



The Stark Law Outline: A Guide for Ophthalmologists

Stark: Not the Same as Medicare's "Fraud and Abuse/Anti-Kickback"

1. Fraud and abuse is exchange of money for referrals
2. Stark applies to "financial interest" (including ownership) in entity that receives a referral of "designated health services" ("DHS")
 - This includes a physician's ownership interest in his own practice
 - Therefore, when a physician orders a DHS supplied within the four walls of his or her practice, Stark is triggered
 - ▶ i.e., no external "referral" required for Stark to apply
3. Fraud and abuse requires "bad intent"
 - Stark is strict liability (intent irrelevant)
4. Fraud and abuse is generally a "gray area"
 - Stark has lots of "bright line" rules
 - ▶ satisfy them "or else"
5. Enforcement
 - Both fraud and abuse and Stark have criminal and civil penalties
 - ▶ Stark: give back 3x all fees billed in violation of Stark, plus up to \$15,000 per claim

When Does Stark Apply?

1. Only to DHS
 - Clinical laboratory services
 - Physical therapy services; occupational therapy services
 - Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services (including A scans and B scans)

- Radiation therapy services and supplies
 - Durable medical equipment and supplies
 - Parenteral and enteral nutrients, equipment, and supplies
 - Prosthetics, orthotics, and prosthetic devices and supplies; home health services: not eyeglasses
 - Outpatient prescription drugs
 - Inpatient and outpatient hospital services: not independent ASC services
2. Must be a “referral” of a DHS
 - “Referral” can be the ordering of a DHS to be provided within your office
 - Also includes referral to another entity in which you have a “financial interest,” such as ownership or compensation arrangement

Application to Ophthalmology Practices

1. Must be dealt with if you bill Medicare/Medicaid for ultrasounds.
2. In this situation, the physician is profiting from a DHS furnished by an entity (the medical practice) in which it has a financial interest
3. This is illegal unless the group qualifies as a “group practice” as defined by Stark
 - This is typically not a problem for a “real” group practice.
 - But it may be a problem for a “group practice without walls”
 - ▶ e.g., a collection of independent dermatologists who are technically employees of a single entity, but who have no real relationship with one another, other than on paper
 - It may also be a problem for a Practice that has many part-time physician employees or many independent contractors
4. If the Practice meets Stark’s “group practice” definition, it must then meet the “in office ancillary services” exception tests

Qualifying as a Group Practice

1. Must be a single legal entity (corporation, LLC, partnership of PCs)
 - Per CMS “a single legal entity does not include informal affiliations of physicians formed to share profits from referrals...”
2. Must be a “unified business” with the following features:

- “Centralized decision making” by a representative body (e.g., Board, management committee) that “maintains effective control over the group’s assets and liabilities (including, but not limited to, budgets, compensation, and salaries)”
 - Consolidated billing, accounting, and financial reporting
3. Profit centers are permitted, except with respect to DHS \$\$
- DHS \$\$ may be retained by the site only if there are five or more members at the site
4. Even in profit centers of five or more ophthalmologists, DHS \$\$ generally may not, in the physician compensation formula, be credited to the individual ordering doctor
5. Must meet two separate “75%” tests
- First test: 75% of the total patient care services rendered by the employees and partners of the group (for all entities) must be rendered on behalf of the group practice
 - ▶ Example:
 1. Dr. A is a partner rendering full time services to Group Practice #1 - 40 hours per week
 2. Dr. B is an associate employee rendering full time services to Group Practice #1 - 40 hours per week
 3. Dr. C is a part time employee rendering services 10 hours per week at Group Practice #1 and 30 hours per week at Group Practice #2
 4. Total hours provided (at all practices) by the doctors who are partners and employees of Group Practice #1 are 120 (40 + 40 +40).
 5. Of the 120 hours, 90 (40+40+10), or 75%, are provided at Group Practice #1. Therefore Group Practice #1 meets this 75% test
 6. Group Practice #1 would fail the 75% test if Dr. C rendered only 5 hours per week at Group Practice #1 (percentage would be 85/120, or 71%)
 - Second test: employees and partners of the group (as opposed to independent contractors of the group) must render at least 75% of the total physician-patient encounters provided by the group practice
 - ▶ Example:
 1. Dr. A is a owner doctor who does 4,500 encounters per year, on a full time basis, for his practice
 2. Dr. B is an associate employee who does 4,500 encounters per year, on a full time basis, for the practice

3. Dr. C is an independent contractor who provides 1,000 encounters per year for the practice
4. Total practice encounters are 10,000
5. Employees and partners/owners provide 9,000 of the group's 10,000 encounters, or 90% of the total patient care encounters provided by the group
6. Therefore, the group meets this 75% test
7. If Dr. C, the contractor, provided 4,500 encounters per year, then the percentage of encounters provided by employees and owners would be only 9,000/13,500 or 67%, and would fail this 75% test

If the Practice Qualifies as a Group Practice, It Must Then Meet the Tests for "In Office Ancillary Services Exception"

1. Provision of DHS is properly supervised, per Medicare supervision rules
2. The DHS are billed out under the group's billing number
3. The DHS are furnished in
 - The "same building" (post office address) as the place where the referring physician or the group practice provides physician services (e.g., office visits) in a certain volume OR
 - In a "centralized building" used by the group for provision of some or all of its DHS

Professional Courtesy is Not a Financial Relationship So Long as Six Criteria Are Met

1. Courtesy is offered uniformly
2. Item or service provided is typically offered by the practice
3. Courtesy policy is written and approved by the practice's governing body in advance
4. If recipient is a beneficiary of a federal health care program; there is a good faith showing of financial need
5. If a whole or partial reduction in co-insurance is given, the insurer is informed in writing
6. Arrangement does not violate the anti-kickback statute or any other federal law

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