

HIPAA, Fraud & Abuse: 101

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Overview of HIPAA

- **PRIVACY RULE**
 - Must maintain privacy of PHI
- **SECURITY RULE**
 - Required to conduct risk analysis and implement physical, administrative and technical safeguards to secure e-PHI and systems
 - Must manage business associate and subcontractor relationships
- **BREACH NOTIFICATION RULE**
 - Requires incident assessment and mitigation
 - Must provide notice to affected individuals, media and OCR

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Who does HIPAA apply to?

- Covered Entities
 - A health care provider
 - A health plan
 - A health care clearinghouse
- Business Associates
 - “a person or entity that performs certain functions or activities that involve the use or disclosure of PHI on behalf of, or provides services to, a covered entity”
 - Covered entities can be business associates
- <https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html>



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What is Protected Health Information?

- PHI is defined as all "**individually identifiable health information**" held or transmitted by a CE or its BA, in any form or media, which includes demographic data that identifies the individual and relates to:
 - the individual's past, present or future physical or mental health or condition;
 - the provision of health care to the individual; or
 - the past, present, or future payment for the provision of health care to the individual
- “**Electronic protected health information**” or e-PHI, is PHI that is transmitted or maintained electronically

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What is a Breach?

- A breach is an impermissible use or disclosure the compromises the privacy or security of PHI
- Factors to be considered:
 - Nature and extent of PHI involved
 - The unauthorized person who used the PHI or to whom it was disclosed
 - Whether the PHI was actually acquired or viewed
 - Extent to which the risk of PHI has been mitigated



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Penalties

- After 2/18/2009 – civil penalties can range from \$100 to \$50,000 or more per violation
 - Capped at \$1,500,000 for same violation in a year
- Criminal penalty can be up to \$50,000 and 1.5 years in prison
 - Can increase to \$100,000 and up to 5 years in prison if it involves false pretenses
 - Can increase to \$250,000 and up to 10 years in prison if it involves intent to sell, transfer or use PHI for commercial advantage, personal gain or malicious harm



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Fraud & Abuse: 101

- The False Claims Act
- The Stark Law
- The Anti-Kickback Statute
- The Eliminating Kickbacks in Recovery Act



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The False Claims Act

- 31 U.S.C. §§ 3729 - 3733 enacted in 1863 by Congress during the Civil War to combat fraud
- The statute provides that one who is liable must pay a civil penalty and treble the amount of the government's damages.
- § 3729(a)(1)(A) requires the person to (1) make a claim; (2) that is false or fraudulent; (3) knowing of falsity; and (4) seeking payment from the Government
- § 3729(a)(1)(B) requires the person to (1) create, use or cause to be used, a false or fraudulent record or statement, (2) with knowledge of falsity; and (3) that is material to the claim
- § 3729(a)(1)(G) requires the person to (1) make, use or cause to be a false or fraudulent record or statement, (2) material to an obligation to pay or transmit money or property to the government, or (3) knowingly conceals or knowingly avoids or decreases an obligation to pay



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Overview of Stark Law

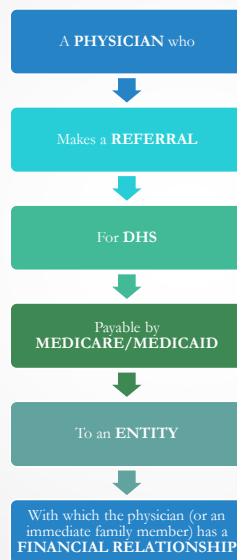
- If a physician (or an immediate family member of such physician) has a financial relationship with an entity ..., then--
 - (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under [Medicare and Medicaid], **and**
 - (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 USC 1395nn(a)(1)
- Law of STRICT Liability



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What are the Key Elements?



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A
Physician

Doctor of Medicine or Osteopathy

DDS/DMD

Podiatrist

Doctor of Optometry

Chiropractor



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“Referral”

Defined broadly

- A request by a physician for an item or service for which payment may be made under Medicare Part B *or*
 - Includes a request for a consultation with another physician
 - “an establishment of a plan of care by a physician which includes the provision of a designated health service”

“Request”

- Ordering or “certifying or recertifying the need for” any DHS

Can be written, oral, electronic or another form



42 CFR 411.351

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What is NOT a Referral

Personally performed services

Certain requests made by pathologists, radiologists and radiation oncologists



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Designated Health Services

Clinical
Laboratory
Services

PT, OT, outpatient
speech-language
pathology

Radiology and
certain other
imaging

Radiation therapy
services and
supplies

Durable medical
equipment and
supplies

Parental and
enteral nutrients,
equipment and
supplies

Prosthetics,
orthotics, and
prosthetic devices
and supplies

Home health
services

Outpatient
prescription drugs

Inpatient and
outpatient hospital
services



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Payable by Medicare and Medicaid

- Stark law prohibitions' generally relate to Medicare fee-for-service referrals
- Stark law's application to Medicaid is via section 1903(s) of the Social Security Act
 - Notwithstanding the preceding provisions of this section, no payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service (as defined in subsection (h)(6) of section 1877) furnished to an individual on the basis of a referral that would result in the denial of payment for the service under title XVIII if such title provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan, and subsections (f) and (g)(5) of such section shall apply to a provider of such a designated health service for which payment may be made under this title in the same manner as such subsections apply to a provider of such a service for which payment may be made under such title. [42 USC 1396(b)(s)]



Entity

“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.”

Furnishing DHS:

- (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(d) of this title), and other than any managed care organization (MCO), sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

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.



Financial Relationship

A direct or indirect ownership or investment interest in the entity that furnishes DHS

- Through debt, equity, or other means

A direct or indirect compensation arrangement between the physician (or an IF) and the entity that furnishes DHS

Stark Exceptions

General Exceptions (411.355)

Ownership/Investment only (411.356)

Compensation only (411.357)

General Exceptions

Group Practice

Physician Services

In-office ancillary services

- Supervision
- Location
- billing

Prepaid Plan

Academic Medical Center Services

Others



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Ownership Exceptions

Publicly-traded securities/mutual funds

“Whole Hospital”

Rural providers



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Compensation Arrangement Exceptions

Statutory

Rental of Office Space and Equipment
Bona Fide employment relationships
Personal Service Arrangements
Physician Incentive Plans
Remuneration unrelated to provision of DHS
Physician Recruitment
Isolated Transactions
Certain Group Practice Arrangements with a Hospital
Payments by a Physician
Electronic Prescribing Items and Services



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Compensation Arrangement Exceptions

Regulatory

Charitable Donations
Nonmonetary Compensation
Fair Market Value Compensation
Medical Staff Incidental Benefits
Risk-Sharing Arrangements
Compliance Training
Indirect Compensation Arrangements
Referral Services
Obstetrical malpractice insurance subsidies
Professional Courtesy
Retention in underserved areas
Community-wide health information systems
Electronic health record items and services
Assistance to compensate a nonphysician practitioner
Timeshare arrangements



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Penalties

- Automatic overpayment or disallowance
- Knowing violation can result in civil monetary penalty liability
- Exclusion from federal programs



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Overview of the Anti-Kickback Statute

- 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—
 - (A) 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
 - (B) 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 \$100,000 or imprisoned for not more than 10 years, or both.

- (2) 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--
 - (A) 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
 - (B) 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 \$100,000 or imprisoned for not more than 10 years, or both.



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What are the Key Elements?

Inducing a Referral by

- offering
- paying
- Soliciting, *or*
- Receiving anything of value

What is covered?

- Anything paid by a federal health care program

Intent

- Knowing
- Willful



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The Analysis

Is there remuneration?

Is there a potential for referrals?

Are the referrals payable by a federal health care program?

Does the Arrangement fit within a safe harbor?

- If no, what is the risk?



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AKS Safe Harbors

Safe Harbors

Investment Interests
Space Rental
Equipment Rental
Personal Services & Management Contracts
Sale of Practice
Referral Services
Warranties
Discounts
Employees
Group Purchasing Organizations
Waiver of beneficiary copayment, coinsurance, deductible
Increased coverage, reduced cost-sharing etc
Price reductions to health plans
Practitioner recruitment



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Safe Harbors Cont.

Obstetrical malpractice insurance subsidies
Investments in group practice
Cooperative hospital service organizations
Ambulatory surgical centers
Referral arrangements for specialty services
Price reductions for eligible MCOs
Price reductions by contractors with substantial financial risk to MCOs
Ambulance replenishing
Health centers
Electronic Prescribing items and services
Electronic health items and services
FQHCs
Medicare Coverage Gap Discount Program
Local Transportation



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Eliminating Kickbacks in Recovery Act

- Part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (“SUPPORT Act”)
- Signed into law on October 24, 2018
- Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”) a component of the SUPPORT Act
- Initially EKRA was introduced by Senator Marco Rubio and Senator Amy Klobuchar to “establish criminal penalties for unlawful payments for referrals to recovery homes and clinical treatment facilities”
- Legislative intent: to assure that patients seeking drug and opioid treatment are not taken advantage of – to mirror the AKS to apply to commercial insurance



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DEFINITIONS

- ✓ “clinical treatment facility means a medical setting , other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law” 18 USC 220(e)(2)
- ✓ “laboratory has the meaning given the term in section 353 of the Public Health Service Act (42 U.S.C. 263a)” 18 USC 220(e)(4)
- ✓ “recovery home” means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.” 18 USC 220(e)(5)



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Whoever...knowing 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 a *patient or patronage to a recovery home, clinical treatment facility, or laboratory*; or

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--

(A) 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
(B) 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...



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EKRA

VS

AKS

Whoever...knowing and willfully

(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
(A) to induce *a referral of an individual to a recovery home, clinical treatment facility, or laboratory*; or
(B) *in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory*,

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--
(A) 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
(B) 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,



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The Major Change in the Exception

EKRA

a payment made by an employer to *an employee or independent contractor* (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by:

- (A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;
- (B) the number of tests or procedures performed; or
- (C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

VS

AKS

(B) *any amount paid by an employer to an employee* (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

i.e. in Safe Harbor:

- (i) Employees. ...“remuneration” does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer...



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Penalties

EKRA

- ✓ Fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence



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- ✓ Guilty of a felony and upon conviction thereof, shall be fined not more than \$100,000 or imprisoned for not more than 10 year, or both.



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Thank You

Questions?

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