

Stark Law and Related Limitations on Financial Interests in Health Care Reimbursement

**Linda Grimms, Assistant Attorney General
Oregon Department of Justice
January 6, 2012**

Context

This Report was prepared at the request of the Oregon Health Authority for purposes of responding to the request of the Legislative Assembly in HB 3650, 2011 Or Laws Chapter 602 Section 16(1)(c). This Report is intended to provide general background information and is not intended to be legal advice to anyone. Persons or entities that may be subject to the Stark Law, anti-kickback laws or false claims laws should confer with their own legal counsel about their specific duties or restrictions under these laws.

Contents

Executive Summary	2
I. What is the Stark Law?	3
II. What is the Relationship Between the Stark Law and Anti-Kickback Laws?.....	7
III. False Claims Law May Also Apply	8
Conclusion	9
Summary of Stark Law Exceptions.....	10

Executive Summary

In the Health Care Transformation law enacted in 2011 (2011 Or. Laws Chapter 602, referred to herein as HB 3650), the Oregon Health Authority was required to study several issues related to health care cost containment, including in Section 16(1)(c):

(c) An analysis of utilization, testing, services ordered, prescribed or delivered through centers or facilities in which there is a financial interest between the provider requesting a test or service and the entity or individual providing the test or service, including an examination of Stark laws and exemptions.

This report is limited to the examination of applicable laws, primarily the Stark Law, applicable to financial relationships between providers and the individuals or entities that provide tests or services.¹ A listing of the Stark Law exemptions is provided at the end of this report, as Attachment A. This report also provides a brief summary of other laws applicable to financial relationships between providers and the individuals or entities that provide tests or services, including the anti-kickback law and the federal and state false claims laws.

The Stark Law and related statutory and regulatory limitations on financial interests in health care reimbursement impose legal constraints on certain types of health care arrangements among providers and entities making referrals for services and submitting health care claims to publicly funded Medicare and Medicaid programs. These laws seek to limit health care costs by reducing costs attributable to the overutilization of health services and procedures and by reducing fraud and abuse in the publicly funded health care system. Oregon law applicable to health care providers or entities reimbursed by the Medicaid program administered by the Oregon Health Authority is generally aligned with federal requirements.

I. What is the Stark Law?

The Ethics in Patient Referrals Act, also known as the Stark Law, generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship. Likewise, the Stark Law prohibits the entity with the financial relationship from submitting claims for reimbursement that were not authorized for referral under the law.

In 1989, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (DHHS) reported that patients of referring physicians who had a financial interest in independent clinical labs received 45% more services than Medicare patients in general and 34% more services directly from clinical labs than Medicare patients in general. The OIG concluded that this increased utilization cost Medicare approximately \$28 million in 1987. Magazines, newspapers and journals had also featured articles outlining the profits physicians could make by referring patients to providers in which they had a financial interest.

In response to these reports, Congress included the Ethics in Patient Referrals Act provisions in the 1989 Omnibus Budget Reconciliation Act, banning certain financial arrangements between physicians and clinical laboratories and creating limited exceptions. Congress' goal was to limit the influence of financial relationships on physician referrals.

In 1993, Congress amended the ban by extending it to additional services and applying it to both Medicare and Medicaid, and clarifying exceptions included in the 1989 legislation. These amendments are known as "Stark II."

Initially, the Stark Law was narrowly tailored as a proscription against physician referrals for clinical laboratory services, covered by Medicare or Medicaid, to an entity in which the physician had a financial interest. It has since evolved into a broader law, covering a wide array of health-related services and financial arrangements.

The 1989 and 1993 legislation are collectively known as the Stark Law (the "Law"). They are codified in the Medicare statutes and regulations at 42 USC §1395nn and the federal regulations related to the Law are at 42 CFR §411.350-411.389.²

In 2010, the Patient Protection and Affordable Care Act³ ("ACA") updated a few provisions of the Stark Law:

- Section 6001 placed restrictions on hospitals with physician ownership that formerly had been eligible for the "whole hospital" exception. This change was made, in part, due to the growth of physician-owned specialty hospitals.

- Section 6003 added new disclosure requirements to the in-office ancillary services exception. The referring physician must inform the individual in writing at the time of the referral that the individual may receive the services from another person, and the individual must be provided with a list of alternative suppliers of the services.
- Section 6409 requires the Secretary of DHHS, in cooperation with the OIG, to develop a protocol to allow health care providers and suppliers of services to disclose actual or potential violations of the Stark Law using a self-referral disclosure protocol. Use of a self-disclosure protocol may result in a reduction of amounts owed for Stark Law violations.

How does the Stark Law apply to Oregon’s medical assistance program?

Oregon’s medical assistance program is administered in accordance with federal Medicaid regulations. Medicaid providers are required to disclose certain ownership interests at the time of enrollment, and to update any changes in that information.⁴ Consequently, Oregon’s medical assistance program includes these disclosure requirements in its provider enrollment process.⁵ The Stark Law is primarily enforced through the federally-administered Medicare program.

Does Oregon have a Stark Law?

The State of Oregon has the following statutory requirement for disclosure of financial relationships in ORS 441.098:

441.098 Physician referral of patient to treatment facility. (1) As used in this section:

- (a) “Facility” means a hospital, ambulatory surgical center or freestanding birthing center.
- (b) “Financial interest” means a five percent or greater direct or indirect ownership interest.
- (c) “Health practitioner” means a physician, podiatric physician and surgeon, dentist, direct entry midwife or licensed registered nurse who is certified by the Oregon State Board of Nursing as a nurse midwife nurse practitioner.
- (d) “Physician” has the meaning given that term in ORS 677.010.

(2) If a health practitioner refers a patient for treatment at a facility in which the health practitioner or an immediate family member has a financial interest, the health practitioner shall inform the patient orally and in writing of that interest at the time of the referral.

(3) In obtaining informed consent for treatment that will take place at a facility, a health practitioner shall disclose the manner in which care will be provided in the event that complications occur that require health services beyond what the facility has the capability to provide.

What types of health care and services are covered by the Stark Law?

The Stark Law and related regulations broadly prohibit a physician (or an immediate family member of a physician) from referring a patient to an entity in which he or she has a financial relationship for **designated health services** payable by Medicare or Medicaid.

Designated health services are defined as the following:

1. Clinical laboratory services
2. Physical therapy services
3. Occupational therapy services
4. Outpatient speech-language services
5. Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services
6. Radiation therapy services and supplies
7. Durable medical equipment and supplies
8. Parenteral and enteral nutrients, equipment, and supplies
9. Prosthetics, orthotics, and prosthetic devices and supplies
10. Home health services
11. Outpatient prescription drugs
12. Inpatient and outpatient hospital services⁶

What financial relationships are covered by the Stark Law?

The **prohibited financial relationship** can be in the form of:

1. An ownership or investment interest in the entity; or
2. A compensation arrangement between the physician and the entity.⁷

A prohibited financial relationship can be direct or indirect between the physician and an entity. For example, where a physician refers patients to a physical therapy business in which he or she owns stock, there is a direct financial relationship. An example of an indirect financial

relationship is where a physician refers patients to a MRI Center, and the physician is employed by a group practice which owns shares in the MRI Center.

Similarly, both direct and indirect compensation arrangements are prohibited. A direct compensation exists, for example, where a physician who serves as the part-time director of a clinical lab under an independent contractor agreement refers patients to the lab. If a physician who was a co-owner of a group practice and shared in the practice's revenues and the group practice leased office space to a hospital, the physician would have an indirect financial interest in the hospital.

The Law defines an "ownership or investment interest" as one created "through equity, debt or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service."⁸

The Law further defines "compensation arrangement" in part as "any arrangement involving any remuneration between a physician (or immediate family member of the physician) and an entity."⁹

"Remuneration" includes "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind."¹⁰

The Law imposes **self-reporting requirements** on all businesses that bill Medicare and Medicaid. Upon request of the DHHS Centers for Medicare and Medicaid Services (CMS), or the OIG, a business must report its "ownership, investments and compensation arrangements" including covered services it provides and the names and physician identification numbers of all doctors with investment interests or compensation agreements or with immediate family members with such interests.¹¹

What are the sanctions for violation of the Stark Law?

The Law also imposes the following **sanctions for violations**, ranging in degree of severity, enforced by the federal government:

1. Payment may be denied.
2. The government may require refunds for certain claims. CMS enforces the Law and has taken the position that the Law requires providers to refund to Medicare all amounts collected from bills submitted in violation of the Law. CMS has promulgated regulations requiring the same. The regulations require a full refund within 60 days of furnishing the designated service under a prohibited referral.

3. Doctors who bill for a service they know or should know is improper may face civil penalties of \$15,000 for each service wrongly billed-for and may be excluded from the Medicare and Medicaid programs.
4. A physician or entity who enters into an arrangement or scheme which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity is subject to civil penalties of up to \$10,000 per day for each arrangement or scheme.
5. Anyone failing to meet a reporting requirement faces fines up to \$10,000 for each day for which reporting is required to have been made.

CMS has authority to issue advisory opinions to provide guidance on the application of the Law to an existing or proposed business arrangement. A CMS advisory opinion is legally binding on DHHS and the requesting party or parties. It is not binding on any other governmental department or agency. A party that receives a favorable advisory opinion is protected from CMS administrative sanctions, so long as the arrangement at issue is conducted in accordance with the facts submitted to the CMS.

What are the exceptions to the Stark Law?

The Law contains exceptions to prohibited referrals, which fall into three categories: (1) general exceptions; (2) exceptions related to ownership/investment interests; and (3) exceptions related to compensation arrangements. Due to the large number of these exceptions, a list is provided at the end of this report as Attachment A.

II. What is the Relationship Between the Stark Law and Anti-Kickback Laws?

Whether an action or relationship is permissible under the Stark Law does not provide a defense to or immunity from civil penalties or criminal prosecutions or other sanctions applicable under state or other federal laws other than the Stark Law. As explained in the Stark Law regulations,¹² an arrangement permissible under the Stark Law may nevertheless violate other laws including but not limited to the anti-kickback laws or other state or federal fraud and abuse laws. The OIG often combines violations of anti-kickback laws with violations of physician self-referral in civil monetary cases, as demonstrated by the settlements with OIG described on the OIG website.¹³

Congress enacted the anti-kickback statutes out of concern that decisions of health care providers can be improperly influenced by a profit motive.¹⁴ The anti-kickback laws prohibit any individual or entity from knowingly and willfully soliciting, receiving, offering, or paying any form of remuneration (“in cash or in kind”) in order to induce the referral of an individual

for the furnishing or arranging for the furnishing of, any item or service payable under the Medicare or Medicaid programs.¹⁵ A party found to have violated the anti-kickback laws can be subject to civil money penalties, criminal prosecutions and imprisonment for up to five years, and exclusion from the Medicare and Medicaid programs.

As a result, the anti-kickback laws are broader than the Stark Law. Any physician referral arrangement that is subject to the Stark Law will also be subject to anti-kickback requirements.

The federal anti-kickback laws and regulations have established several “safe harbors” that are similar to but not necessarily identical to the Stark Law exceptions. The OIG has indicated that their safe harbors are not the only acceptable business arrangements. The OIG regularly issues advisory opinions and compliance guidance, as well as special fraud alerts.¹⁶

Presently, Oregon law does not explicitly impose an anti-kickback requirement, except to the extent that those laws are applicable to providers receiving payments through the Oregon medical assistance program due to Medicaid requirements.

III. False Claims Law May Also Apply

The federal False Claims Act (FCA) imposes civil liability on persons who knowingly submit a false or fraudulent claim. False claims for health care programs include (but are not limited to) billing for services not provided, for unnecessary services, double billing, and upcoding. Penalties under the federal FCA can include triple damages for each claim filed.¹⁷ Some federal courts have held that a Stark Law violation can support a FCA violation.¹⁸

The Oregon False Claims Act is found in ORS 180.750 – 180.785. It addresses claims (defined as a request or demand for payment) made to a public agency that seeks money that will be provided in whole or in part by a public body, whether directly or through reimbursement of another public body. Oregon’s False Claims Act is not limited to health care claims, but includes health care claims. The Attorney General may bring a civil action for recovery of damages, including penalties, and claims may be joined with other remedies available under other provisions of law.

Oregon law provides a number of additional authorities to address false claims in the health care setting. ORS 165.690 – 165.696 authorizes the Attorney General or a district attorney to bring criminal actions for making false claims for health care payments. If convicted, the prosecutor must notify the Oregon Health Authority and any appropriate licensing boards.¹⁹

The Attorney General is actively engaged in the investigation and prosecution of Medicaid fraud and false claims, as well as abuse. The Medicaid Fraud Unit is located within the Oregon Department of Justice. The Medicaid Fraud Unit receives referrals from many

sources, including: federal, state and local agencies; social service organizations; law enforcement agencies; provider associations; insurance companies; and private citizens. The Unit must first consider all referrals for potential criminal prosecution and, in appropriate cases, the unit may utilize available civil remedies. In addition to prosecution of local fraud and abuse cases, Oregon's Medicaid Fraud Unit works with the FBI, OIG investigators, and U.S. Justice Department officials in investigations of Medicaid providers alleged to be involved in nationwide or regional billing fraud schemes. These large-scale cooperative cases may take several years to investigate, but cases already pursued have brought hundreds of millions of dollars back to the Medicaid program, and millions of dollars back to the Oregon program.

Conclusion

The Stark Law and related statutory and regulatory limitations on financial interests in health care reimbursement impose legal constraints on certain types of health care arrangements among providers and entities making referrals for services and submitting health care claims to publicly funded Medicare and Medicaid programs. These laws seek to limit health care costs by reducing costs attributable to the overutilization of health services and procedures and by reducing fraud and abuse in the publicly funded health care system. Oregon law applicable to health care providers or entities reimbursed by the Medicaid program administered by the Oregon Health Authority is generally aligned with federal requirements.

ATTACHMENT A

SUMMARY OF STARK LAW EXCEPTIONS

The full text of the exceptions and exemptions is found in the federal Stark regulations, 42 CFR 431 Subpart J. The following summary is provided for the convenience of the reader, and should not be relied upon as a complete recital of all federal requirements.

- A. General Exceptions Applicable to Ownership/Investment Interests and Compensation Arrangements.**
- 1. Physician Services Provided Personally or under the Personal Supervision of another Physician in the Same Group Practice as the Referring Physician.** (This does not apply to “incident to” services—e.g., diagnostic tests, physical therapy.)
 - 2. In-office Ancillary Services Furnished by the Referring Physician, Another Physician in the Same Group Practice or Personally by Individuals Directly Supervised by the Physician or another Physician in the Group Practice.** The services must be furnished in (1) a building where the referring physician or other member of the group practice provides services unrelated to furnishing of designated health service; or (2) in another building used for the centralized provision of the group’s designated health services.
 - 3. Services provided by a prepaid health plan to its enrollees.** This includes coordinated care plans under the Medicare Advantage Program and Medicaid managed care organizations.
 - 4. Academic Medical Centers (AMCs) services meeting the conditions for the referring physician.¹** The referring physician must (a) be a bona fide employee of a component of the AMC on a full-time or substantial part-time basis; (b) be licensed to practice medicine in the state(s) in which he or she practices medicine; (c) have a bona fide faculty appointment at the affiliated medical school or at one or more of educational programs at the accredited academic hospital; and (d) provide either substantial (academic services or substantial clinical services or a combination) for which the faculty member receives compensation as part of his or her employment relationship with the AMC. (A physician meets the last requirement if the physician spends at least 20% of his or her professional time or eight hours per week providing such services.) The total compensation paid by each AMC must be component to the referring physician must be set in advance and not be determined in a manner that takes into account the volume or value of referrals or other business generated by the physician. The total compensation must not exceed fair market value.

¹ An AMC is (1) an accredited medical school or an accredited academic hospital; (2) one or more faculty practice plans affiliated with the medical school, the affiliated hospital(s) or the accredited academic hospital; and (3) one or more affiliated hospital(s) in which a majority of physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions are made by physicians who are faculty members.

5. **Implants furnished by an ambulatory surgical center (ASC).** This exception includes cochlear implants, intraocular lenses and other implanted prosthetic devices.
6. **Erythropoietin (EPO) and other dialysis-related drugs furnished in or by an end-stage renal disease (ESRD) facility exception.** This includes certain outpatient drugs that are required for the efficacy of dialysis and identified on the list of drugs that appear on the CMS website, updated annually.
7. **Preventive screening tests, immunizations and vaccines.** The items must meet Medicare frequency requirements and be on the list specifying items eligible for the exception.
8. **Eyeglasses and contact lenses following cataract surgery.** This applies to items provided in accordance with Medicare coverage and payment provisions.
9. **Intra-family rural referrals.** This exception applies when the patient resides in a rural area and no other person or entity is available to furnish the services in a timely manner within 25 miles or 45 minutes transportation time. This exception does not apply to home-based services.

B. Exceptions relating only to the ownership or investment prohibition.

1. **Ownership of Publicly Traded Investment Securities.** These are securities (1) purchased in a corporation listed on a major stock exchange; or (2) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers. The corporation must have stockholder equity in excess of \$75 million, either at the end of its most recent fiscal year or on an average during the previous three fiscal years. This exception also applies to ownership of shares in a regulated investment company, provided the company has total assets of over \$75 million either at the end of its most recent fiscal year or on an average during the previous three fiscal years.
2. **Hospital Ownership.** Prior to the ACA, this exception is for designated health services provided by a hospital where (1) the referring physician is authorized to perform services at the hospital; and (2) the ownership or investment interest is in the hospital itself and not merely a subdivision. The ACA has imposed some limits on this exception, described above.
3. **Rural Providers.** Applies to designated health services provided by an entity in a rural area. The exception applies only where substantially all (not less than 75%) of the designated health services furnished by the entity are furnished to individuals residing in rural areas.

C. Exceptions relating only to other compensation arrangements.

1. **Rental of Office Space and Equipment.** Payments made by a lessee to a lessor are not considered a compensation arrangement if:
 - a. The lease is in writing, signed by the parties, and specifies the premises or equipment covered by the lease;

- b. The space or equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate purposes of the lease or rental and is used exclusively by the lessee;
 - c. The term of the rental or lease is at least one year;
 - d. The rental charges over the term of the lease are set in advance, consistent with fair market value, and are not determined by taking into account the volume or value of any referrals or other business generated between the parties;
 - e. The lease would be commercially reasonable even if no referrals were made between the parties; **AND**
 - f. The lease meets any other requirements imposed by the HHS Secretary to protect against abuse.
- 2. Bona Fide Employment Relationships.** Applies to payments made by an employer to a physician (or immediate family member) who has a bona fide employment relationship with the employer if:
- a. The employment is for identifiable services;
 - b. The amount of remuneration is consistent with fair market value and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals;
 - c. The remuneration is pursuant to an agreement that would be commercially reasonable without such referral; **AND**
 - d. The employment meets other requirements the HHS Secretary may impose as needed to protect against program abuse.
- 3. Personal Service Arrangements.** Applies to payments from an entity (or downstream contractor) under an arrangement if:
- a. The arrangement is written, signed by the parties and specifies the services covered;
 - b. The arrangement covers all of the services to be provided by the physician (or immediate family member) to the entity;
 - c. The aggregate services contracted for do not exceed those reasonable and necessary for legitimate business purposes;
 - d. The term of the agreement is at least one year;
 - e. The compensation is set in advance, does not exceed fair market value, and (except for physician incentive plans) is unrelated to the volume or value of referrals or other business generated between the parties;

- f. The services do not involve the counseling or promotion of activities counter to state or federal law; **AND**
 - g. The arrangement meets other requirements imposed by the HHS Secretary to protect against abuse.
- 4. Physician Incentive Plans.** These are compensation arrangements between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided to the entity's enrollees.
- 5. Remuneration Unrelated to the Provision of Designated Health Services Exception.** This exception applies when a hospital provides remuneration to a physician, which is unrelated to providing direct health services.
- 6. Physician Recruitment Exception.** This exception applies to physician recruitment arrangements under which a hospital pays to relocate to become a member of the hospital's staff as long as there are no requirements for the physician to refer patients to the hospital; and the amount of remuneration is unrelated, directly or indirectly, to the volume or value of referrals. DHS regulations require that:
- a. The arrangement must be in writing and signed by both parties;
 - b. The arrangement is not conditioned on the physician's referral of patients to the hospital;
 - c. The hospital does not determine (directly or indirectly) the amount of remuneration to the physician based on the volume or value of actual or anticipated referrals; **AND**
 - d. The physician is allowed to establish staff privileges at other hospital or hospitals and refer business entities, except as otherwise restricted under a separate employment or services contract that complies with the requirements for a bona fide employment relationship, as discussed above.
- 7. Isolated Transactions Exception.** One example of this exception is a one-time sale of a property or practice where:
- a. The amount is consistent with fair market value and is unrelated (directly or indirectly) to the volume or value of referrals; **AND**
 - b. The transaction would be commercially viable without such referrals.
- 8. Group Practice Arrangements with a Hospital Exception.** This exception applies to certain arrangements under which designated health services are provided by a group practice but billed by a hospital where:
- a. In the case of services provided to inpatients, the arrangement is pursuant to the provision of inpatient services;

- b. The arrangement began before December 19, 1989 and has continued in effect, without interruption, since that date;
 - c. Substantially all of the direct health services covered under the arrangement and furnished to patients are furnished by the group under the arrangement;
 - d. The arrangement is in writing and specifies the services to be provided and the compensation for the services;
 - e. The compensation is consistent with fair market value, the amount per unit of service is fixed in advance and is unrelated to the volume or value of referrals or other business generated by the parties;
 - f. The agreement would be commercially reasonable even if there were no referrals; **AND**
 - g. The agreement meets other requirements the HHS Secretary may impose to protect against program or patient abuse.
- 9. Payments by a Physician for Items and Services.** This exception is for payments by a physician to a lab for clinical services and payments to another entity for items and services if they are furnished at a price consistent with fair market value.
- 10. Additional Exceptions.** The HHS Secretary provides the following additional exceptions, specified by regulation:
- a. ***Charitable Donations by a Physician.*** This applies to bona fide charitable donations made by a physician or immediate family member to an entity where:
 - i. The donation is made to a tax-exempt organization or to a supporting organization;
 - ii. It is not solicited nor offered in any manner that takes into account the volume or value of referrals or other business generated by the referring physician; **AND**
 - iii. The donation does not violate the anti-kickback statute or any law governing billing or claims submission.
 - b. ***Non-Monetary Compensation.*** This exception applies to non-monetary compensation an aggregate amount per calendar year, adjusted yearly for inflation (e.g., \$359 for 2011 and \$373 for 2012), where:
 - i. The non-monetary compensation cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician;
 - ii. The compensation is not solicited by the physician or physician's practice: **AND**

- iii. The arrangement does not violate the anti-kickback statute or any law governing billing or claims submission.
- c. **Fair Market Value Compensation.** This exception applies to compensation arising from an arrangement between an entity and physician (or immediate family member) or any group of physicians for the provision of items or services either by the physician (or family member) or group of physicians to the entity or by the entity to the physician (or family member) or group of physicians where:
- i. The arrangement is in writing and covers identifiable items or services all of which are specified;
 - ii. The time frame is specified;
 - iii. The compensation is specified, set in advance, consistent with fair market value and does not take into account the volume or value of referrals or other business generated by the referring physician;
 - iv. The arrangement is commercially reasonable;
 - v. The arrangement does not violate the anti-kickback statute or any law governing billing or claims submission; and
 - vi. The services do not involve counseling or promotion of a business arrangement or other activity that violates federal or state law.
- d. **Medical Staff Incidental Benefits.** This exception applies to non-monetary compensation from a hospital to a member of its staff when the item or service is used on the hospital's campus where:
- i. The compensation is offered to all members of the medical staff practicing in the same specialty without regard to the volume or value of referrals or other business generated between the parties;
 - ii. The compensation is provided during periods when the medical staff members are engaged in services or activities that benefit the hospital or its patients;
 - iii. The compensation is provided by the hospital and used on the campus;
 - iv. The compensation is reasonably related to or designed to facilitate directly or indirectly the delivery of medical services;
 - v. The compensation for each occurrence is less than an amount adjusted each calendar year (\$359 for 2011) for inflation;
 - vi. Compensation is not determined by the volume or value of referral or other business generated between the parties; **AND**

- vii. The arrangement does not violate the anti-kickback statute or any law governing billings or claims submission.
- e. **Risk-Sharing Arrangements.** This exception applies to compensation provided pursuant to a risk-sharing agreement between a managed care organization or an independent practice association and a physician (either directly or through a subcontractor) for services provided to health plan enrollees if the arrangement does not violate the anti-kickback statute or any law governing billing or claims submission.
- f. **Compliance Training.** This exception applies to compliance training provided by an entity to a physician (or immediate family member or office staff) who practices in the entity's local community or service area if the training is held in such area.
- g. **Indirect Compensation Arrangements.** This exception applies where:
 - i. The compensation received by the referring physician (or immediate family member) is fair market value for services and items actually provided and does not take into account the volume or value of referrals or other business generated by the referring physician;
 - ii. The arrangement is in writing and specifies the covered services; **AND**
 - iii. The compensation does not violate the anti-kickback statute or any law or regulation governing billing or claims submission.
- h. **Referral Services.** This exception applies to remuneration which fits into the anti-kickback safe harbor as defined in 42 CFR §1001.952(f) for referral services.
- i. **Obstetrical Malpractice Insurance Subsidies.** This exception applies to remuneration which fits into the anti-kickback safe harbor as defined in 42 CFR §1001.952(f) for obstetrical malpractice insurance subsidies.
- j. **Professional Courtesy Exception.** An exception for the provision of free or discounted health care items or services offered to a physician (or immediate family member, or office staff) applies where:
 - i. The professional courtesy is offered to all physicians on the entity's bona fide medical staff or entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties;
 - ii. The health care items and services are of a type routinely provided by the entity;
 - iii. The entity's professional courtesy policy is written and approved in advance by the governing board;

- iv. The courtesy is not offered to a physician or immediate family member who is a federal health care program beneficiary, unless there is a good-faith showing of financial need; **AND**
- v. The arrangement does not violate the anti-kickback statute or any law or regulation governing billing or claims submission.
- k. **Retention Payments in Underserved Areas.** This exception applies to remuneration provided by a hospital directly to a physician on its staff in order to retain the physician's medical practice in the geographic area served by the entity. It also applies to remuneration provided by a federally qualified health center or a rural health clinic.
- l. **Community-Wide Health Information Systems.** This exception applies to items or services of information technology provided by an entity to a physician that allow access to and sharing of electronic health care records and any complimentary drug information systems, general health medical alerts and related information for patients served by community providers and practitioners in order to enhance overall health where:
 - i. The items and services are available as necessary to enable the physician to participate in a community-wide information system; are principally used by the physician as part of that system; and are not provided in any manner that takes into account the value or volume of referrals or other business generated by the physician;
 - ii. The community-wide systems are available to all providers and practitioners and residents of the community who participate; **AND**
 - iii. The arrangement does not violate the anti-kickback statute or any law or regulation governing billing or claims submission.

JUSTICE.3125701

ENDNOTES

¹ Analysis of utilization, testing, services ordered, prescribed or delivered in relation to the requirements of these laws is beyond the scope of this report.

² Additional background on the rationale for the Stark Law and the documentation of self-referral studies can be found in the following materials: Sutton, Patrick A., "The Stark Law in Retrospect," 20 Annals of Health Law 15 (Winter 2011); O'Sullivan, Jennifer, "Medicare: Physician Self-Referral ('Stark I and II')" (Congressional Research Service September 27, 2007); "Making Sense of the Stark Law, Compliance for the Medical Practice" (Massachusetts Medical Society, 2005); Wales, Steven D., "The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals," 27 Law and Psychology Review 1 (Spring 2003).

³ The Patient Protection and Affordable Care Act was enacted as Pub.L. 111-148 (2010).

⁴ See, e.g., 42 USC 1320a-5; 42 CFR 455.100 – 455.106.

⁵ See OAR 410-141-0120 (Managed care plans responsible for disclosure requirements of its contracted providers); OAR 410-120-1260 (fee-for-service provider enrollment disclosure requirements).

⁶ 42 USC 1395nn(h)(6); 42 CFR 411.351 (definition of “designated health services”)

⁷ 42 USC 1395nn(a)(2); 42 CFR 411.354.

⁸ 42 USC 1395nn(a)(2); 42 CFR 411.354.

⁹ 42 USC 1395nn(h)(1)(A); 42 CFR 411.354(c).

¹⁰ 42 USC 1395nn(h)(1)(B); 42 CFR 411.351 (defining “remuneration”).

¹¹ 42 CFR 411.361(c).

¹² 42 CFR 411.350(b).

¹³ See US DHHS Office of Inspector General web site, “Enforcement Actions: Kickback and Physician Self-Referral,” <http://www.oig.hhs.gov/fraud/enforcement/cmp/kickback.asp> ; see also Witten, Jesse A., Norby, Erin, “Stark Law Enforcement and Compliance Developments, 2009-2010” (ABA-CLE 2010).

¹⁴ Staman, Jennifer, “Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview” 3 (Congressional Research Service, Aug. 10, 2010).

¹⁵ 42 USC 1320a-7b(b).

¹⁶ See US DHHS Office of Inspector General web site for advisory opinions: <http://oig.hhs.gov/compliance/advisory-opinions/index.asp>. Other OIG resources are available on their website.

¹⁷ The federal False Claims Act is codified at 31 USC 3729 – 3733.

¹⁸ See Turcotte, Claire, “Health Care Law Enforcement and Compliance: Leading Lawyers on Understanding Recent Trends in Health Care Enforcement, Updating Compliance Programs, and Developing Client Strategies; Keeping Clients Compliant with Stark and Other Health Care Laws,” (Aspatore, September 2011).

¹⁹ ORS 165.698.