

# Legal Issues for the Small and Solo Medical Practice

Presented by:



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# Health Care Clinic Act




# Health Care Clinic Act

- Purpose: To require non-physician owners of health care entities to have the clinic licensed through the Agency for Health Care Administration (AHCA)
  - Applies: If **ANY** portion of the business is owned by a non-physician
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# Requirements for a Health Care Clinic License from AHCA

- Clinic must have a medical director
    - Medical director duties:
      - Ensure medical professionals are properly licensed and certified
      - Ensure record keeping compliance
      - Report noncompliance
      - To review clinic billings for fraud
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# Requirements for a Health Care Clinic License from AHCA


- Providing proof of financial ability to operate
  - Background screenings, including screening of the director and chief financial officer
  - Disclosures of certain additional information
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# Traps for the Unwary


- If a non-physician owns the clinic, practice or facility.
  - If a non-physician controls all major decision making for the clinic, practice or facility.
  - If all financial matters are controlled by a non-physician.
  - If a corporation or LLC owns the clinic, practice or facility.
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# Real-Life Scenarios

- Scenario 1: A physician practices medicine through a limited liability company which the physician owns with his non-licensed wife. The physician dies and his wife remains sole owner of the practice, hiring a locum tenens physician to come in and treat patients.
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# Real-Life Scenarios

- Result 1: As of the date of death of the physician, the practice is operating illegally, in violation of Florida law. Each day of operations is a separate felony offense.
- 


# Real-Life Scenarios

- Scenario 2: A physician licensed in Florida operates a medical practice as a sole proprietorship. The physician desires to reward her practice manager, a non-licensed business person, by making him a partner in her practice. The practice continues to operate as before without a health care clinic license.
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# Real-Life Scenarios

- Result 2: The practice is operating illegally as of the day the practice manager is made a partner.
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# Real-Life Scenarios

- Scenario 3: A physician licensed in Florida decides to sell her practice and retire. Three non-licensed business people decide to form a corporation to purchase and operate the practice. The corporation purchases the medical practice's assets, including patient records. The corporation has not applied for or received a Health Care Clinic License.
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# Real-Life Scenarios

- Result 3: On the day of closing or the day the practice is transferred to the new corporation, the corporation is operating illegally, in violation of Florida law. Each day of operation is a separate felony.
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# HCCA Consequences


- Third-degree felony with each day of operation is an offense
  - If an individual has an interest in more than one clinic, AHCA may revoke the license for all of the clinics
  - Administrative fines of up to \$5,000 per day
  - Potential recoupment of claims made to third-party payors
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# Keep in Mind

- Some health professions cannot be owned or controlled by anyone outside of that
  - This means that a health care clinic license may not be obtained for them:
    - Dentistry
    - Optometry
    - Chiropractic medicine
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# Do Not Work at an Illegal Health Care Clinic

- Checking the Secretary of State's website to identify the business entity actually owning the practice
  - Identify the office's directors, managers or members of the business entity and check to see if they are all physicians
  - If they are not, inquire with AHCA as to the existence of a valid health care clinic license or exemption
  - Inquire with the managers, officers or owners as to the identity of all owners
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# Stark Law



# Stark Law

- “Conflict of Interest” Statute
  - Physician prohibited from referring to an entity in which he/she has non-exempt financial interest
  - Provider receiving the referral is prohibited from accepting it
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# Stark Law

- Stark Law only prohibits referral to entities from designated health services, which include:
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# Designated Health Services

- Clinical laboratory services
  - Physician, occupational, & speech-language pathology services
  - Radiology & other imaging services
  - Radiation therapy services & supplies
  - Durable medical equipment & supplies
  - Parenteral & enteral nutrition supplies
  - Prosthetics, orthotics & prosthetic devices
  - Home health services
  - Outpatient prescription drugs
  - Inpatient & outpatient hospital services
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# Real-Life Example: Tuomey Healthcare

- The government alleged Tuomey Hospital violated the Stark Law in regard to employment contracts held with physicians at its Outpatient Surgery Center. Tuomey entered into part-time employment agreements with 19 specialist physicians, whereby the physicians agreed to perform outpatient services exclusively at Tuomey Hospital and reassign all amounts paid by third-party payers to the hospital. In exchange, Tuomey agreed to provide benefits and pay each physician a salary that fluctuated based on the previous year's net case collections for outpatient procedures, a productivity bonus equal to 80% of net collections, and an incentive bonus up to 7% of the productivity bonus.
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# Real-Life Example: Tuomey Healthcare

- Result: Jury verdict that Tuomey violated the Stark Law
  - Jury found that Tuomey submitted \$39.3 million in claims predicated on improper referrals but penalties and damages under the FCA could exceed \$350 million
  - Amount paid by Tuomey: \$39,300,000
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Real-Life Example:






# Real-Life Example:

- Result:




# Stark Law Consequences

- Denial of Medicare/Medicaid/third-party payors payment
  - Civil penalty of up to \$100,000 for the DHS entity, referring physician or both
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# Anti-Kickback Statute



# Anti-Kickback Statute (AKS)

- Prohibits anyone from knowingly or willfully paying or offering to pay remuneration, directly or indirectly
  - To induce someone to refer patients, or recommend the purchase of any facility, item or service that may be paid for by a federal health care program
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# AKS Problem Areas

- Bundled discounts – if the bundled products were reimbursed under the same federal healthcare methodology
  - Free supplies or equipment – manufacturers may offer free supplies or equipment
  - Product support/reimbursement support – manufacturers may offer free product support or reimbursement assistance by providing information regarding insurance coverage criteria and reimbursement levels for their product.
- 


# Real-Life Example:

- The Health Alliance of Greater Cincinnati and The Christ Hospital in Ohio, were accused of illegally paying physicians in exchange for referring cardiac patients to The Christ Hospital, a former member hospital of the Health Alliance of Greater Cincinnati. A qui tam lawsuit was brought forth alleging The Christ Hospital limited the opportunity to work at the Heart Station, a center where patients receive non-invasive procedures such as stress tests, to those cardiologists who referred cardiac business to The Christ Hospital. The suit also alleged that cardiologists were rewarded with a percentage of time at the Heart Station based on their contributions to the hospital's yearly gross revenues, and these physicians earned additional income for treating patients at the facility.

# Real-Life Example:

- Result: The government claimed The Christ Hospital's use of Heart Station panel time to induce lucrative cardiac referrals violated the federal Anti-Kickback Statute
  - Claims submitted to Medicare/Medicaid violated the False Claims Act.
  - The two hospitals agreed to pay \$108 million to settle claims they violated the Anti-Kickback Statute and the False Claims Act
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# Anti-Kickback Statute (AKS) Consequences

- Considered felony for anyone who receives a form of payment in return for referring a patient for Medicare/Medicaid/Etc. covered services
  - Imprisonment up to five years
  - Exclusion from Medicare/Medicaid/Ect.
  - \$25K fine ea. violation
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# Anti-Kickback Safe Harbors

- Congress and the HHS have provided several “safe harbors” allowing entities to avoid violations of the Anti-Kickback Statute

# Safe Harbors- Investment Interests



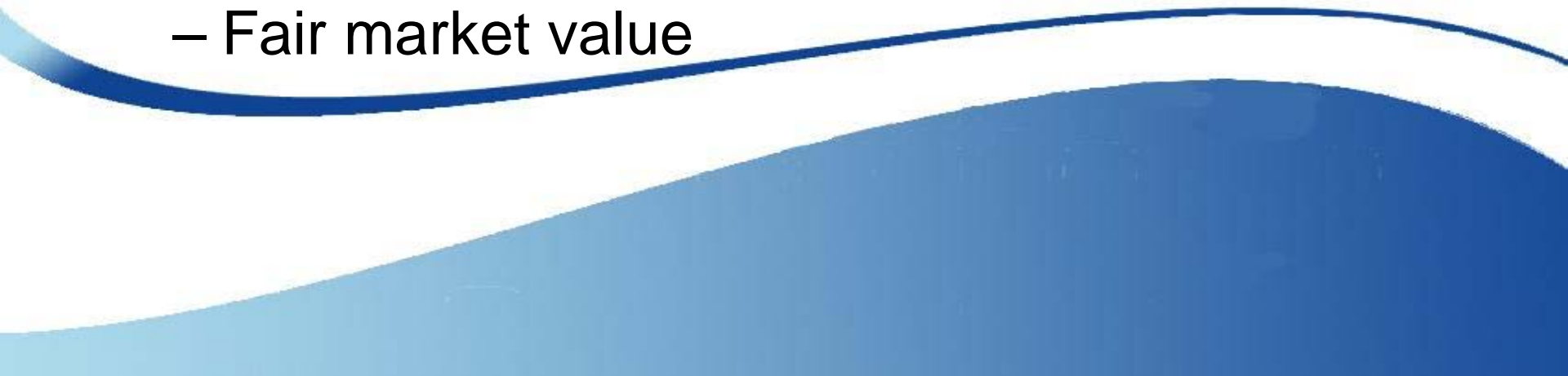
# Safe Harbors- Space Rental

- Anti-Kickback law forbids certain leasing agreements, except if:
    - Lease is for a duration of one year
    - Rent does not reflect the volume or value of referrals
    - Lease is not for more space than necessary
    - Rent is at fair market value
    - Lease is in writing
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# Safe Harbors- Equipment Rental

- Many offices find it more economical to rent rather than own their equipment
- Same conditions as applied to the space rental lease applies to the equipment lease

# Safe Harbors-Personal Services/Management Contracts

- Payment made to agents as compensation, so long as the agency agreement:
    - Covers all services the agent will provide
    - Cannot reflect the volume or value of referrals
    - Set out in writing
    - Not less than one year
    - Fair market value
- 


# Safe Harbors – Referral Services

- Payments can be made to a referral service if:
    - Doesn't reflect the volume or value of referrals
    - No restrictions on the manner in which the services referred are provided
    - Disclosures made and written down
- 

# Safe Harbors – Payments Made to Employees

- Payments made to an employee will be safe so long as there is a real employment relationship and the payments do not take into account the value or volume of referrals for Medicare or Medicaid services

# Safe Harbors - Recruitment


- Safe harbor for payments made to induce a practitioner to join with an entity, with litany of conditions including:
    - Recruit is leaving an established practice
    - Recruit can only bring 25% of patients with him or her from old practice
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# Florida Self Referral Laws



# Florida Patient Self-Referral Act

- Prohibits the patient referral by a health care provider or immediate family member who has an ownership or investment interest in the entity providing the service or treatment, unless specific exceptions apply.
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# Real-Life Example




# Real-Life Example

- Result




# Florida Self-Referral Act Consequences

- Possible licensure discipline
  - Civil penalty of up to \$100,000 for each such circumvention arrangement or scheme
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# HIPAA v. FIPA



# Florida Information Protection Act of 2014 or FIPA

- Effective July 1, 2014
  - Law requires specified entities to:
    - Take reasonable measures to protect and secure personal information in electronic form
    - Notify DLA of certain data security breaches
    - Provide notice to effected individuals
    - Properly dispose of consumer records
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# FIPA Overview

- FIPA protects consumers by requiring certain entities to take reasonable measures to protect and secure data in electronic format that contains personal information
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# Who Must Adhere to FIPA

- Businesses and government agencies that acquire, maintain, store or use the personal information of a consumer
  - Term personal information is broader

# FIPA Breach v. HIPAA Breach


- HIPAA Breach definition is more specific than FIPA definition




# FIPA V. HIPAA Requirements

- FIPA – Data Security
  - Covered entities, government entities, third-party agents shall take reasonable measures to protect and secure data in electronic form containing personal information


# FIPA V. HIPAA Requirements

- HIPAA – Data Security
    - Covered entities and business associates must ensure confidentiality, integrity and availability all EPHI created, received, maintained or transmitted
    - Protect against reasonably anticipated threats, uses and disclosures
    - Ensure compliance
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# FIPA V. HIPAA Requirements

- FIPA – If personal information was accessed as a result of breach:
    - Notice must be provided to consumers within 30 days unless good cause is shown for a 15-day delay
    - Notice must be provided to the AG for a breach affecting 500 or more individuals
    - Defines what information must be included in a proper notice
    - Expands the data breach statute to include state governmental entities and their instrumentalities
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# FIPA V. HIPAA Requirements

- HIPAA – Notice to individual
    - Shall notify each individual whose unsecured PHI has or is believed to have been accessed, acquired, used or disclosed as a result of a breach.
    - Notice is to be provided no later than 60 days after the breach
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# Risk of Harm and Notice


- FIPA and HIPAA use different risk of harm methodologies for determining whether a breach requires notices to the individual
  - FIPA focuses on a risk assessment related to the harm of the individual, whereas HIPAA focuses its risk assessment on whether or not PHI has been compromised
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# FIPA Consequences

- Civil penalties could be imposed in the amount of \$1,000 per day for the first 30 days
  - \$50,000 for each subsequent 30-day period
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# FIPA Compliance Recommendations

- HIPAA-covered entities need to updated breach policies and procedures
  - Entities that have PHI but are not HIPAA-covered entities will now have security compliance standards to follow
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