
Stark Update HCCA – Hawaii Conference

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Today's Agenda

- Review of healthcare Anti-Kickback statute and Stark law and regulations
- Discuss implications of recent settlement/enforcement activity
- Discuss preventative measures to promote compliance



Healthcare 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



Healthcare Anti-Kickback Statute

Possible Consequences of Kickback Violation

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



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



Definitions – “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)*



“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*



One Purpose Test (majority of circuits)

“[If] 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)



What Does the AKS Prohibit?

U.S. v. Anderson, 85 F.Supp.2d 1047 (Kan 1999)

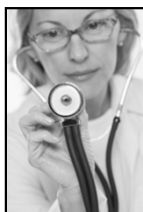
STARK - Plain Language



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)

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



■ 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
 - Incident-to services are not personally performed

Definitions – Designated Health Services



X-Ray



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



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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Personal Services Exception

- Remuneration from an entity to a physician if:
 - Set out in writing and specifies services covered,
 - Signed by all parties,
 - Term of agreement is at least one year,
 - Compensation is (i) 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,
 - 6 month holdover.



What Causes Problems?

- No contract
- Failure to adhere to compensation set in agreement
- Failure to provide services
- Inadequate documentation
 - Failure to obtain invoice required by contract
 - Time sheet form and documentation
- Not commercially reasonable
- Missing/late signatures
- Not fair market value



Toumey Healthcare System (South Carolina)

- Toumey – 242 bed hospital in Sumter, SC
- Exclusive part-time employment contracts with 19 specialist (incl. non-compete, 10 year term)
- Compensation guaranteed to exceeded hospitals collections:
 - Annual base salary based on prior year production
 - Productivity bonus equal to 80% of collections
 - Incentive bonus equal to 7% of collections
- Valuation consultant found FMV and unlikely to violate Stark
- Surgeon – *qui tam relator* had attempted to notify Toumey Board of concerns

Toumey Healthcare System (South Carolina)

- Toumey – 1 \$45M jury verdict (overturned)
- DOJ sought \$39M in penalties (Medicare payments) and \$237M in fines (treble damages plus \$5,500 per for 21,730 Medicare claims)
- \$277M judgment (9/30/2013)

Intermountain Healthcare

- \$25.5M Settlement (April 8, 2013)
- 44 months after initiating self-disclosure
 - 37 employment arrangements w/bonus structure that may have violated “volume or value of referrals”
 - 18 lease arrangements – no lease or not FMV;
 - 154 arrangements with “technical” violations

What Causes Problems? Example:

Cardiologists at UMDNJ

“The UMDNJ contracts with the community cardiologists required them to work part-time at University Hospital as Clinical Assistant Professors, and to perform bona fide services, such as teaching at UMDNJ’s medical school, providing on-call coverage, attending weekly conferences, lecturing, and supporting UMDNJ’s research efforts . . .”

US Department of Justice, D. New Jersey, Press Release dated May 7, 2008

Cardiologists at UMDNJ

Excerpts from the Federal Monitor Report Dated November 13, 2006

“ . . . none of the doctors provided sufficient academic services warranting the “salaries” that they received.” (Report at 4)

“ . . . the doctors provided little-to-no service to UMDNJ for their respective ‘salaries’” (Report at 9)

“the listed services [the physicians were supposed to render] were, with only a few exceptions, all the same.” (Report at 14)

Cardiologists at UMDNJ

“Dr. Desai was unable to answer questions regarding approximate hours spent teaching or providing services in connection with his compensation from UMDNJ.” (Report at 15)

“Had UMDNJ paid these doctors fair market value for bona fide services, including teaching and research, UMDNJ would not have run afoul of the law.” (Report at 4)

Cardiologists at UMDNJ Settlements

- Ravindra Patel, MD - \$300,000 (2x salary received)
- Jasjit Walia, MD - \$300,000 (2x salary received)
- Rakesh Sahni, MD - \$360,000 (2x salary received)
- Trevor Atherley, MD - \$180,000 (return of full salary)
- Abdul Ameen, MD - \$38,000
- Michael Benz, MD - \$30,000

Cardiologists at UMDNJ Settlements & Pleas

- Joven Dungo, MD - \$138,000 (2x salary received)
- Bakul Desai, MD – Plead guilty: criminal embezzlement – \$1.4 Million (2½ x salary received)
- Lamipathi Garipalli, MD – Plead guilty: criminal embezzlement - \$560,000 (2x salary received)
- Joseph Campbell, MD – found not guilty by a jury after three year investigation and trial
- UMDNJ - \$8.3 Million

What May Cause a Stark Violation?

Non-Monetary Compensation



Memorial Hospital of Union County (6-29-2009).


After it self-disclosed conduct to the OIG, Memorial Hospital of Union County (MHUC), Ohio, agreed to pay \$31,202 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals. The OIG alleged that MHUC provided excess non-monetary compensation to physicians and the immediate family member of a physician who referred patients to MHUC.


- Aggregate overpayment of approx \$3100 to 10 physicians between 1/1/2007 and 12/31/2008.
- Gifts, including weather clocks. Seminars with board members.

What Does Effective Compliance Require?

- Legal and valuation reviews when arrangements are initiated
- Periodic reviews of all arrangements
- Monitoring
- Structure for approval of physician payments
- Policies & training
- NMC tracking process

Questions /Discussion



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