

# **Patient Protection and Affordable Care Act – Compliance Implications**

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# THE UNIVERSITY OF TEXAS SYSTEMWIDE COMPLIANCE OFFICE

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PROVIDING COMPLIANCE LEADERSHIP AND GUIDANCE TO THE UNIVERSITY OF TEXAS SYSTEM

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# **Compliance Programs**

**Compliance Programs are arguably an industry standard now in healthcare**

**Some background on the evolution of compliance programs is helpful**

# Compliance Programs

- **Federal Sentencing Guidelines**
  - To have an effective compliance program under the Guidelines, an organization must exercise due diligence to prevent and detect criminal conduct and otherwise promote an organizational culture that encourages ethical conduct and commitment to compliance with the law

# Compliance Programs

- **Federal Sentencing Guidelines**
  - Such compliance and ethics program must be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct

# Compliance Programs

- **Federal Sentencing Guidelines**
  - What does due diligence require?

# Compliance Programs

- **Federal Sentencing Guidelines**
  - What does due diligence require?
    - Standards and Procedures to prevent and detect violations
    - Governing authority that is knowledgeable about the program and which shall exercise reasonable oversight with respect to implementation and effectiveness of the program

# Compliance Programs

- **Federal Sentencing Guidelines**
  - What does due diligence require?
    - Reasonable steps not to give substantial authority to individuals who the organization knew or should have known through the exercise of due diligence have engaged in misconduct
    - Reasonable steps to communicate periodically and in a practical manner its policies, procedures, and other aspects of the program (including training)

# Compliance Programs

- **Federal Sentencing Guidelines**
  - What does due diligence require?
    - Reasonable steps
      - to ensure compliance program is followed, including monitoring and auditing activities
      - to periodically evaluate compliance program for effectiveness
      - to publicize a system for reporting misconduct anonymously, confidentially, and without fear of retaliation

# Compliance Programs

- **Federal Sentencing Guidelines**
  - What does due diligence require?
    - Promote and enforce compliance program through appropriate incentives and appropriate disciplinary action
    - After misconduct is identified, take appropriate corrective action

# Compliance Programs

- **Federal Sentencing Guidelines in the Healthcare Industry**
  - False Claims Act amendments in 1986
  - Healthcare industry fraud investigations and settlements
  - Exclusion authority of HHS-OIG
  - “Negotiated” Corporate Integrity Agreements
  - HHS-OIG Compliance Program Guidance

# Compliance Programs

- **HHS-OIG Compliance Guidance**
  - Hospitals
  - Physician Groups
  - Pharmaceutical Manufacturers
  - DME, Prosthetics, Orthotics and Supply Companies
  - Recipients of PHS Research Awards
  - Nursing Facilities
  - Many others . . .

# Compliance Programs

- **OIG Compliance Guidance**
  - Compliance Officer/Compliance Committee
  - Policies and Procedures
  - Training and Education
  - Effective Lines of Communication / Hotlines
  - Disciplinary Action / Background & Exclusion
  - Internal Investigations and Corrective Action
  - Auditing and Monitoring

# Compliance Programs

- **OIG Compliance Guidance**
  - No specific requirements
    - “guidelines . . . must be considered depending upon their applicability to each particular [organization]”
    - “guidance does not establish a set of . . . standards by which to evaluate the compliance of an institution”
  - Not a model compliance program
    - “it is not in and of itself a compliance program”
    - “there is no “one size fits all” compliance program”
  - Not mandatory
    - “the suggestions made in these CPGs are not mandatory”

# **Mandatory Compliance Programs**

## **Patient Protection and Affordable Care Act (PPACA)**

### **Mandatory Compliance Programs**

- Providers and Suppliers participating in Medicare and Medicaid are required to implement a compliance program with core elements as a condition of enrollment.

# Mandatory Compliance Programs

## Mandatory Compliance Programs

### Nursing facilities

- Mandatory compliance program that is reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations
- and in promoting quality of care

# Mandatory Compliance Programs

## Mandatory Compliance Programs

### Nursing facilities

- Compliance program oversight to “high-level personnel” with “sufficient resources and authority” to assure compliance
- Exercise of due care not to delegate “substantial discretionary authority” to individuals whom facility knew or should have known had a “propensity to engage” in criminal, civil, and administrative violations

# Mandatory Compliance Programs

## Mandatory Compliance Programs

### Nursing facilities

- Standard have been consistently enforced through disciplinary measures, including discipline of individuals responsible for the failure to detect an offense
- Compare the above to the U.S.S.G.
  - *The failure to prevent or detect the instant offense does not necessarily mean the program is not generally effective in preventing and detecting criminal conduct*

# Evaluating Effectiveness

## What is required to be “effective”

- U.S. Sentencing Guidelines
- HHS-OIG Guidance
- Core Elements?

# Evaluating Effectiveness

## How can you evaluate “effectiveness”

- What documentation is available
- What titles, authority, responsibilities, and support do compliance personnel maintain
- What is publicized about the compliance program and how
- What auditing activities are conducted
- Are the compliance personnel effective

# Individual Responsibility

## Employees and Owners

- **Background checks**
- **Exclusion checks**
- **Proposed Rule for Enhanced Screening**
  - Only qualified individuals and organizations allowed to enroll
  - Meant to ensure compliance and to promote high quality care
  - Limited, Moderate, and High levels of screening
  - Site visits, criminal background checks, fingerprinting

# Individual Responsibility

## Management, Boards, and Compliance Office

- **Proposed revisions to the U.S. Sentencing Guidelines**
  - Requires direct reporting to Board
  - No compliance person involved in misconduct
- **Proposed revisions to OIG exclusion authority**
  - Authority to exclude executives of a company that is excluded or convicted of fraud (even if the executives have left the company)

# Individual Responsibility

## Management, Boards, and Compliance Office

- ***U.S. v. Caputo***

- *“Corporate compliance officers are very much today’s corporate ‘fire personnel.’ They are often the company’s ‘first responders’ and must focus on both proactive and reactive efforts to be effective.”*

# Overpayments

- **PPACA § 6402**
- **Reporting and Returning Overpayments**
  - If a person has received an overpayment, the person shall report and return the overpayment
    - Notify in writing of the reason for the overpayment

# Overpayments

- **PPACA § 6402**
- **Reporting and Returning Overpayments**
  - An overpayment must be reported and returned within 60 days after being identified or by the date any corresponding cost report is due

# Overpayments

- **PPACA § 6402**
- **Reporting and Returning Overpayments**
  - An overpayment is any money received or retained to which the person is not entitled to, after applicable reconciliation

# Administrative Authority and Sanctions

- **Authority to obtain information**
  - To protect the integrity of the program
  - Directly or indirectly involved in program
  - Any records necessary for the economy, efficiency, and effectiveness of the programs

# Administrative Authority and Sanctions

- **Civil Monetary Penalties**
  - Misrepresentation of material fact on application
  - Making false statement material to payment
  - Retention of overpayments
  - Failing to grant timely access (\$15,000 per day)

# **Administrative Authority and Sanctions**

- **Suspension of payments**
- **Permissive exclusion for obstructing investigation or audit**
- **\$350 million dollars in funding for fraud and abuse enforcement activities**

# Anti-Kickback Law

- **PPACA Changes**

- No requirement for actual knowledge of law and intent to violate
- Violation constitutes false claim

# Beneficiary Inducement

- **PPACA Changes**

- Exclusion from definition of remuneration expanded to include:

- Remuneration that promotes access to care and poses low risk of harm
- Coupons from retailer

# **Stark Law**

## **In-Office Ancillary Services**

- **Disclosure for In-Office Ancillary Services**
  - Physician must disclose prior to furnishing in-office MRI, PET or CT scans
  - Physician must provide written list of alternate suppliers
- **Proposed rules**
  - List of 10 suppliers within 25 miles of office
  - Written notice signed by patient

# **Stark Law Self-Disclosure Protocol**

- **Resolve actual or potential violations of Stark Law**
- **60-day limit to return overpayments suspended until settlement**
- **Electronic submission required**
- **Legal analysis required**

# **Stark Law Self-Disclosure Protocol**

- **Full financial analysis required**
- **No obligation to reduce penalties, but will consider**
  - Nature and extent of practice
  - Timeliness of disclosure and cooperation
  - Financial position

# Transparency

- **PPACA requires annual reporting to HHS of certain payments**
  - From manufacturers of certain drugs, devices, medical supplies
  - To covered recipients (i.e., physicians or teaching hospitals)

# Transparency

- **Reported information includes**
  - Names and address
  - Amounts and dates of payment or other transfer of value
  - Description of payment or other transfer of value
  - Description of the nature of the payment or transfer of value
  - Other information required by HHS
- **Reported information to be available online**

# Quality of Care

- **Reporting requirements**
- **Payments tied to quality**
- **Compliance program focus**

# Conclusion

**A robust commitment to compliance will be essential for Healthcare providers and entities.**