

# Medical Practice Compliance Issues

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# Objectives

- Health Care Clinic Act
  - Stark Law
  - Anti-Kickback Statute
  - Florida Self-Referral Act
  - Florida Patient Brokering Act
  - HIPAA v. FIPA
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# Health Care Clinic Act




# Health Care Clinic Act

- Purpose: To require non-healthcare provider 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-exempt person
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# Exemptions: A Practice Owned By:


- Acupuncture Physicians
  - Allopathic Physicians
  - Osteopathic Physicians
  - Chiropractic Physicians
  - Podiatric Physicians
  - Naturopaths
  - Optometrists
  - Dentists
  - Massage Therapists
  - Nurse Practitioners
  - Other Providers Licensed Under Chapter 464, Florida Statutes
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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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# 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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# Traps for the Unwary

- If a non-exempt person 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.
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# 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
  - 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 prohibit ownership by anyone outside of that specialty
  - Examples include:
    - 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 exempt providers
  - 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

- Physician Self-Referral Prohibition
  - Physician prohibited from referring to an entity in which he/she has non-exempt financial interest
  - Two-Way Street
    - Provider receiving the referral is prohibited from accepting it
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# Stark Law

- Stark Law prohibits referral to entities for the provision of designated health services such as:
    - 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.
- The improper portion of the arrangement was that the physicians were compensated (based on the collections bonus) for the technical component of the services which they were referring to the hospital

# 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:

- A physician practice owns a DME provider and refers its patients to the DME company for supplies and equipment.
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# Real-Life Example:

- Result: This is a Stark violation as the physician has a financial interest in the DME company and is in a position to influence referrals.
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# 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
  - If the violation is knowing it can subject a provider to criminal and civil liability under the False Claims Act
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# Anti-Kickback Statute




# Anti-Kickback Statute (AKS)

- Under the Anti-Kickback Statute, it is illegal to knowingly or willfully:
  - Offer, pay, solicit, or receive remuneration directly or indirectly, in cash or in kind, in exchange for referring and individual, or furnishing or arranging for a good or service for which payment may be made by a federal healthcare program

# AKS Problem Areas

- Bundled discounts – if the bundled products were reimbursed under the same federal healthcare methodology
  - 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.
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# AKS Problem Areas


- Free supplies or equipment – manufacturers may offer free supplies or equipment
  - Waiving co-pays
  - Offering transportation to appointments
  - Offering free or reduced priced medications
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# 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 a 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.
  - Possible fine of up to \$25K for ea. violation
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# Anti-Kickback Safe Harbors

- Safe Harbors Include:
    - Investment interests in certain entities
    - Space and equipment rental agreements
    - Personal Services and Management Contracts
    - Sales of practices
    - Employment relationships
    - Group Purchasing Arrangements
    - Health Plans and Managed Care Plans
    - Warranties
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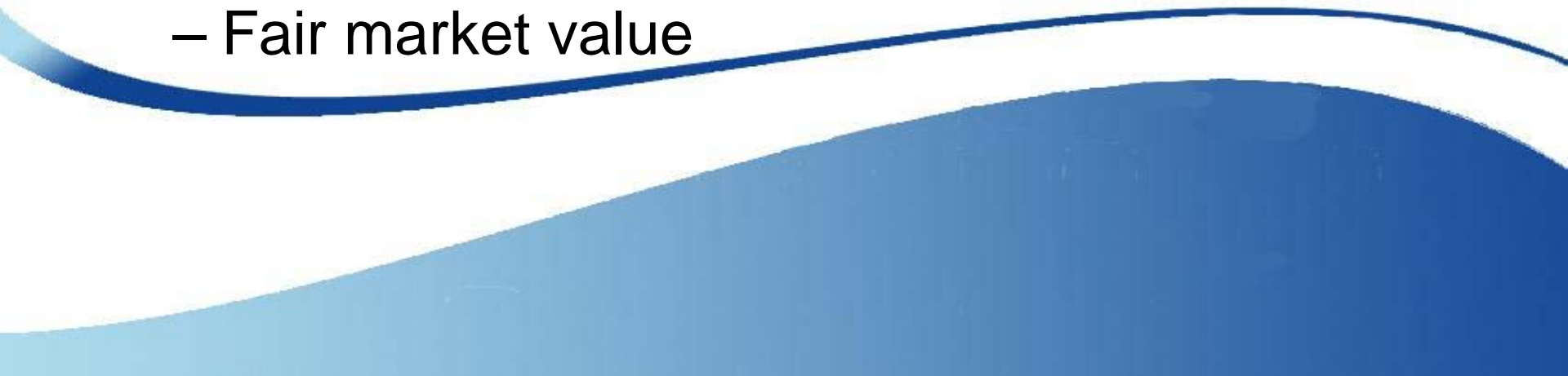
# Safe Harbors- Space Rental

- 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
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# 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
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# 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 Act




# 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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# Key Differences

- The key differences between the federal and state self-referral laws are:
    - the “investment interest” is defined differently
    - Florida law applies to all payors, not just federal
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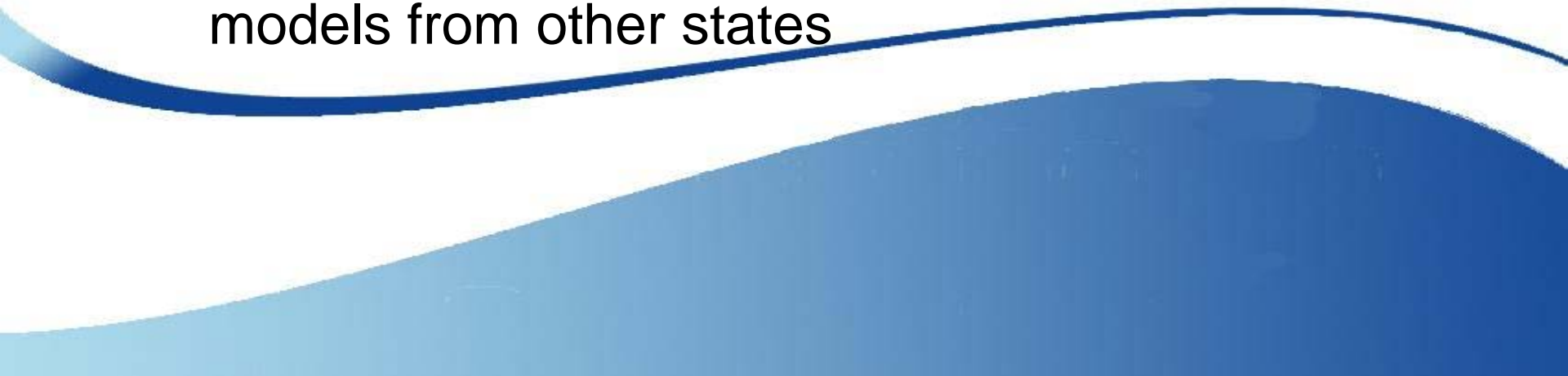
# Florida Self-Referral Act Consequences

- Possible licensure discipline
  - Civil penalty of up to \$100,000 for each such circumvention arrangement or scheme
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# Florida Patient Brokering Act



# Florida Patient Brokering Act


- Florida's version of the Anti-Kickback Statute
  - Key difference to remember is that it applies to all payor sources
    - This means an arrangement that would be ok under federal law may be illegal in Florida
    - Keep this in mind when trying to adopt business models from other states
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# HIPAA v. FIPA






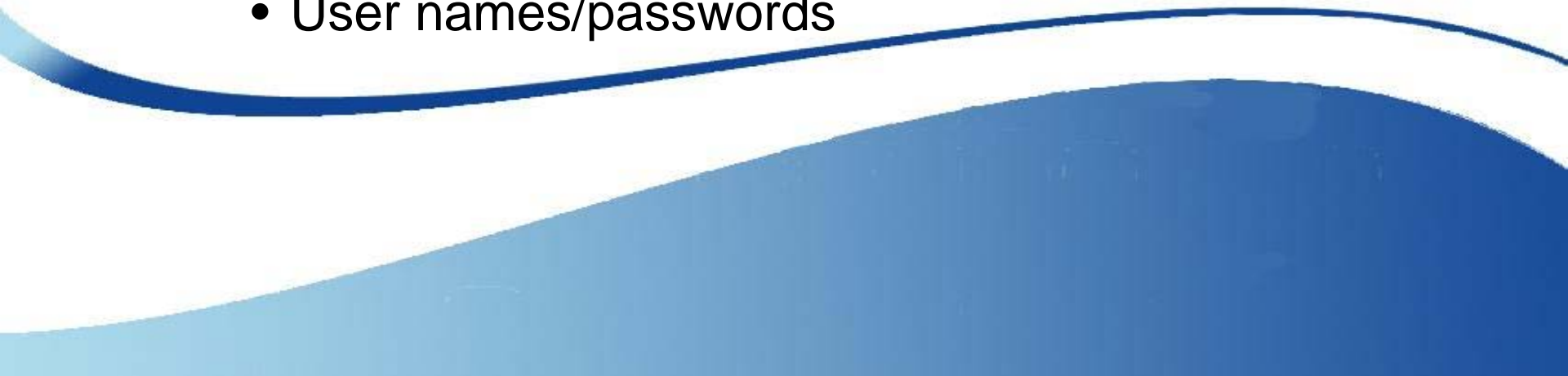
# Florida Information Protection Act of 2014 or FIPA

- Effective July 1, 2014
  - Commonly called the “Target Law”
  - Law requires specified entities to:
    - Take reasonable measures to protect and secure personal information in electronic form
    - Notify Department of Legal Affairs of certain data security breaches
    - Provide notice to effected individuals
    - Properly dispose of 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
    - Personal Information is broadly defined & includes:
      - Medical history
      - Partial names in conjunction with SSNs, DL or other similar ID numbers
      - Financial account numbers
      - Health insurance policy number
      - User names/passwords
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# FIPA Breach v. HIPAA Breach

- HIPAA
  - The acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which compromises the security or privacy of the protected health information
- FIPA
  - Unauthorized access of data in electronic form containing personal information


# 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 update 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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