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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
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
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
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.
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.
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.
Real-Life Scenarios

• Result 2: The practice is operating illegally as of the day the practice manager is made a partner.
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.
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.
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
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
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
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
Stark Law

- Stark Law only prohibits referral to entities from designated health services, which include:
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
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.
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
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
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
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 – manufactures may offer free product support or reimbursement assistant 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.
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/Etc.
- $25K fine ea. violation
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
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
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.
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
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
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
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 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
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
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.
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.
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
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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