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Completing the Journey through the World of Compliance

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COMMITMENT

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Conflict of Interest

Gabriel L. Imperato, Esq.
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Has no real or apparent conflicts of interest to report.

Agenda

- Board Oversight for Organization Compliance
- Major Compliance Risk Areas
- Essential Elements and an Effective Compliance Program
- Role of Health IT in Health Care Compliance

Learning Objectives

- Recognize major areas of risk across the continuum of care that impacts all stakeholders
- Discuss the role of health IT in tackling compliance requirements
- Identify how to align efforts and resources in collaboration with Federal and state agencies in order to create a timely and proactive risk management program
- Explain how to support and manage compliance issues and requirements in the absence of a dedicated compliance officer

General Expectations of Boards

- Understand member role and responsibilities
- Awareness of complexity of health care laws and regulations governing provision of care and reimbursement of services
- Provide advisory oversight and direction

Two Primary Obligations

- Decision-making function
 - Applying duty of care principles to a specific decision or board action
- Oversight function
 - Applying duty of care principles with respect to the general activity in overseeing the day-to-day business activities of the organization

The Anti-Kickback Statute

- 42 USC § 1320a-7b(b)(2)

It is unlawful to knowingly and willfully offer or pay 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

The Stark Law

- ❑ Section 1877 of the Social Security Act, 42 U.S.C. 1395nn
- ❑ The law is complicated and consists of the original statute (Stark I in 1989) and the amended provisions (Stark II in 1996)
- ❑ Stark regulations have gone into effect in phases (I, II and III) in 2002 and 2004, 2008 and 2009, but some are still pending.
- ❑ A prohibition on physician self-referrals
- ❑ If a physician (or immediate family member) has a direct or indirect financial relationship (ownership or compensation) with an entity that provides designated health services (“DHS”), the physician cannot refer the patient to the entity for DHS and the entity cannot submit a claim for the DHS, unless the financial relationship fits an exception

The False Claims Act

□ 31 USC § 3729 – The False Claims Act (“FCA”) sets forth seven bases for liability. The most common ones are:

1. Knowingly presenting, or causing to be presented, to the Government a false or fraudulent claim for payment
2. Knowingly making, using, or causing to be made or used, a false record or statement material to get a false or fraudulent claim paid
3. Conspiring to commit a violation of the False Claims Act
4. Knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or avoiding or decreasing an obligation to pay or transmit money or property to the government

□ Obligation defined as an established duty, whether or not fixed, arising...from retention of any overpayment

Knowing & Knowingly

- ❑ No proof or specific intent to defraud is required
- ❑ The Government need only show person:
 - ❖ had “actual knowledge of the information”; or
 - ❖ acted in “deliberate ignorance” of the truth or falsity of the information; or
 - ❖ acted in “reckless disregard” of the truth or falsity of the information.

Corporate Integrity Agreements (“CIA’s”)

- ❑ The OIG imposes compliance obligations on health care providers as part of settlements of Federal enforcement actions arising under a variety of health care fraud statutes
- ❑ The option for a health care provider to agree to corporate integrity obligations is in return for the OIG’s agreement as part of global criminal and/or civil settlements
- ❑ May represent OIG’s opinion on the effectiveness of the organization’s compliance program
- ❑ CIA’s adhere to the essential elements of an effective compliance program in the United States Sentencing Guidelines for Organizations
 - ❖ Board and Management Accountability

Settlement Trends-HIPAA and HITECH

- Increase in cases and settlement amounts
 - ❖ *Hospice of No. Idaho paid \$50k (lost laptop; OCR claims 1st settlement based upon security rule affecting less than 500 individuals)*
 - ❖ *Idaho State Univ. paid \$400K (data breach involving 17,500 records)*
 - ❖ *Affinity Health Plan paid \$1.2M (photocopier hard drive with 344K individuals' records)*
 - ❖ *Dermatology group paid \$150K (lost thumb drive with 2200 individuals' data, OCR claims 1st settlement based upon CE's failure to have P&Ps)*
 - ❖ *Shasta Regional Med Center paid \$275K (privacy breach; PHI shared with reporters)*

What Does the Government Expect from Business Organizations

- ❑ Partnership with Federal and State governments in detecting and preventing misconduct and promoting an ethical corporate culture
- ❑ Organizations which fail to ferret out wrongful conduct and non-compliant activity will likely suffer the consequences of not doing so
- ❑ Cooperation in investigating and organization's own wrongdoing- self-disclosure and individual liability.

Self Disclosure Process

1. Investigation and Evaluation
2. Consider the Benefits and Risks
3. Consider Which Entity to Disclose to
4. Submit a Timely, Complete and Transparent Disclosure
5. Anticipate Government Validation
6. Resolution – Strategies and Options

Is it “Voluntary?”

- ❑ Misprision of a Felony – 18 U.S.C. § 4 provides that “whosoever...having knowledge...of a felony...conceals and does not as soon as possible make known the same...shall be fined...imprisoned...or both
 - ❖ Requires active concealment
- ❑ Medicare Statute – 42 U.S.C. § 1320a-7b(a)(3) arguably makes it a felony to conceal or “fail to disclose” facts affecting right to receive payment

Is it “Voluntary?”

- ❑ False Claims Act – Amendments to the FCA made as part of Fraud Enforcement and Recovery Act of 2009 (FERA) – 31 U.S.C. § 3729(a)(1)(G)
 - ❖ Illegal to “knowingly conceal...or knowingly and improperly avoid...or decrease...an obligation to pay or transmit money or property to the Government...”
- ❑ Presentment of claim not essential and False Claims Act Liability can be based on “inaction”
- ❑ FCA and Civil Money Penalty Law and Regulations (Medicare Reporting and Returning of Self-Identified Overpayments – February 12, 2016, 81 Federal Register 7652) establishes “obligation” to report “identified” overpayment within sixty (60) days

How is the Compliance Program Addressing Effectiveness and Significant Risks

- ❑ One of the primary goals of the organization compliance program is to manage compliance risk and take remedial action when necessary.
- ❑ Response to reports of non-compliant activity.
- ❑ New business ventures are evaluated for potential risk.
- ❑ Timely response is made to newly developed rules and regulations.

CIA's Require Resolution by the Board Related to the Effectiveness of the Compliance Program

- “The Board of Directors has made reasonable inquiry into the operations of the organization’s Compliance Program, including the performance of the Hospital Compliance Officer and the Hospital Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, the organization has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

What does an “Effective” Compliance Program Mean?

- The concept of an “effective compliance program” is derived from the U.S. Federal Sentencing Guidelines for Organizations (“FSG”)
- “To have an effective compliance and ethics program, an organization must
 1. exercise due diligence to prevent and detect criminal conduct; and
 2. promote an organizational culture that encourages ethical conduct and commitment to compliance with the law.”

Resources/Standards Used

- Federal Sentencing Guidelines for Organizations
- CIA requirements for Compliance Programs
- OIG's Compliance Program Guidance and Supplemental Compliance Program Guidance for Hospitals
- U.S. Department of Justice, Criminal Division, Fraud Section's *Evaluation of Corporate Compliance Programs*
- *OIG's Measuring Compliance Program Effectiveness – A Resource Guide*, published March 27, 2017
- *Practical Guidance for Health Care Governing Boards on Compliance Oversight*, published April 20, 2015.

FSG Seven Essential Elements of an Effective Compliance Program (Forms the Basis of Review Metrics)

1. Has standards and procedures to prevent criminal conduct and to promote an ethical culture
 - Policies and procedures about how the compliance program will operate
 - Code of Ethics to set expectations for employees – based on the company's values

FSG Seven Essential Elements of an Effective Compliance Program (Cont'd.)

2. Its leaders understand and oversee the compliance program/
designate a Compliance Officer
 - Board is knowledgeable about and oversees the compliance program
 - Leaders set the tone for compliance/integrity
 - Compliance Officer and Compliance Committee are designated

FSG Seven Essential Elements of an Effective Compliance Program (Cont'd.)

3. Denies employment to people who have engaged in misconduct/performs exclusion screening
 - Conducts screening to detect individuals who are excluded from Federal programs or who have committed health care crimes
 - Screen using OIG's List of Excluded Individuals and Entities, among others

FSG Seven Essential Elements of an Effective Compliance Program (Cont'd.)

4. Communicates compliance standards and conducts effective education and training
 - Training plan for compliance education
 - Communicates with employees about expectations in other ways (i.e. emails, signage, staff meetings, intranet)

FSG Seven Essential Elements of an Effective Compliance Program (Cont'd.)

5. Takes reasonable steps to achieve compliance by using monitoring and auditing systems and by maintaining a compliance reporting mechanism
 - Monitoring and Auditing plan
 - Anonymous method for individuals to report suspected violations (hotline and email)
 - Non-retaliation policy for individuals who report suspected violations

FSG Seven Essential Elements of an Effective Compliance Program (Cont'd.)

6. Provides consistent enforcement of standards through incentives and discipline for violations of the compliance program
 - Compliance is a factor in employee performance evaluations
 - Policies enforced through discipline – warnings, re-training, termination
 - Positive incentives for compliant conduct.

FSG Seven Essential Elements of an Effective Compliance Program (Cont'd.)

7. Takes reasonable steps to respond appropriately to criminal or non-compliant activity and to prevent further such activity
 - Conducts inquiry into all credible reports of potential violations
 - Conducts thorough, prompt, fair investigations as warranted
 - Takes corrective action if violations are confirmed
 - Makes refunds if overpayments are identified.

Two Additional FSG Expectations

1. Organization conducts periodic risk assessments
 - Hospital departments identify compliance risks
 - Risks are prioritized based on severity / impact
 - Monitoring and auditing plan is developed based on the risk assessment
 - Annual process

Two Additional FSG Expectations (Cont'd.)

2. Organization promotes an ethical organizational culture
 - Starts at the top with the Board
 - Consistent message throughout the company
 - Actions, not only words, support ethical culture

Health IT (“HIT”) and Compliance

Changes in Payment Methodology

As the healthcare systems moves from fee-for-service to payment for quality and cost-effectiveness

- There is a greater focus on health information technology (“HIT”)

Accountable Care Organizations want to meet quality and savings requirements

Healthcare organizations participate in bundled payment initiatives and/or forms of risk contracting

HIT facilitates data analytics and data analysis to successfully manage in this new paradigm of quality and reimbursement for health care services

ACOs and HIT

The rules governing ACOs require that

- ACOs explain how they will develop HIT tools and infrastructure to ensure care coordination
 - Across and among physicians and other providers

Compliance professionals need to understand these HIT tools, how they work and be able to

- Track whether the HIT tools and infrastructure are effective in accomplishing ACO and compliance objectives

HIT Compliance Functions

HIT should be used to assist in cyber security and risk management to provide and monitor secure, private sharing of information

- HIT report on quality data and aggregating data across provider sites
- Track quality measures, deploying clinical decision support tools that provide access to
 - Billing alerts, checks and balances
 - Alerts and evidence-based medicine guidelines

HIT Develops Software/Systems to Collect, Track Analyze Data

Need to establish mechanisms to effectively monitor and control the utilization of health care services

- Can be facilitated by HIT

Compliance professionals need to understand how these mechanisms were set up

- How they monitor and control utilization

Compliance professionals need to understand

- mHealth, social media, telemedicine and its interplay with compliance

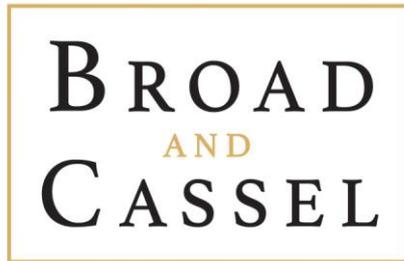
A Data Analytics Driven World

The nature of compliance is changing in a data analytics driven world

Healthcare organizations that use predictive analytics to determine

- What interventions may be required for certain patients
- Are going to face compliance issues that are dynamic and novel

Questions



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