

Stark Law 101 – Back to the Basics

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The Prohibition

- The physician self-referral law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies
- Strict liability law
 - Intent or state of mind doesn't matter
 - Even purely technical violations create issue
- Billing for a service referred in violation of Stark law creates overpayment
- Overpayment that is not repaid becomes false claim
- Huge potential liability under the False Claims Act, other federal laws

Key Terms

- Physician
- Referral
- Designated Health Services
- Entity
- Financial Relationship
- Exceptions
- Group Practice

Physician

Physician has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

§1861(r)(1) of the Social Security Act (Act) defines physician as “... a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the state in which he performs such function or action...”

Referral

- The request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, 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, but not including any designated health service personally performed or provided by the referring physician.
- A request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician.

“Personally Performed”

- Personally performed services are exempt from the Stark law.
- A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.
- The rule makes no distinction between the professional component and the technical component of designated health services.
- Services performed by others are reasonably considered to be performed as a result of a “request.”

Designated Health Services (DHS)

The following items or services are DHS:

1. Clinical laboratory services
2. Physical therapy services
3. Occupational therapy services
4. Outpatient speech-language pathology services
5. Radiology and certain other imaging 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 services

Entity – Three Elements

Entity means —

(1) A physician's sole practice or a practice of multiple physicians 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. An entity does not include the referring physician himself or herself, but does include his or her medical practice.

What is “Furnishing DHS”?

A person or entity is considered to be furnishing DHS if it —

- (i) Is the person or entity that has performed services that are billed as DHS; or
- (ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with § 424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at § 1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

Entity ...

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under § 424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.

(3) For purposes of this subpart, “entity” does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with § 414.50 of this chapter and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9.

Financial Relationship

Financial relationship means —

- (i) A direct or indirect ownership or investment interest in any entity that furnishes DHS; or

- (ii) A direct or indirect compensation arrangement with an entity that furnishes DHS.

Exception

- If Stark law is applicable, all financial arrangements between referring physician and entity must fit within exception.
 - May be multiple financial relationships between physician and entity
 - Compliance with an exception for just one relationship is not sufficient.
- Employment exception
- Personal services exception
- Space, equipment rental exception
- Fair market value exception
- In-office ancillary services exception
 - Often relied upon by group practices
 - Group practice must also meet “group practice” definition within Stark law
- Indirect compensation exception

Group Practice

- Special Stark law exclusions for certain referrals among group practice physicians
- “Member of group practice” vs. “physician in the same group practice”
- Requirements to qualify as group practice:
 - Single legal entity
 - Group operates as unified business
 - At least two physician members
 - Members engage in full range of patient care through group
 - At least 75% of members’ patient care performed through group
 - Members perform at least 75% of group’s physician-patient encounters
 - Distribution of expenses and income and physician compensation comply with specific requirements

Restrictions on Group Practice Compensation/Distributions

- Generally, payments to member physicians may not be based on the volume or value of referrals
- Special rule for profit-share payments
 - Must not be directly related to volume/value of referrals
 - Specific methods of profit distribution deemed to not relate to referrals, include per capita division, division based on non-DHS services
 - Effective January 1, 2021, CMS clarified that profits from DHS may not be divided differently among physicians in group practice based on type of service/specialty
- Special rule for productivity bonus
 - Must be calculated in reasonable, verifiable manner, and not directly related to volume/value of referrals
 - Specific productivity bonuses deemed to not relate to referrals, include division based on physician's total patient encounters or RVUs, division based on non-DHS services

Group Practice Compliance with In-Office Ancillary Services Exception

- To be eligible for exception, group must fit within Stark law “group practice” definition
- Requirements for the exception to apply to a referred service:
 - Must be personally furnished by (i) the referring physician, (ii) a physician who is a member of the same group practice as the referring physician, or (iii) an individual supervised by the referring physician or other physician in his or her group practice
 - Must be performed in either (i) the “same building” where the referring physician or other physicians in his/her group practice perform certain services or (ii) a “centralized building” used by referring physician’s group practice for DHS
 - Must be billed by (i) the performing/supervising physician or his or her group practice, (ii) an entity wholly owned by the physician/group practice, or (iii) a third-party billing agent of the physician/group practice
- Special disclosure requirements apply to certain imaging services

Stark Law Enforcement Case Examples

Case Example #1: Paying Over FMV

- Large health system purchased assets of a cardiology practice and affiliated surgery center from single physician owner for about \$10 million
- Physician owner then became employee of an affiliate of the health system
- Allegation:
 - Amount system paid physician for the assets of the practice and center was nearly three times FMV
 - Health system paid physician “steeply inflated” salary of \$1.2 million per year, plus bonus
- Stark law “fair market value exception” and “employment exception” FMV payments
- Whistleblowers filed qui tam lawsuit alleging that excessive purchase price, salary were kickbacks for referrals
- Total settlement: \$37.5 million
 - Health system paid more than \$35 million
 - Physician paid \$2 million
 - CEO of the health system personally paid more than \$1.7 million
- **Lesson: Paying FMV is essential in transactions with physicians, for both parties.**

Case Example #2: No Written Agreement

- Physician practice enters into medical director agreements with local hospital.
- Written medical director agreements expired and were not renewed for 11 months.
- Whistleblower filed qui tam compliant alleging Stark law violation.
 - Stark law “personal services exception” and “fair market value exception” both require written agreement.
 - Whistleblower alleged that there was no written agreement for 11 months.
 - Without written agreement, no Stark law exceptions are applicable.
- Hospital response:
 - Met all other requirements for Stark law exceptions
 - Combination of other documents meet “written agreement” requirement
- Court: Stark law “expressly prohibits Medicare from paying claims that do not satisfy each of its requirements, including every element of any applicable exception.”
- **Lesson: Even minor Stark law violations matter; ensure you retain written physician contracts.**

Case Example #3: Providing Free Space

- Hospital leased space to a local physician for a three-year period.
- Hospital only required physician to pay rent for half of the space the physician was using and occupying.
- For the half of the space for which the physician paid rent, arrangement met “office-space lease exception” to Stark law.
- Hospital’s provision of free space did not meet “office-space exception”, which requires FMV rent.
- Allegation: The hospital provided the free space as a kickback to refer to the hospital.
- Hospital ultimately agreed to pay \$425,000 as a settlement.
- **Lesson: All aspects of a financial relationship between an entity and physician need to fit within an applicable exception.**

Case Example #4: Lease Holdover

- Hospital leased space to a local physician for a three-year period.
 - January 1, 2020, to January 1, 2023
- Lease did not contain auto-renewal provision.
- Local physician continued to occupy the space, pay rent, etc.
- Is there a violation?
- No, if –
 - The other requirements of the “office space exception” were being met at the time when the lease expired.
 - The holdover lease is on the same terms and conditions as the immediately preceding arrangement.
 - The holdover lease continues to satisfy the other requirements of the office space exception to the Stark law.
- **Lesson: Track lease expiration carefully; be careful with lease holdover arrangements.**

Case Example #5: Failure to Follow IOASE, Group Practice Definition

- Physician practice performs DHS imaging services referred by the practice's physicians at a location it leases for a few days per week.
 - Not a 24/7 lease
 - Group's physicians do not perform any other services at that location.
- Physician group divides profits from those imaging services based on which group physician ordered the service.
- Allegation #1: The services performed at the location do not meet the IOASE.
 - The location is not the "same building" in which the group's physicians perform other services.
 - The location is not a "centralized building" because it isn't leased 24/7.
- Allegation #2: The practice does not qualify as a "group practice" under the Stark law.
 - Dividing DHS profits based on referrals is inconsistent with "group practice" definition.
 - Results in a Stark-law compliance issue that extends to other DHS of the practice
- **Lesson: Ensure your group provides DHS at permissible locations, divides DHS overall profits in a way that is not directly tied to referrals.**

Thank you



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