



**Why Physicians and
Physician Organizations
Should be Concerned
about Stark Compliance**

Steven W. Ortquist
Partner, Aegis Compliance & Ethics Center, LLP




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Introduction
What do the Stark Statute and
the Anti-Kickback Statute
Require?




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STARK - Plain Language




If a *Physician* (or immediate family member) has a direct or indirect *Financial Relationship* with an *Entity*, unless an exception applies:

- the *Physician* may not Refer any Designated Health Services ("DHS") to the *Entity*,
- the *Entity* may not bill for any DHS referred by the physician,
- no Medicare payments may be made for DHS referred by the physician, and
- the *Entity* must refund all moneys collected for DHS referred by the physician (unless no actual knowledge or reckless disregard re: the physician's identity)





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Definitions




PHYSICIAN – Doctor of Medicine; Doctor of Osteopathy; Dentist; Dental Surgeon; Doctor of Podiatric Medicine; Doctor of Optometry; or a Chiropractor.

ALSO: IMMEDIATE FAMILY MEMBER - husband or wife; birth or adoptive parent, child or sibling; stepchild; stepparent; stepbrother or stepsister; in-laws (mother, father, son, daughter, sister, brother); grandparent, grandchildren and the spouses of either.

Definitions





Financial Relationship

Compensation—any remuneration (payment or benefit, directly or indirectly, overtly or covertly, in cash or in kind) between a physician (or immediate family member) and an entity.


Includes Indirect Compensation—an unbroken chain of either compensation or ownership/ investment interests between **Physician and Entity**

Ownership/Investment (direct or indirect)

- Includes equity, debt or other means
- Stock, options, partnership, bonds, loans, etc.
- NOT retirement plan interest, options received as compensation until exercised

Definitions







ENTITY – “Furnishes DHS”

Person or organization that performs DHS service billed to Medicare, or

The person or organization that bills for the DHS service.

May include a physician’s sole practice (not the physician him or herself), a practice of multiple physicians, any other person, sole proprietorship, public or private agency or trust, corporation, partnership, LLC, foundation, not-for-profit corporation or unincorporated association.

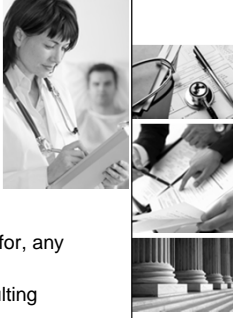






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Definitions







Referral

- request (any form—written, oral, electronic, other) by a physician for DHS
- ordering of DHS
- certifying or recertifying the need for, any DHS
- Includes DHS ordered by a consulting physician
 - Does NOT include personally performed services of a physician (but incident-to services are not personally performed)

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Definitions – Designated Health Services

1. Clinical Laboratory Services

2. Physical Therapy, Occupational Therapy and Speech-Language Pathology Services

3. Radiology and certain other imaging services

4. Radiation Therapy services and supplies

5. Durable medical equipment and supplies

6. Parenteral and enteral nutrients, equipment, and supplies

7. Prosthetics, orthotics, and prosthetic devices and supplies


8. Home health services

9. Outpatient prescription drugs

10. Inpatient and outpatient hospital services


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Anti-Kickback Statute

Unlawful to:

- Knowingly and willfully
- Offer, give, solicit or receive
- Any remuneration (directly or indirectly, overtly or covertly, in cash or kind)
- In return for
 - referring for any item or service reimbursable by Federal health care programs, or
 - purchasing, leasing, ordering or arranging for (or recommending any of the same) any good, facility or service reimbursable by Federal health care programs








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Anti-Kickback Statute

Penalties for Anti-Kickback Violation

- **CRIMINAL:** "shall be guilty of a felony and upon conviction"
 - Fined not more than \$25,000
 - Imprisoned not more than 5 years, or
 - Both
- **CIVIL:** OIG Civil Money Penalty and Exclusion Authorities
 - Up to \$50,000 per violation
 - Up to 3-times the amount of improper remuneration
 - Exclusion




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Definition-Remuneration

REMUNERATION (note—same for Stark)

"For purposes of the anti-kickback statute, 'remuneration' includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly." OIG Advisory Opinion 01-10, July 26, 2001.

No de-minimis exception






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Definition – “Knowingly and Willfully”
 KNOWINGLY AND WILLFULLY

“We construe “knowingly and willfully” in § 1128B(b)(2) of the anti-kickback statute as requiring appellants to (1) know that § 1128B prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law.”

The Hanlester Network V. Shalala, 51 F.3d 1390 (9th Cir. Ct. App. 1995)




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“Knowingly & Willfully” after PPACA of 2010
 Section 6402 (f) (2)

“With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”

Legislatively overrules *Hanlester*



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One Purpose Test (majority of circuits)

“[I]f payments were intended to induce the physician to use [the company’s] services, the statute was violated, even if payments were also intended to compensate for professional services.”

“We . . . hold that if one purpose of the payment was to induce future referrals, the Medicare statute has been violated.”



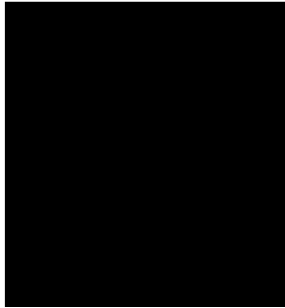
United States v. Greber, 760 F.2d 68 (3d Cir.1985)



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What Does the AKS Prohibit?
U.S. v. Anderson, 85 F.Supp.2d 1047 (Kan 1999)



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Why Should Physicians Care?
Recent Settlements and
What They Tell Us.





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Belmont Cardiology, Inc. & Dr. Devender Batra (4/2014)

- Ohio Valley Health self-discloses improper arrangements with physicians and settles for \$3.8M (2011)
- “Improper financial arrangements” between January 2009 & August 2010
- Pursued on theory that Dr. Batra caused the hospitals to submit false claims
- \$1M settlement




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Cardiovascular Specialist, P.C., d.b.a. New York Heart Center (8/2014)

- From September 2007 to August 2008 compensation for partner physicians took into account volume/value of each physicians referrals for nuclear and CT scans not personally performed
- \$1.33M settlement (8/14/2014)
- DOJ investigation was based on a tip




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Diagnostic Physicians Group, P.C./Infirmiry Health 7/2014)

- DPG (70 physician group) physician services agreement with Infirmiry Health
- Physicians were paid in part based on value of referrals for technical services
- Infirmiry Heath and DPG settle for \$24.5M




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Dr. Andrew Pippas (Columbus Regional Health System) (9-2015)

- Initial qui tam complaint against CRHS - improper billing (Pippas billed largely level 5)
- Amended complaint alleges that Dr. Pippas was paid in excess of FMV
- Complaint details Pippas' resistance to correcting his documentation/ coding practices CRHS settlement: \$25 - 35M
- Dr. Pippas settlement: \$425K




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OIG Fraud Alert: *Physician Compensation Arrangements May Result in Significant Liability (6-2015)*

- Followed 2012 settlement with Fairmont Diagnostic Center (TX)
- Medical director agreements and provision of office staff
- Not FMV and “physicians did not provide the services”
- “OIG determined that the physicians were an integral part of the scheme.”
- 12 physicians settle for \$50K to \$196K each (\$1.4M total)




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Personal Services

What does the exception generally cover?


- Call coverage
- Medical director agreements
- Medical staff leadership agreements
- Professional service agreements (e.g., EKG reads)
- Others? (any service agreement)



Personal Services Exception


Remuneration from an entity to a physician if:

- Set out in writing and specifies services covered,
- Term of agreement is at least one year,
- Compensation is (1) set in advance, (2) FMV, and (3) not determined by considering volume or value of referrals or other business between parties,
- Writing covers all services provided by physician; each agreement cross-references all others; or contract database,
- Aggregate services don't exceed reasonable and necessary,
- Indefinite holdover.



Group Practice

- What are the benefits of meeting the definition?
 - Profit sharing
 - Productivity bonuses
 - Ability to refer in-office ancillary services




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Group Practice (What is Required?)

a) Single legal entity

- Partnerships, PCs, LLCs, foundation, nonprofit corporation, faculty practice plan or similar all OK
- May be owned by another entity (e.g., a hospital)
- A group operating in more than one contiguous state will be considered a single entity notwithstanding organization in each state (if so required)



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Group Practice (What is Required?)

b) Physicians

- There must be at least two physicians members (can be owners or employees)

c) Range of Care.

- Each member must furnish substantially the full range of patient care services that the physician routinely furnishes through the joint use of shared office space, facilities, equipment & Personnel




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Group Practice (What is Required?)

d) **Services Furnished by Group Practice Members**

- Substantially all (75%) of the patient care services provided by members must be furnished and billed through the group (group billing number) and receipts must be treated as receipts of the group.
- Does not apply in HPSA & time spent by members in a HPSA should not be counted in calculating
- 12 month start up period allowed



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Group Practice (What is Required?)

e) **Distribution of Income & Expenses**

- Must be done according to a pre-determined formula that does not take into account volume or value of DHS referrals

f) **Unified Business**

- Centralized decision making, and
- Consolidated billing, accounting & financial reporting



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Group Practice (What is Required?)

g) **Volume or value of referrals**

- No physician member receives compensation based on volume or value of DHS referrals (unless personally performed) except for productivity bonuses and profit sharing.

h) **Physician patient encounters**

- Members of the group must conduct no less than 75% of physician-patient encounters




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Group Practice (What is Required?)

i) Profit sharing

- May pay a share of overall profits (must be determined in any manner not directly related to volume or value of a physician's DHS referrals)
- The following are OK:
 - Profits are divided per-capita
 - Profits are divided based on physicians revenue generation that is not DHS referrals
 - Revenues derived from DHS constitute less than 5% of groups revenues, and less than 5% of each physician's total compensation




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Group Practice (What is Required?)

i) Productivity bonuses

- Bonuses OK based on personally performed (and incident to) services (cannot be determined in any manner related to physicians DHS referrals)
- The following are OK:
 - Bonuses based on total patient encounters or RVU generation
 - Bonuses based on physician services that are not DHS
 - DHS revenues are less than 5% of groups revenues and less than 5% of each physicians compensation




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In Office Ancillary Services

Not "referrals" if . . .

- Who provides?
 - Physician, group practice member/staff
- Where?
 - Group's buildings
- Who Bills?
 - Physician, group, wholly owned entity, third party biller who meets reassignment rules
- What?
 - Special rules re: DME
- Disclosure & choice for certain imaging services




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Steven Ortquist
sortquist@aegis-compliance.com
312-285-4850

QUESTIONS?



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COMPLIANCE & ETHICS
1801 West Warner Avenue
Suite 100
Chicago, IL 60613 | 888.730.8194
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