

UW MEDICINE | HCAA 2013 Compliance Institute

**HCCA 2013
COMPLIANCE INSTITUTE
ANTI-KICKBACK STATUTE 101**

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2

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3

LEARNING OBJECTIVES

- Understand the AKS (Anti-Kickback Statute)
- Understand Safe Harbors
- Recognize transactions that might implicate the AKS
- Learn about common pitfalls and how to avoid them

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OVERVIEW OF THE ANTI-KICKBACK STATUTE

- Goals of the AKS
 - Promote unbiased physician decision-making
 - Reduce healthcare costs
 - Improve quality of care
- Sanctions
 - Civil, criminal and/or other penalties

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WHAT DOES THE GOVERNMENT HAVE AGAINST PAYMENTS FOR REFERRALS?

Government believes payments tied to referrals:

- Corrupt the health care system
- Increase overutilization of items/services
- Increase overall costs of health care
- Inappropriately steer patients
- Create a system of unfair competition

67 Fed. Reg. 60202

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THE STATUTE - 42 U.S.C. §1320a-7b

Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind:

- in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- in return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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7

THE STATUTE - 42 U.S.C. §1320a-7b

Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person:

- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- to purchase, lease, order or arrange for, or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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8

ANTI-KICKBACK STATUTE

- Is confusing, controversial and broad:
- A blunt tool that makes certain activities illegal and then provides "safe harbors" to make them legal again
- Penalties apply to both sides of the transaction
- Doesn't matter if many legit reasons for the money exist, so long as one of the purposes of the payment is improper, then the AKS is violated

- One purpose vs. primary purpose test

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9

ANTI-KICKBACK STATUTE PROHIBITION

Prohibits a person from:

- Knowingly or willfully (amended by PPACA)
- Giving or getting
- Any **remuneration** (directly or indirectly)
- To induce or reward another party for referrals for medical services or items, or
- For **purchasing, leasing or ordering an item or service** (or recommending for purchase)
- **Paid for or covered by a federal health care program**

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TO WHOM AKS APPLIES

- Any "person"
 - Corporate
 - Individual
- Not limited to physicians; applies to non-physicians and entities
- Applies to *both* parties of the transaction
- Applies to any referral source, including suppliers of goods and services

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REMUNERATION

Is broadly interpreted to mean **anything of value**

- Meals
- Trips
- Rebates or discounts (*statutory exception)
- Profits or dividends
- Gifts
- Furnishing of supplies
- Credit Arrangements
- Cash payments or waivers of cash payments due

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FOR REFERRALS OF:

- An Individual or a Person
 - Individual means Federal Healthcare Program Beneficiaries
 - Person means an Individual or Corporation
- Items or Service
 - Diagnostic tests
 - DME
 - Ancillary Services
 - Ambulance Services
 - Office Calls
 - Inpatient Stays
 - Surgeries

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PAID BY FEDERAL HEALTHCARE PROGRAMS

- Traditionally meant only Medicare and Medicaid
- Now any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part by federal government (such as Tricare or CHAMPUS) or any state health care program

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STATUTORY EXCEPTIONS

- Accurately disclosed and reflected discounts to the provider
- Payments by employer to employee for bona fide services
- Amounts paid by providers to a group purchasing organization
- Certain risk sharing arrangements
- Waivers of co-insurance amounts for FQHC's

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SAFE HARBORS

- Arrangements that meet the criteria of a safe harbor are fully protected from criminal and civil liability
- Not falling exactly within the safe harbor does not mean the activity is illegal or that it will be investigated or prosecuted
 - Conduct outside the safe harbor is analyzed on a case-by-case basis
 - OIG will use prosecutorial discretion and not pursue cases where there appears to be a good faith effort to comply with the safe harbor or does not appear to induce over-utilization of services

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THERE ARE SAFE HARBORS FOR

<ul style="list-style-type: none"> • Investment Interest • Space Rentals • Equipment Rentals • Personal Services and Management Contracts • Waiver of Beneficiary Co-insurance and Deductibles • Warranties • Discounts • Bona-fide Employees 	<ul style="list-style-type: none"> • Group Purchasing Organizations • Referral Services • Sale of Practice • Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans. • Price reductions offered to health plans
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THERE ARE SAFE HARBORS FOR

<ul style="list-style-type: none"> • Practitioner recruitment • Obstetrical malpractice insurance subsidies • Investments in group practices • Cooperative hospital service organizations • Ambulatory surgical centers • Referral arrangements for specialty services • Price reductions offered to eligible managed care organizations 	<ul style="list-style-type: none"> • Price reductions offered by contractors with substantial financial risk to managed care organizations • Ambulance replenishing • Health centers • Electronic prescribing items and services • Electronic health records items and services
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SAFE HARBORS

- Don't assume you are out of the woods if you meet a safe harbor:
 - "improper intent" (OIG term) could exist even when you meet the letter of the law
- Don't assume you are in violation of the AKS if you don't meet a safe harbor:
 - OIG may still approve, or decline to investigate if the risk of abuse is low; case by case review

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DISCOUNTS- 42 CFR 1001.952(h)

If the buyer is an entity which reports its costs on a cost report then:

- Discount must be earned based on purchases of that same good or service bought within a single fiscal year
- Buyer claims the benefit of the discount in the same or following fiscal year in which the discount is earned
- Buyer fully and accurately reports the discount in the applicable cost report
- Buyer provides information regarding the seller's disclosure of the discount upon demand of HHS

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DISCOUNTS

If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made by a federal health care program (contract/claim/invoice):

- Discount is made at the time of the sale or
- Terms of the rebate are fixed and disclosed in writing at the time of the initial sale and
- Buyer provides, upon request of HHS, information provided by the seller of its disclosure of the discount

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DISCOUNT DOES NOT INCLUDE

- “Bundled” items
 - Supplying one good/service at reduced charge or at no cost to induce the purchase of a different good or service
 - Example: Vendor who offers free equipment along with the purchase of certain supplies

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DISCOUNT EXCEPTIONS

- Exceptions
 - Reimbursed by the same federal healthcare program using same methodology
 - Discount is fully disclosed and accurately reported on the hospital cost report
 - Negotiated at arms length
 - Does not have the potential to increase costs to a federal healthcare program or beneficiary

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SANCTIONS FOR VIOLATIONS

- Criminal - felony with a maximum fine of \$25,000 and five years imprisonment
- Civil monetary penalties of up to \$50,000 for each violation plus three times the amount of the remuneration
- Potential exclusion from the Medicare program

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HEALTHCARE REFORM – AKS CHANGES

- In 2010 PPACA amended “intent” requirement to clarify that a defendant need not know about the AKS or intend to violate the AKS specifically (just that they intended to violate “the law”) Pub. L. No. 111-148, § 6402(f)(2), 124 Stat 119 (2010)
- The government still has to prove “scienter”
- Merely engaging in the transaction may be proof enough of intent
- False Claims Act expanded to include civil liability for violation of AKS

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25

COMMON PITFALLS

Fair Market Value

- Need to demonstrate fair market value of goods or services
- FMV is the price at which the good or service would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy or to sell and both having reasonable knowledge of relevant facts

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26

COMMON PITFALLS

- Inducement to Beneficiaries
 - Avoid economic incentives that would increase the risk of over-utilization of services paid for by federal health care programs
- Vendor Perks
 - Consulting panels, training offers, indulgence packages, free meals, free equipment, free travel
- Medical Director Contracts
 - Set forth in writing, one year or longer duration, fair market value for actual services rendered, method to track hours/services

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27

HOW DOES THE AKS STATUTE APPLY TO YOU? – PURCHASING DECISIONS

- Relationships between drug and device manufacturers and persons in a position to make or influence **purchasing decisions or prescribing patterns**. Examples include:
 - Free or discounted use of equipment for research purposes or on a trial basis
 - Relationships with Pharmacy and Therapeutic (P&T or Formulary) Committee members
 - Educational grants
 - Research funding

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HOW DOES THE AKS STATUTE APPLY TO YOU? – PURCHASING DECISIONS

Compliance Response

- Look for safe harbors
- Document in writing
- FMV
- No commitments for future purchases
- Disclose relationships to relevant purchasing committees
- Implement process for dealing with disclosures

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HOW DOES THE AKS STATUTE APPLY TO YOU? – REFERRALS

Relationships between health care entities or others in a position to **refer patients** whose care is reimbursed by federal health care programs. Examples:

- Non-fair market value payment for services that might appear to be payments for referrals (Consulting, speaking and travel)
- Monetary compensation or other form of remuneration, such as attendance at a conference, appear to be in exchange for referrals

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HOW DOES THE AKS STATUTE APPLY TO YOU? – REFERRALS

Compliance Response:

- Institution’s Conflict of Interest Policy that requires actual work to be performed consistent with fair market value with disclosure and advance permission, and discourages acceptance of remuneration for anything except bona fide services

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EQUIPMENT LOANS OR FREE EQUIPMENT IN THE RESEARCH CONTEXT

- Must ensure equipment is used solely for research and not for clinical services (no patient care)
- Post-marketing research (e.g., software in exchange for services)
- Best practice is to have a written agreement that details purpose, scope, use, liability and return of equipment
- Role of Office of Sponsored Programs
- Reportable under Physician Payments Sunshine Act

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EXAMPLE

You are a manager with a health care entity. You have a long-standing relationship with a vendor from whom you have purchased equipment and supplies and they value your opinions about their products.

During the most recent sales call, the rep announces their new “Consulting Panel,” to which they would like to fly you and a physician from your division to their Las Vegas HQ twice a year, all expenses paid, plus they will pay you both a consulting fee.

Since you are a “Subject Matter Expert,” your opinion is invaluable to them as they develop new products. Anything wrong with participating in their Consulting Panel or is it “Vegas, Baby, Vegas!”?

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ANSWER

- The Federal Anti-Kickback Statute applies to physicians and non-physicians alike
- FMV - Are you receiving fair market value for your services? How much time will actually be spent "consulting?"
- Remuneration – Are these perks in exchange or a reward for future and/or past purchases?
- Any applicable safe harbor?
- Bottom line - This vendor's perks appear to implicate the AKS

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34

RESOURCES

- Office of Inspector General Advisory Opinions
<http://oig.hhs.gov/compliance/advisory-opinions/index.asp>
- Safe Harbor regulations
<http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-sec1001-952.pdf>
- Always consult your legal counsel and/or compliance office if you have any doubts about a transaction

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35

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UW Medicine

36
