORY	LIMITATIONS
Clinical laboratory services	Identified by annual CPT/HCPCS code list released by CMS ¹³
Physical therapy, occupational therapy, and outpatient speech-language pathology services	Identified by annual CPT/HCPCS code list released by CMS
Radiology and certain other imaging services	Identified by annual CPT/HCPCS code list released by CMS <i>but specifically excluding the following</i> : <ol style="list-style-type: none"> 1. X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin into a body orifice 2. Radiology or imaging services that are integral to the performance of a medical procedure that is not identified on the list of CPT codes issued by CMS and that is performed either immediately prior to or during the medical procedure, or immediately following the medical procedure to confirm placement of an item placed during the medical procedure 3. Radiology and certain other imaging services that are <i>covered ancillary services</i> for which separate payment is made to an ambulatory surgery center.
Radiation therapy services and supplies	Identified by annual CPT/HCPCS code list released by CMS
Durable medical equipment and supplies	Section 1861(n) of the Social Security Act; 42 C.F.R. § 414.202 ¹⁴
Parenteral and enteral nutrients, equipment, and supplies	Includes all HCPCS level 2 codes for these services; see CMS National Coverage Determinations Manual, Chapter 1, Section 180.2

DHS CATEGORY	LIMITATIONS
Prosthetics, orthotics, and prosthetic devices and supplies	<p>Includes all HCPCS level 2 codes for these items and services that are covered by Medicare:</p> <ol style="list-style-type: none"> 1. Orthotics and Prosthetics — Section 1861(s)(9) of the Social Security Act¹⁵ 2. Prosthetic devices — Section 1861(s)(8) of the Social Security Act¹⁶ 3. Prosthetic supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care)
Home health services	Section 1861(m) of the Social Security Act; 42 C.F.R. § 409, et seq. ¹⁷
Outpatient prescription drugs	All drugs covered by Medicare Part B or D, except for those drugs that are <i>covered ancillary services</i> for which separate payment is made to an ASC
Inpatient and outpatient hospital services	<ol style="list-style-type: none"> 1. Inpatient hospital: Section 1861(b) of the Social Security Act; 42 C.F.R. § 409.10(a) and (b) including inpatient psychiatric hospital and inpatient critical access hospital services¹⁸ 2. Outpatient hospital: therapeutic (Section 1861(s)(2)(B) of the Social Security Act) and diagnostic (Section 1861(s)(2)(C) of the Social Security Act) services including partial hospitalization services as well as outpatient psychiatric hospital and outpatient critical access hospital services¹⁹ 3. Includes inpatient and outpatient hospital services furnished by the hospital directly or under arrangements 4. Excludes professional services performed by physicians and certain nonphysician practitioners (e.g., NP, PA) if they are separately reimbursed from the inpatient or outpatient hospital service 5. Excludes lithotripsy²⁰

The law specifically carves out the following from being considered DHS:

- Implants in an Ambulatory Surgical Center (ASC)²¹
- Preventive screening/immunizations²²
- Eyeglasses and contact lenses following cataract surgery²³
- Epoetin Alfa in End-Stage Renal Disease facilities²⁴
- DHS paid as part of a composite payment under another Medicare benefit (e.g., radiology services paid as part of the ASC case rate payment, physical therapy paid as part of the Skilled Nursing Facility (SNF) Part A per diem payment) except to the extent that the services listed above are payable through a composite rate (e.g., home health, inpatient hospital services)²⁵



Physicians should be careful with respect to the carve-out for services paid by Medicare as part of a composite payment. For example, if an SNF (either directly or under arrangements) provides physical therapy to a patient in a covered Part A stay, the physical therapy services are bundled into the composite per diem payment it receives from Medicare and thus are not considered DHS in this case. However, if an SNF provides physical therapy to a patient who has exhausted his or her Medicare benefits, such services are considered DHS under the Stark Law if they are eligible for payment by Medicare under Part B.



Some DHS categories, like radiology and certain other imaging services, have both a technical component (representing the facility charge for the service) and a professional component (representing the portion performed by the physician) as part of the service. Under the Stark Law, both the technical component and the professional component of the service are considered DHS.²⁶



It is important to note that a service provided in one practice setting may not be considered DHS (e.g., physician office, IDTF) but would be considered DHS if delivered in the hospital setting. For example, a sleep study is not considered a DHS when delivered in a physician office laboratory, but if the same test were conducted in the hospital setting, the service becomes an **outpatient hospital service** and is considered a DHS covered by the law.



Each year physician practices that provide clinical laboratory services, physical therapy, occupational therapy, speech language pathology, radiology, or radiation therapy should perform a compliance review of the revised annual CPT/HCPCS code list released by CMS (usually in November) to ensure that any services being provided continue to be excluded from being considered a DHS under the Stark Law.

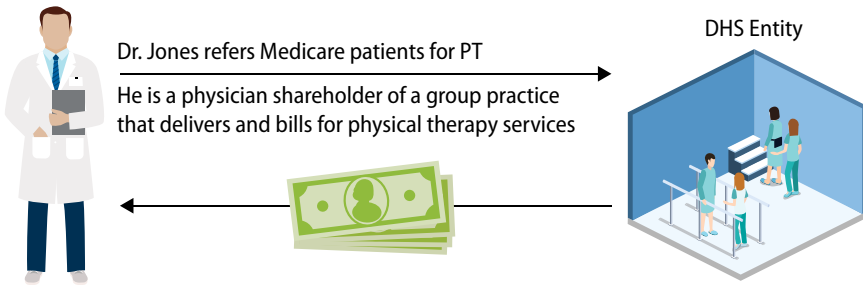
WHICH FINANCIAL RELATIONSHIPS MAY EXPOSE A PHYSICIAN TO THE STARK LAW?

There are four types of financial relationships between a physician or an immediate family member and an entity which implicate the Stark Law:

1. Direct ownership
2. Indirect ownership
3. Direct compensation
4. Indirect compensation

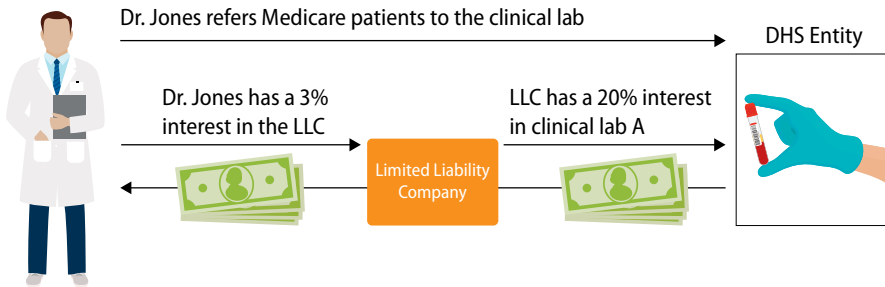
Direct or Indirect Ownership or Investment Interests

A **direct** ownership or investment interest exists if it is held without any intervening persons or entities between the DHS entity and the physician or an immediate family member.²⁷



An **indirect** ownership or investment interest exists when the following occur:

- There is an unbroken chain of any number of persons or entities having ownership or investment interests between the physician or an immediate family member and the entity furnishing DHS.
- The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact the referring physician or an immediate family member has some ownership or investment interest (through any number of intermediary ownership or investment interests) in it.²⁸



EXAMPLE Dr. Jones holds a 3% interest in a limited liability company that holds an interest in several clinical laboratories including a 20% interest in clinical lab A. Dr. Jones routinely refers certain patient specimens, including for patients covered by Medicare, for processing to clinical lab A. Dr. Jones will be deemed to hold an indirect ownership interest in that lab *if and only if* it has actual knowledge of or acts in reckless disregard or deliberate ignorance of the fact that Dr. Jones holds an ownership interest in the LLC.

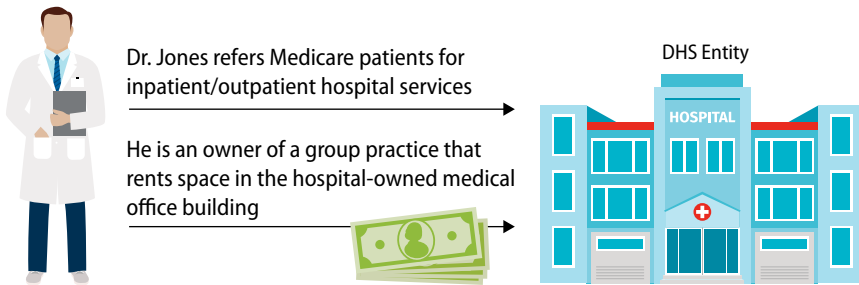
- An ownership or investment interest in an entity may be through equity, debt, stock, partnership shares, limited liability company membership, as well as loans, bonds, or other financial instruments that are secured with its property or revenue or a portion of either.²⁹
- CMS has clarified that the financial attributes or benefits typically associated with ownership must be present in order for an ownership interest to exist under the Stark Law.³⁰ Membership in a nonprofit corporation does not constitute an ownership or investment interest under the Stark Law.³¹
- Ownership or investment in a subsidiary company does not create an interest in the parent company or any of its other subsidiaries, unless the subsidiary itself has an interest in the parent company or its other subsidiaries.³²
- Common ownership or investment interest in an entity does not, in and of itself, establish an indirect interest between one common owner or investor and another.³³

Direct or Indirect Compensation Arrangements

A **direct** compensation arrangement exists if **remuneration**³⁴ passes between the physician or an immediate family member and the entity furnishing DHS without any intervening parties.³⁵ Split-bill arrangements (i.e., where the physician bills for professional services and the hospital bills for its facility fee) are not considered remuneration.³⁶



An *under arrangements* agreement between a hospital and an entity performing a DHS (as described below) creates a compensation relationship under the Stark Law.

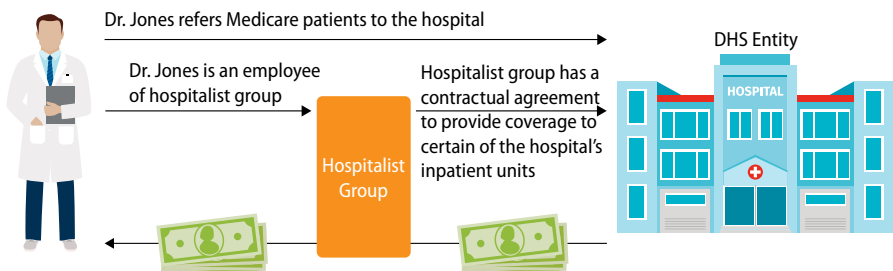


- A physician with an ownership or investment interest in a **physician organization** (e.g., group practice, sole PC) *stands in the shoes* of that organization and is deemed to have the same compensation arrangement(s) with the DHS entity as the organization.³⁷ Stand in the shoes does not apply if the entity between the referring physician and the DHS entity is not a physician organization.
- Non-owner physicians (and titular owners) *may* elect to stand in the shoes of their physician organizations but are not required to.
- The application of the stand in the shoes concept is important as the availability of a Stark Law compensation exception depends on whether the arrangement is classified as direct (24 available exceptions) or indirect (1 available exception). The adoption of this rule converted many indirect compensation arrangements to direct compensation arrangements.

EXAMPLE Dr. Jones, Dr. Smith, and Dr. Johnson are owners of ABC Medical Practice; Dr. Montgomery is not an owner. ABC Medical Practice enters into a written agreement with hospital A to lease space in its medical office building. Prior to the adoption of stand in the shoes, such a lease arrangement would have been analyzed under the indirect compensation arrangement definition and its applicable exception with respect to all four doctors (physician-> ABC Medical Practice [physician organization]-> hospital A). With the application of stand in the shoes, Dr. Jones, Smith, and Johnson are now considered to have a direct compensation relationship with hospital A (ABC Medical Practice [Drs. Jones/Smith/Johnson standing in the shoes of their physician organization]-> hospital A) while Dr. Montgomery, the non-owner, may either elect to stand in the shoes of ABC Medical Practice or may choose to continue to analyze her financial relationship with hospital A under the rules for indirect compensation arrangements. It is worth noting, however, that if ABC Medical Practice has a separate management LLC that enters into the lease agreement with hospital A, stand in the shoes does not apply and the financial relationship would continue to be analyzed under the indirect compensation arrangement definition and its applicable exception (physician -> ABC Medical Practice [physician organization] -> Management LLC -> hospital A).

An *indirect* compensation arrangement exists if the following occurs:

- There is an unbroken chain of any number of persons or entities having financial relationships (either ownership/investment or compensation arrangements) between the referring physician or an immediate family member and the entity furnishing DHS.
- The referring physician receives aggregate compensation from the person or entity in the chain with which the physician or an immediate family member has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.
- The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact the referring physician or an immediate family member receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.³⁸



EXAMPLE In the example on the previous page, Dr. Jones is an employee of the hospitalist group. As compensation for his services, he receives an annual base salary of \$220,000. This arrangement does not create an indirect compensation arrangement under the Stark Law because Dr. Jones receives a fixed, aggregate payment from the group that does not vary with, or take into account, the volume or value of referrals or other business generated by Dr. Jones for the hospital. However, even if the total compensation Dr. Jones received from the hospitalist group did vary with, or take into account, the volume or value of his hospital referrals, the hospital would have to have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that Dr. Jones was compensated in such a manner in order for an indirect compensation arrangement to exist.

- If the referring physician's or immediate family member's direct financial relationship is an ownership/investment interest, then the aggregate compensation test is applied to the first compensation arrangement in the chain nearest the individual's ownership/investment interest.³⁹
- It is important to note that in evaluating whether the aggregate compensation received by the referring physician or immediate family member varies with, or takes into account, the volume or value of referrals or other business generated by this individual for the entity furnishing DHS, the Stark Law special rules on compensation which *deem* certain kinds of unit-based compensation (e.g., time-based or per-unit of service-based compensation) to meet this standard do not apply.⁴⁰



As a compliance measure to ensure that no indirect compensation arrangement exists, a DHS entity may elect to obtain written assurance from the referring physician or, where applicable, his or her immediate family member, or from the entity from which that individual receives direct compensation that his or her aggregate compensation is fair market value for services furnished and does not take into account or otherwise reflect referrals or other business generated for the DHS entity.

WHEN DOES A REFERRAL OCCUR UNDER THE LAW?

Under the law, a referral is defined as a request by a physician for the ordering of, or the certifying or recertifying of the need for, any DHS covered by Medicare, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by or under the supervision of that other physician. A referral is also made when a physician establishes a plan of care that includes the provision of DHS.⁴¹ Referrals for DHS which are made by another person or entity may be attributed to a physician under the Stark Law if that physician directs or controls the referrals being made by the other person or entity.⁴²

EXAMPLE If a nurse practitioner always refers patients to a particular durable medical equipment (DME) supplier because a physician has instructed the clinical staff at the practice to refer patients to that supplier, then under the Stark Law, such a referral would be attributable to the physician since it was made pursuant to his or her direction and control.

Certain types of physician conduct, however, are excepted from the definition of referral under the law. These include the following:

1. **Exception for Personally Performed DHS.** A physician does not make a referral when he or she personally performs or provides the DHS.⁴³



However, CMS has clarified that a referral *does* occur when the DHS is performed by a physician's employees or independent contractors, including *incident to* services, or other members of the physician's group practice.⁴⁴

EXAMPLE If a physician orders an antigen for a patient and requests that a physician assistant employed by his or her group practice administer the antigen to the patient, the physician will be deemed to have made a referral to that physician assistant under the Stark Law.

2. **Exception for Consultation by a Pathologist, Radiologist, or Radiation Oncologist.** A referral does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if the following occurs:
 - a. The request results from a *consultation*⁴⁵ initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated).
 - b. The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice.

WHEN IS AN ENTITY CONSIDERED TO BE FURNISHING A DESIGNATED HEALTH SERVICE UNDER THE LAW?

The referral in question needs to be made to an *entity*⁴⁶ that furnishes DHS in order for the Stark Law to be implicated. An entity furnishes DHS if it does either of the following:

1. Bills the Medicare program for the DHS services
2. Performs⁴⁷ the services that are billed as DHS to the Medicare program

EXAMPLE A physician group practice is a DHS entity when it bills the Medicare program for the clinical laboratory services it provides to its patients in its offices. In this case, the physician group practice has both billed and performed the DHS. However, in some cases the entity that bills for the DHS and the one that performs the DHS are different. For example, an independent diagnostic testing facility is a DHS entity when it contracts with hospital A to provide diagnostic testing services under arrangements for its inpatients and outpatients because it performs services that are billed as DHS. Hospital A is also a DHS entity in this arrangement because it bills the Medicare program for the DHS (inpatient and outpatient hospital services) performed by the IDTF.

END OF THE ROAD

- A physician or an immediate family member has a financial relationship with an entity that performs or bills for a designated health service.
- The physician refers Medicare patients to that entity for designated health services.



The Stark Law is implicated. The financial relationship between the physician or an immediate family member and the entity that performs or bills for the DHS must meet all of the terms and conditions of an applicable exception.

Again, given the strict liability nature of the Stark Law, physicians should not proceed without an evaluation of any proposed arrangement with a DHS entity by competent legal counsel. However, as already discussed in detail, the law, while nuanced, does require that each of the key components be present in order for the prohibition to even be implicated. If one or more of the key components of the law are not present, then the arrangement is not required to be structured in accordance with an applicable Stark Law exception but may implicate the federal⁴⁸ or Massachusetts⁴⁹ Anti-kickback Statutes. If all of the key components discussed above are present, however, the arrangement must be structured in accordance with an appropriate statutory or regulatory exception. On the following page is a chart of all of the available Stark Law exceptions.

In our next Issue Brief, we will discuss the Stark Law exceptions that are most commonly relied upon to protect a physician's or immediate family member's financial relationships with DHS entities.

WHAT ARE THE STARK LAW EXCEPTIONS?

GENERAL EXCEPTIONS	Physician Services* ⁵⁰
	In-Office Ancillary Services* ⁵¹
	Prepaid Plans* ⁵²
	Academic Medical Centers ⁵³
	Implants Furnished by an ASC ⁵⁴
	EPO and Other Dialysis-Related Drugs ⁵⁵
	Preventive Screening Tests, Immunizations, and Vaccines ⁵⁶
	Eyeglasses and Contact Lenses Following Cataract Surgery ⁵⁷
	Intra-Family Rural Referrals ⁵⁸
OWNERSHIP EXCEPTIONS	Publicly Traded Securities* ⁵⁹
	Mutual Funds* ⁶⁰
	Specific Providers: (1) Rural Providers, (2) Hospitals in Puerto Rico, and (3) "Whole" Hospitals* ⁶¹
COMPENSATION EXCEPTIONS	Rental of Office Space* ⁶²
	Rental of Equipment* ⁶³
	Bona Fide Employment Relationships* ⁶⁴
	Personal Service Arrangements* ⁶⁵
	Physician Recruitment* ⁶⁶
	Isolated Transactions* ⁶⁷
	Certain Arrangements with Hospitals* ⁶⁸
	Group Practice Arrangements with a Hospital* ⁶⁹
	Payments by a Physician* ⁷⁰
	Charitable Donations by a Physician ⁷¹
	Nonmonetary Compensation ⁷²
	Fair Market Value Compensation ⁷³
	Medical Staff Incidental Benefits ⁷⁴
	Risk-Sharing Arrangements ⁷⁵
	Compliance Training ⁷⁶
	Indirect Compensation Arrangements ⁷⁷
	Referral Services ⁷⁸
	Obstetrical Malpractice Insurance Subsidies ⁷⁹
	Professional Courtesy ⁸⁰
	Retention Payments in Underserved Areas ⁸¹
Community-Wide Health Information Systems ⁸²	
Electronic Prescribing Items and Services ⁸³	
Electronic Health Records Items and Services ⁸⁴	
Assistance to Compensate a Nonphysician Practitioner ⁸⁵	
Timeshare Arrangements ⁸⁶	

*Exceptions with an asterisk have both a statutory and a regulatory exception.

Endnotes

¹This Issue Brief series is intended to provide the Massachusetts Medical Society's membership with a general understanding of the Stark Law. Given the intricacies of the law and the variety of fact patterns that may be presented, this series of Issue Briefs was developed to provide physicians with an overview of key concepts so that physicians are equipped to recognize potential Stark Law issues that may be associated with his or her financial relationships. The examples provided are for illustration only and are not a substitute for the advice of qualified legal counsel. The MMS provides these Issue Briefs with the understanding that no attorney-client relationship is created between the MMS, its agents, and the reader. The MMS is not providing legal advice.

²Sen. Orrin Hatch. *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models*, Senate Committee on Finance, S. Doc. No. 13-2219, 2 (2016), citing *United States ex rel. Drakeford v. Tuomey Healthcare Sys. Inc.*, 792 F. 3d 364, 395 (4th Cir. 2015). Available at www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%205FC%20Majority%20Staff.pdf.

³See Office of the Inspector General, Office of Analysis and Inspections, OAI-12-88-01410, *Financial Arrangements Between Physicians and Health Care Businesses* (1989); Hillman BJ et al. Frequency and costs of diagnostic imaging in office practice — a comparison of self-referring and radiologist-referring physicians, *N Eng J Med* 1990; 323:1604. Available at www.nejm.org/doi/pdf/10.1056/NEJM199012063232306. McDowell TN. Physician self referral arrangements: Legitimate business or unethical entrepreneurialism. *Am J Law Med* 1989; 15:61. Mitchell JM, E Scott E. Physician self-referral: Empirical evidence and policy implications. *Advances in Health Economics and Health Services Research* 1992; 13:27 (1992). Relman AS. The future of medical practice. *2 Health Affairs* 1983; 2:5, 7. Available at <http://content.healthaffairs.org/content/2/2/5.full.pdf+html>.

⁴In 1993, when "Stark II" was enacted, new language was added under Section 1903(s) of the Social Security Act which extended the application of the Stark Law to the Medicaid program. To date, however, CMS has not promulgated regulations addressing Section 1903(s). Thus, enforcement and compliance efforts concerning the Stark Law have focused on referrals for items and services reimbursable under the Medicare program only. As such, these Issue Briefs solely address the application of the Stark Law to referrals for DHS payable by the Medicare program. It is important to note, however, that several recent court cases have held that the Stark Law also applies to items and services reimbursable under the Medicaid program (42 U.S.C. § 1396b(s)) through application of the False Claims Act, the primary law used by the federal government to enforce the Stark Law. Physicians and other health care providers should be aware of the recent efforts in False Claims Act cases to apply the Stark Law to Medicaid claims and be mindful of this trend when developing and reviewing their compliance programs.

⁵A full listing of all rulemakings is available on the CMS web site at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Significant-Regulatory-History.html.

⁶Financial arrangements that violate the Stark Law create a Medicare overpayment liability. Section 6402(a) of the Affordable Care Act established Section 1128J(d) of the Social Security Act which requires Medicare and Medicaid providers who have received an overpayment to report and return the overpayment to the appropriate governmental entity and to notify the entity to whom the overpayment was returned, in writing, of the reason for the overpayment. An overpayment must be reported and returned by the later of (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Any overpayment retained beyond the 60-day period not only may be considered an *obligation* under the federal False Claims Act but also provides grounds for the imposition of civil monetary penalties of not more than \$10,000 per item or service. 42 U.S.C. §1320a-7k(d) (2010).

⁷42 C.F.R. §§ 411.370(b), 411.387 (2017). The requestor(s) must be a party to the existing or proposed arrangement which is the subject of the request, and the advisory opinion may only be relied on by the party or parties requesting the opinion.

⁸Self-Referral Disclosure Protocol. Centers for Medicare and Medicaid Services website. www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html. Updated June 6, 2017. Since the inception of the Self-Referral Disclosure Protocol in 2011, CMS has settled approximately 233 disclosures for amounts ranging from as low as \$60 to as high as \$1,195,763.

⁹42 U.S.C. § 1395nn (2010); 42 C.F.R. § 411.353(a)–(b) (2017).

¹⁰42 U.S.C. § 1395x(r) (2016).

¹¹42 C.F.R. § 411.351 (2017) (defining immediate family member of a physician).

¹²66 Fed. Reg. 855, 923 (January 4, 2001).

¹³Code List for Certain Designated Health Services (DHS). Centers for Medicare and Medicaid Services website. www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html. Updated November 11, 2016.

¹⁴42 U.S.C. § 1395x(n). In brief, *durable medical equipment* covered by Medicare includes equipment that (i) meets the definition of DME; (ii) is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of a malformed body member; and (iii) is used in the patient's home. For the equipment to be considered DME, it must be able to (i) withstand repeated use; (ii) be primarily and customarily used to serve a medical purpose; (iii) is generally not useful to a person in the absence of an illness or injury; and (iv) is appropriate for use in the home. Centers for Medicare and Medicaid Services, 100–02. Medicare Benefit Policy Manual: Durable Medical Equipment — General, c. 15 § 110; 2003.

¹⁵42 U.S.C. § 1395x(s)(9). Orthotics and prosthetics include leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition. *Id.*

¹⁶42 U.S.C. § 1395x(s)(8). This includes prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. *Id.*

¹⁷42 U.S.C. § 1395x(m). In brief, Medicare covers *home health services* that meet the following criteria: (i) the person to whom the services are provided is an eligible Medicare beneficiary; (ii) the home health agency that is providing the services to the beneficiary has in effect a valid agreement to participate in the Medicare program; (iii) the beneficiary qualifies for coverage of home health services because he or she is (a) confined to the home, (b) under the care of a physician, (c) receiving services under a plan of care established and periodically reviewed by a physician, (d) in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology, or (e) has a continuing need for occupational therapy; (iv) the services for which payment is claimed are covered services (e.g., part-time or intermittent skilled nursing care; part-time or intermittent home health aide services; physical therapy; speech-language pathology; occupational therapy; medical social services); (v) Medicare is the appropriate payer; and (vi) the services for which payment is claimed are not otherwise excluded from payment. Centers for Medicare and Medicaid Services, 100–02. Medicare Benefit Policy Manual: Home Health Services, c. 7; 2017.

¹⁸42 U.S.C. § 1395x(b). In brief, *inpatient hospital services* includes bed and board; nursing services and other related services; use of hospital facilities; medical social services; drugs, biologicals, supplies, appliances, and equipment; certain other diagnostic or therapeutic services; medical or surgical services provided by certain interns or residents-in-training; and transportation services, including transport by ambulance. Centers for Medicare and Medicaid Services, 100–02. Medicare Benefit Policy Manual: Definition of Inpatient Hospital Services, c. 1 § 1; 2003.

¹⁹42 U.S.C. §§ 1395(x)(s)(2)(B), 1395(x)(s)(2)(C). In brief, *outpatient hospital services* includes both diagnostic and therapeutic services (including partial hospitalization services) furnished by hospitals to outpatients. Centers for Medicare and Medicaid Services, 100–02. Medicare Benefit Policy Manual: Definition of Inpatient Hospital Services, c. 6 § 20; 2012.

²⁰Am. Lithotripsy Soc'y v. Thompson, 215 F. Supp. 2d 23 (D.D.C. 2002). See also 69 Fed. Reg. 16054, 16106 (March 26, 2004). Physician Self-Referral Law Frequently Asked Questions. Centers for Medicare and Medicaid Services website. Published on September 14, 2017. Available at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf.

²¹42 C.F.R. § 411.355(f) (2017).

²²42 C.F.R. § 411.355(h).

²³42 C.F.R. § 411.355(i).

²⁴42 C.F.R. § 411.355(g).

²⁵42 C.F.R. § 411.351 (2017). See also 66 Fed. Reg. 855, 923 (January 4, 2001).

²⁶66 Fed. Reg. 855, 924 (January 4, 2001).

²⁷42 C.F.R. § 411.354(a)(2)(i) (2017).

²⁸42 C.F.R. § 411.354(b)(5). An entity is only required to make *reasonable inquiry* concerning a possible indirect ownership or investment interest if it learns of facts that might suggest that an indirect ownership relationship exists. "The knowledge element does not impose an affirmative obligation to inquire as to indirect financial relationships." 66 Fed. Reg. 855, 865 (January 4, 2001).

²⁹42 C.F.R. § 411.354(b).

³⁰Centers for Medicare and Medicaid Services Advisory Opinion No. CMS-AO-2005-08-01. Published in 2005. Available at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2005-08-01.pdf.

³¹63 Fed. Reg. 1659, 1707 (January 9, 1998).

³²Such relationships may, however, create an indirect financial relationship. 42 C.F.R. § 411.354(b)(2).

³³42 C.F.R. § 411.354(b)(5)(iii).

³⁴Remuneration is broadly defined to include any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind but *excludes* the following: (1) the forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors; (2) the furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely for the purposes of collecting, transporting, processing, or storing specimens for the entity furnishing the items, devices, or supplies or ordering or communicating the results of tests or procedures for the entity furnishing the items, devices, or supplies; and (3) any payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if (a) the health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician; (b) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and (c) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals. 42 C.F.R. § 411.351 (defining remuneration).

³⁵42 C.F.R. § 411.354(c)(1)(i).

³⁶80 Fed. Reg. 70885, 71322 (December 29, 2015).

³⁷42 C.F.R. § 411.354(c)(1)(ii). A *physician organization* is broadly defined to include an individual physician, including a professional corporation in which the physician is a sole owner, a physician practice, and a group practice that meets the requirements for a *group practice* under Stark. In the CY 2009 IPPS final rule, CMS stated the following:

Physicians with only a titular ownership interest (that is, physicians without the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment) are not required to stand in the shoes of their physician organizations. In addition, we are permitting non-owner physicians (and titular owners) to stand in the shoes of their physician organizations and we are also clarifying that the physician “stand in the shoes” provisions in § 411.354(c) do not apply to an arrangement that satisfies the requirements of the exception in § 411.355(e) for AMCs.

73 Fed. Reg. 48433, 48693 (August 19, 2008). In its Stark Law FAQs, CMS has clarified that physician ownership is not necessary for an organization to be considered a physician organization. In addition, the following entities are not considered physician organizations: Federally qualified health centers, hospitals, or other Part A providers; staffing companies that do not directly provide and bill for patient care services; a single legal entity (that does not satisfy the requirements of a group practice for purposes of § 411.352) that encompasses (that is, operates) a faculty practice plan and either a medical school or hospital, or both; and a medical school that does not operate a faculty practice plan but employs physicians to provide clinical and academic service. Physician Self-Referral Law Frequently Asked Questions. Centers for Medicare and Medicaid Services website. Published on September 14, 2017. Available at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf.

³⁸42 C.F.R. § 411.354(c)(2)(iii).

³⁹42 C.F.R. § 411.354(c)(2)(ii).

⁴⁰Unit-based compensation (including time-based or per unit of service-based compensation) is deemed not to take into account the volume or value of referrals or other business generated between the parties provided the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or DHS or other business generated by the referring physician. 42 C.F.R. § 411.354(d)(2)–(3).

⁴¹42 C.F.R. § 411.351 (defining referral).

⁴²42 C.F.R. § 411.351 (defining referring physician).

⁴³42 C.F.R. § 411.351 (defining referral).

⁴⁴72 Fed. Reg. 51012, 51020 (September 5, 2007).

⁴⁵A “consultation” occurs when: (i) a physician requests the advice or opinion of another physician regarding the evaluation and/or management of a medical problem; (ii) the request and need for the consultation are documented in the patient’s medical record; (iii) after the consultation is provided, the physician prepares a report of the findings and provides it to the physician who requested the consultation; and (iv) with respect to radiation therapy services provided by a radiation oncologist, the radiation oncologist communicates periodically with the referring physician about the patient’s course of treatment and progress. 42 C.F.R. § 411.351 (defining consultation). However, if a patient is a walk-in or self-refers to a pathologist, radiologist, or radiation oncologist instead of being referred to the specialist by another physician, the referral for consultation exception would not apply. 72 Fed. Reg., 51012, 51021 (September 5, 2007).

⁴⁶An entity is broadly defined under the Stark Law to include a physician’s sole practice (but not the individual physician), a physician group practice, or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. 42 C.F.R. § 411.351 (defining entity).

⁴⁷CMS has declined to provide a definition of what it means to *perform* the DHS:

We decline to provide a specific definition of “perform,” but rather intend that it should have its common meaning. We note that the language “performing” a service, or “perform” a service, or “performed” a service, or “services performed” appears numerous times in title XVIII of the Act and in our regulations, without a definition of what “perform” or any of its derivations means. For example, section 1861(q) of the Act defines “physicians’ services” as “professional services performed by physicians” without elaboration as to what “performed” means. 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.

73 Fed. Reg. 48433, 48726 (Aug. 19, 2008).

⁴⁸42 U.S.C. § 1320a-7b (describing criminal penalties for acts involving Federal health care programs).

⁴⁹Mass. Gen. Laws chapter 175H, §§ 1–8 (2017) (discussing false health care claims); Mass. Gen. Laws chapter 118E, §§ 36–46A (Medicaid only) (describing false claims, remedies, and civil actions).

⁵⁰42 U.S.C. § 1395nn(b)(1); 42 C.F.R. § 411.355(a).

⁵¹42 U.S.C. § 1395nn(b)(2); 42 C.F.R. § 411.355(b).

⁵²42 U.S.C. § 1395nn(b)(3); 42 C.F.R. § 411.355(c).

⁵³42 C.F.R. § 411.355(e).

⁵⁴42 C.F.R. § 411.355(f).

⁵⁵42 C.F.R. § 411.355(g).

⁵⁶42 C.F.R. § 411.355(h).

⁵⁷42 C.F.R. § 411.355(i).

⁵⁸42 C.F.R. § 411.355(j).

⁵⁹42 U.S.C. § 1395nn(c); 42 C.F.R. § 411.356(a).

⁶⁰42 U.S.C. § 1395nn(c); 42 C.F.R. § 411.356(b).

⁶¹42 U.S.C. § 1395nn(d); 42 C.F.R. § 411.356(c). Please note: The Affordable Care Act limited the availability of the “whole hospital” exception at subsection (c)(3) to existing physician-owned hospitals that had a Medicare provider number as of December 31, 2010.

⁶²42 U.S.C. § 1395nn(e)(1)(A); 42 C.F.R. § 411.357(a).

⁶³42 U.S.C. § 1395nn(e)(1)(B); 42 C.F.R. § 411.357(b).

⁶⁴42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c).

⁶⁵42 U.S.C. § 1395nn(e)(3); 42 C.F.R. § 411.357(d).

⁶⁶42 U.S.C. § 1395nn(e)(5); 42 C.F.R. § 411.357(e).

⁶⁷42 U.S.C. § 1395nn(e)(6); 42 C.F.R. § 411.357(f).

⁶⁸42 U.S.C. § 1395nn(e)(4); 42 C.F.R. § 411.357(g).

⁶⁹42 U.S.C. § 1395nn(e)(7); 42 C.F.R. § 411.357(h).

⁷⁰42 U.S.C. § 1395nn(e)(8); 42 C.F.R. § 411.357(i).

⁷¹42 C.F.R. § 411.357(j).

⁷²42 C.F.R. § 411.357(k).

⁷³42 C.F.R. § 411.357(l).

⁷⁴42 C.F.R. § 411.357(m).

⁷⁵42 C.F.R. § 411.357(n).

⁷⁶42 C.F.R. § 411.357(o).

⁷⁷42 C.F.R. § 411.357(p).

⁷⁸42 C.F.R. § 411.357(q).

⁷⁹42 C.F.R. § 411.357(r).

⁸⁰42 C.F.R. § 411.357(s).

⁸¹42 C.F.R. § 411.357(t).

⁸²42 C.F.R. § 411.357(u).

⁸³42 C.F.R. § 411.357(v).

⁸⁴42 C.F.R. § 411.357(w).

⁸⁵42 C.F.R. § 411.357(x).

⁸⁶42 C.F.R. § 411.357(y).



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