

Large Hospitals and Health Systems
 HCCA 21st Annual
 Compliance Institute

 PREAM1
MARCH 26, 2017

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Session Goals

- Opportunity for large hospital and health system compliance officers to engage in a collaborative discussion of both emerging and chronic challenges unique to such organizations.
- Share model practices and practical solutions.
- A panel of experienced large system compliance professionals will introduce and speak to such topics, engage the audience in an interactive exchange of perspectives and approaches and solicit additional issues of concern.
- Take away from this session an enhanced understanding of challenges common to compliance programs in large organizations, new approaches to these challenges and the wisdom of your colleagues.

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Discussion Facilitators

Suzie Draper – VP, Business Ethics and Compliance
Intermountain Healthcare

Margaret Hambleton – VP, Corporate Compliance Officer
Dignity Health

Cheryl L. Wagonhurst – Law Office of Cheryl L. Wagonhurst
Former Chief Compliance Officer Tenet Healthcare
and former Partner, Foley & Lardner, LLP

John Steiner – Protenus, Inc.

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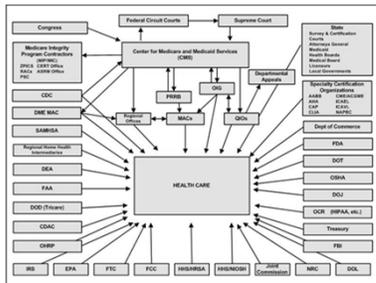
Evolution of a Compliance Program *Birth of Healthcare Compliance*

- 1996 HIPAA – (Health Insurance Portability and Accountability Act)
- Caremark decisions
- Use of FCA in healthcare

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Evolution of a Compliance Program *Government Enforcement and Oversight*



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Evolution of a Compliance Program *Regulatory Agency – Enforcement and Oversight*

- Healthcare compliance in the Trump administration
 - Who knows????
 - Healthcare enforcement continues to be a profitable endeavor for the government
 - Best guess – unlikely to have significant changes to compliance requirements
 - Funding
 - Cut in regulations – President's Executive Order

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Evolution of a Compliance Program
Regulatory Agency – Enforcement and Oversight

- Federal Compliance Program Guidance
 - stipulates the need for an *Effective Compliance Program*
 - Silent on how to measure effectiveness
 - Emphasizes that to be *effective*, the program "**must**"
 - Be fully implemented
 - Be adequately resourced
 - Have an annual independent audit of "effectiveness" (select programs)
 - Have effective board oversight
 - Increased push for "outcomes" and "performance" measures

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Evolution of a Compliance Program
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Evolution of a Compliance Program
Board Oversight

- Compliance function should be separate from, and not report directly to, legal counsel
- Boards should get regular updates on compliance efforts – can't bury head in sand
- Boards must be proactive in identifying areas of risk within particular organization/industry

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Corporate Governance Responsibilities

Duty of Care

Director shall perform his/her duties, including duties as a member of any committee of the board upon which the director may serve:

- o In **good faith**;
- o In a manner that director believes to be in the **best interests of the corporation**; and
- o With **such care**, including reasonable inquiry, **as an ordinarily prudent person** in a like position would use under similar circumstances.

The conscientious pursuit by directors of principles of best practices is the foremost approach to the duty of care and best prophylactic against director liability.

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Corporate Governance Responsibilities

Duty of Inquiry

Cannot be passive and must actively participate in decisions.

Must **make reasonable inquiries** regarding potential decisions:

- o Healthy skepticism and questioning
- o Asking for clarification regarding issues and impact of decisions
- o What would an ordinarily prudent person ask or want to know under similar circumstances?

Reliance on others for information and answers:

- o Reliable and competent officers and employees;
- o Legal counsel, accountants and others with professional or expert competence; and
- o Board committees as to matters within their designated authority.

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Corporate Governance Responsibilities

Duty of Oversight

In re Caremark International Inc. Derivative Litigation

"But it is important that the board exercise a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the board that appropriate information will come to its attention in a timely manner as a matter of ordinary operations, so that it may satisfy its responsibility."

"And obviously too, no rationally designed information and reporting system will remove the possibility that the corporation will violate laws or regulations, or that senior officers or directors may nevertheless **sometimes be misled or otherwise fail reasonably to detect acts** material to the corporation's compliance with the law."

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Review and Oversight of Compliance Program

Based on the legal principles and resources as described, the Board:

- Has an affirmative **duty to reasonably oversee implementation and operation** of an effective program for **organizational compliance** with key federal and state laws.
- Must assure that the Compliance Program has **effective systems in place to regularly report on** the results of the **Compliance Program's work** (including internal audit) to the Board of Directors (or a committee thereof).
- Is entitled to **rely**, in good faith, **on officers and employees as well as corporate professional experts/advisors** (when board believes confidence in experts is warranted) regarding compliance, Compliance Program and effectiveness of Compliance Program.

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DOJ Prosecutorial Manual

- Eligibility for "cooperation credit" - must provide the DOJ with "all relevant facts" regarding corporate misconduct
- Civil and Criminal corporate investigations should focus on individuals
- Routine communications required
- Criminal investigations - "Department lawyers should not agree to a corporate resolution that includes an agreement to dismiss charges against, or provide immunity for, individual officers or employees."
- Focus of civil counsel should be on individuals as well as the company and should evaluate whether to bring suit against an individual based on considerations that go beyond that individual's ability to pay
- Plans to resolve cases should take into consideration resolution of related individual cases

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Evolution of a Compliance Program Regulatory Agency – Enforcement and Oversight

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What are you telling your board with these measurements?

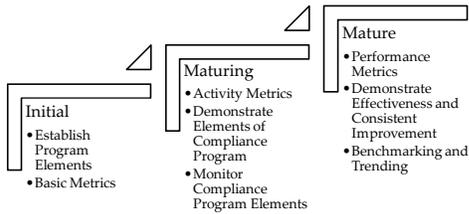
Unintended Stories

- > Hotline statistics – timeliness and adequacy of responses
- > Investigation statistics
- > Likelihood and severity of top risk areas
- > Training completion rates
- > Predictive analytics (behavior, ROI, non-official reporting channels)
- > Policy dissemination
- > Corrective action plans completion – from audits
- > Audit findings

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Compliance Program Evolution



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Risk Assessment

8th Element of an Effective Compliance Program

- Government guidance
 - o Federal Sentencing Guidelines
 - "Organizations shall periodically assess the risk of criminal conduct and shall take appropriate steps..."
 - o OIG Program Guidance
 - "Institutions should consider conducting risk assessments to determine where to devote audit resources..."

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Risk Assessment

Risk Impact

- Severity measure
- Define scoring terms in very specific terms
 - Numeric scoring
 - High – Low
 - Example: High=Loss or additional expense greater than 1% of gross revenue (financial impact)

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Risk Assessment

Vulnerability Scoring

- Consider without controls to understand the inherent risk
- Specific definition of terms (scores)
- Vulnerability may include:
 - Likelihood of failure
 - History of failure
 - Rate of change
 - Complexity of process
 - Detectability of failure

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Risk Assessment

Evaluating the Control Environments

- Extent of variation
- Routine review or audit of process
- Human factors
 - Standard work
 - Communication, hand-offs, redundancy, work around, reliance on memory, etc.

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Risk Assessment

Risk Tolerance

- Continuum ranging from total avoidance of risk to total acceptance
- Tied to mission and organizational governance and leadership
- Understand that you probably cannot address all risks identified

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Risk Assessment

Work Plan Development

- Identifying and prioritizing risks creates risk if nothing will be done with the information
- Audits are not corrective action!
- Understand the root cause
- Resources available

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Work Plan Activities

CMS: Overpayments

CMS: "60 Day Repayment Rule"

- **Rule:** Providers that receive an overpayment must report and return the overpayment.
- **Timing:** Overpayments must be reported by the later of:
 - (i) the date which is 60 days after the date on which the overpayment was identified; or
 - (ii) the date any corresponding cost report is due.
- **Identification:** Occurs when a provider, through reasonable due diligence, has or should have identified receipt of and quantified the amount of the overpayment.
- **Lookback Period:** Overpayments must be reported and returned only if identified within 6 years of the date payment was received.
- **Method:** Use of claims adjustments, credit balances, self-reported refunds or another appropriate process to satisfy the obligation to report

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Work Plan Activities
CMS: Overpayments

- CMS: "60 Day Repayment Rule"

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graph LR
    A[Receipt of Credible Information] --> B[Reasonable Diligence Investigation  
6 Months]
    B --> C[Identification and Quantification  
of an actual Overpayment]
    C -- 60 Days --> D[Report and Return Overpayment]
  
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Stark / Anti-Kickback
Stark Phase 5 Regulations – November 2015

Eased requirements around documenting physician relationships

- Flexibility around how arrangements are documented "in writing"
- Documenting the term of an arrangement
- More flexibility for "holdover" arrangements – arrangements that continue past initial term, under the same terms

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Stark / Anti-Kickback
Stark Phase 5 Regulations – November 2015

Added two new exceptions

- "Timesharing arrangements" for use of equipment, expertise, etc.
- Payments to physicians to assist in compensating non-physician practitioners for primary care

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Stark / Anti-Kickback
Stark Phase 5 Regulations – November 2015

Other

- Clarifications on whether certain situations constitute "remuneration"
- Made regulatory language more consistent throughout

Current discussions of Stark

- Much current discussion relates to how Stark might interfere with **value-based payment** and **population health**.
 - e.g., a February 2017 Healthcare Leadership Council White Paper argues that Stark regulations create challenges for implementing value-based payment initiatives, and recommending solutions

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Stark / Anti-Kickback
Stark Regulations – Recent Cases

Columbus Regional Healthcare System (Georgia – Sept. 2015)

- Overpaid employed physicians in salary and directorships

North Broward Hospital District (Sept. 2015)

- Overpaid nine employed physicians

Adventist Health System (Sept. 2015)

- Overpaid and provided improper benefits to employed physicians

Halifax Hospital Medical Center System

- Employed neurosurgeon salaries were above FMV

Tuomey Health Care System (Sept. 2016)

- Government pursued case against Tuomey CEO

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Stark / Anti-Kickback
Significant Cases

- Tuomey case – bolstered government enforcement actions
- North Broward and other settlements seemed to have similar fact patterns:
 - High compensation levels
 - Relatively low to average production levels
 - Coding and billing issues to boot
- Lack of "commercial reasonableness" unless compensation to physician is covered by personally performed services

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Stark / Anti-Kickback

Stark Regulations – Recent Cases

OIG Fraud Alert (June 2015)

- "Physician compensation arrangements may result in significant liability."
- "Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide."
- OIG will go after physicians who enter into questionable medical directorship arrangements.

Physician Compensation

- Oversight Structure

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Stark / Anti-Kickback

Compliance Tips

- Contract review approval structure – should be reviewed and revised accordingly
- Review arrangements with employed physicians
- North Broward – addressed "downstream" revenue
- Focus on FMV and "commercial reasonableness"
- Don't allow your FMVs to become stale

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Key Decisions Regarding Applicability of CoPs to FCA

- Historically some providers prevailed in FCA cases based upon noncompliance with condition of participation
 - *U.S. ex rel. Ortolano v. Amin Radiology* – State regulation addressing certification of nuclear medicine tech not a condition of payment
 - *U.S. ex rel. Gampie v. Gilead Scis.* - Switch to unapproved manufacturing sources for APIs (that did not have NDA) not a condition of payment
- – But, *U.S. ex rel. Escobar v. Universal Health Svcs.* - Supreme Court held that violation of Medicaid licensing and supervision standards for psychiatric services could potentially raise FCA concerns
 - o Supreme Court rejected blanket distinction between "conditions of participation" and "conditions of payment." Rather, look to the "materiality" of the alleged noncompliance.

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Value Based Reimbursement – Fraud and Abuse Risks

- History
- Goal
- ACA – Patient Protection and Affordable Care Act (PPACA)
 - AHCA ? American Health Care Act

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MACRA

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)
- Quality Payment Program (QPP)
- Rewards based on quality rather than volume of care
- Merit-Based Incentive Payment System (MIPS)
- Advance Alternative Payment Models (APMs)

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Clinical Care Risks

- Quality of Care cases brought pursuant to FCA that seek to hold providers liable for substandard care.
- Submission of false claims when knowing failure to meet standards of care.

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Tips for Ensuring Compliance

- Use of meaningful metrics – quality metrics
- Use of multidisciplinary groups to manage performance of the metrics
- Revisions to contracts
- Policies, training, reporting, monitoring, auditing – Bread and Butter Compliance

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HIPAA Security

Risks

- Phishing Attacks
- Malware and Ransomware
- Encryption Blind Spots
- Cloud Threats
- Employees

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HIPAA Security

OCR Settlements

Memorial HealthCare System

- \$5.5 Million
- Failure to implement procedures for reviewing / modifying / terminating user access
- Affiliated physician offices with an Organized Healthcare Arrangement

Children's Medical Center in Dallas

- \$3.2 Million
- Failure to implement risk management plans and deploy encryption
- Unencrypted ePHI

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HIPAA Security

Collaboration between Privacy and Security Teams

- Annual security and privacy awareness training
- Coordinated Large Scale Breach Plans with mock testing
- Jointly create policy and procedures
- Daily Security Operations Center (SOC) reports
- Joint committee and workgroups



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HIPAA – Privacy

- Case study
- IDN, Integrated networks (OCHA 1, OCHA 2, Affiliated Corporate Entity)
- Business Associates and monitoring 3rd parties
- Access audits (proactive and reported)
- Breach reporting
- Privacy Impact Assessments (PIA)

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Intermountain Healthcare

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- Intermountain Healthcare**
- Serves Utah and southeastern Idaho
 - Not-for-profit healthcare system
 - 22 hospitals
 - >185 clinics
 - o 24 community clinics for low-income, homeless and uninsured; 6 owned, 18 receiving financial support
 - 1,400 physician multi-specialty Intermountain Medical Group
 - Health insurance – SelectHealth
 - o 1 million covered lives
 - Homecare and Hospice
 - Clinical Quality Board Goals
 - 40,000 employees
 - Total assets of \$10 billion



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Dignity Health

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Dignity Health

- Founded in 1986, we've made it our goal to create environments that meet each patient's physical, mental, and spiritual needs.
- Dignity Health is made up of more than 60,000 caregivers and staff who deliver excellent care to diverse communities in 21 states.
- 39 acute care hospitals located in California, Arizona, and Nevada
- Headquartered in San Francisco, Dignity Health is the fifth largest health system in the nation and the largest hospital provider in California.
- Total assets of \$17 billion



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