

INTRODUCTION TO COMPLIANCE RISK FOR BOARDS



2020 Board Audit Committee & Compliance Conference

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OBJECTIVES

- Understand healthcare's complex legal and regulatory environment
- Identify key guidance pertaining to healthcare compliance and the governing body's oversight role
- Identify mechanisms for identifying compliance risk areas
- Understand mechanism for documentation of compliance risk in your organization

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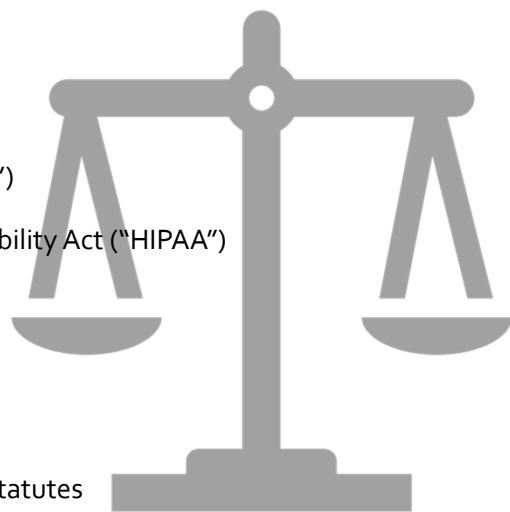
HEALTHCARE LAWS AND REGULATIONS IMPACTING COMPLIANCE PROGRAMS

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A FEW HEALTHCARE FRAUD & ABUSE LAWS

- The False Claims Act
- 60 Day Repayment Rule
- The Anti-Kickback Statute
- The Physician Self-Referral Law ("Stark Law")
- The Health Insurance Portability & Accountability Act ("HIPAA")
- The Civil Monetary Penalties Law
- The Exclusionary Statute
- Beneficiary Inducements
- Criminal Mail Fraud and Health Care Fraud Statutes
- State Fraud & Abuse Laws



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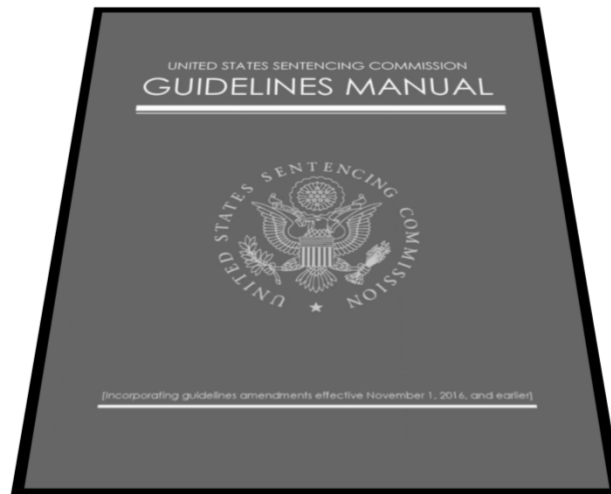
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HEALTHCARE COMPLIANCE BACKGROUND

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FEDERAL SENTENCING GUIDELINES, CH. 8 *SENTENCING OF ORGANIZATIONS*



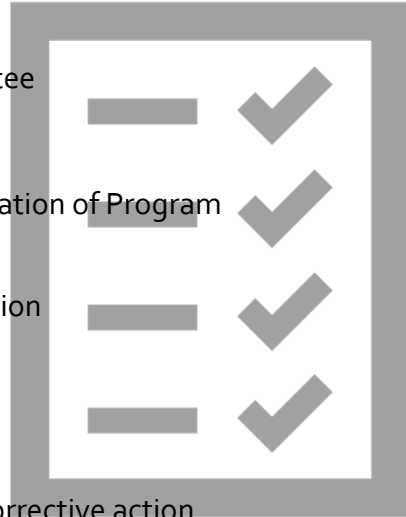
**A Long Time Ago, in the US Sentencing
Commission Office Far, Far Away.....**

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7 FUNDAMENTAL ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

- Policies & Procedures; Code of Conduct
- Chief Compliance Officer; Compliance Committee
- Effective Training & Education
- Ongoing Auditing & Monitoring; Periodic Evaluation of Program Effectiveness
- Anonymous Reporting Mechanism; No Retaliation
- Program promoted and enforced consistently
 - Appropriate incentives
 - Appropriate disciplinary measures
- Respond promptly to detected offenses with corrective action



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US DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

HOSPITALS (2.23.1998;1.31.2005)	
3RD PARTY MEDICAL BILLING COMPANIES (12.18.1998)	
NURSING FACILITIES (3.16.2000; 9.30.2008)	
HOME HEALTH AGENCIES (8.7.1998)	
HOSPICES (10.5.1999)	
INDIVIDUAL & SMALL GROUP PHYSICIAN PRACTICES (10.5.2000)	
CLINICAL LABORATORIES (8.24.1998)	
AMBULANCE SUPPLIERS (3.14.2003)	
DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS & SUPPLY INDUSTRY (7.6.1999)	

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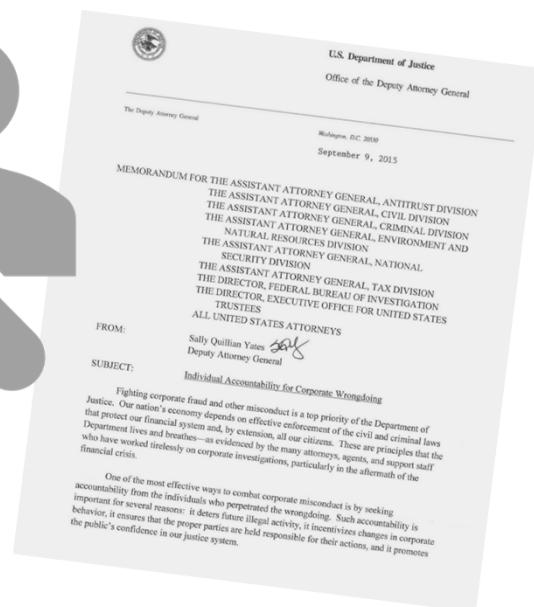
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PATIENT PROTECTION & AFFORDABLE CARE ACT

- Voluntary Guidance not so voluntary any longer
- Section 6401 of the PPACA requires that healthcare providers establish a compliance program as a condition of enrollment in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP)
- No implementation date given
- Many state Medicaid programs have had compliance requirements for some time

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INDIVIDUAL ACCOUNTABILITY



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ISN'T IT OBVIOUS??



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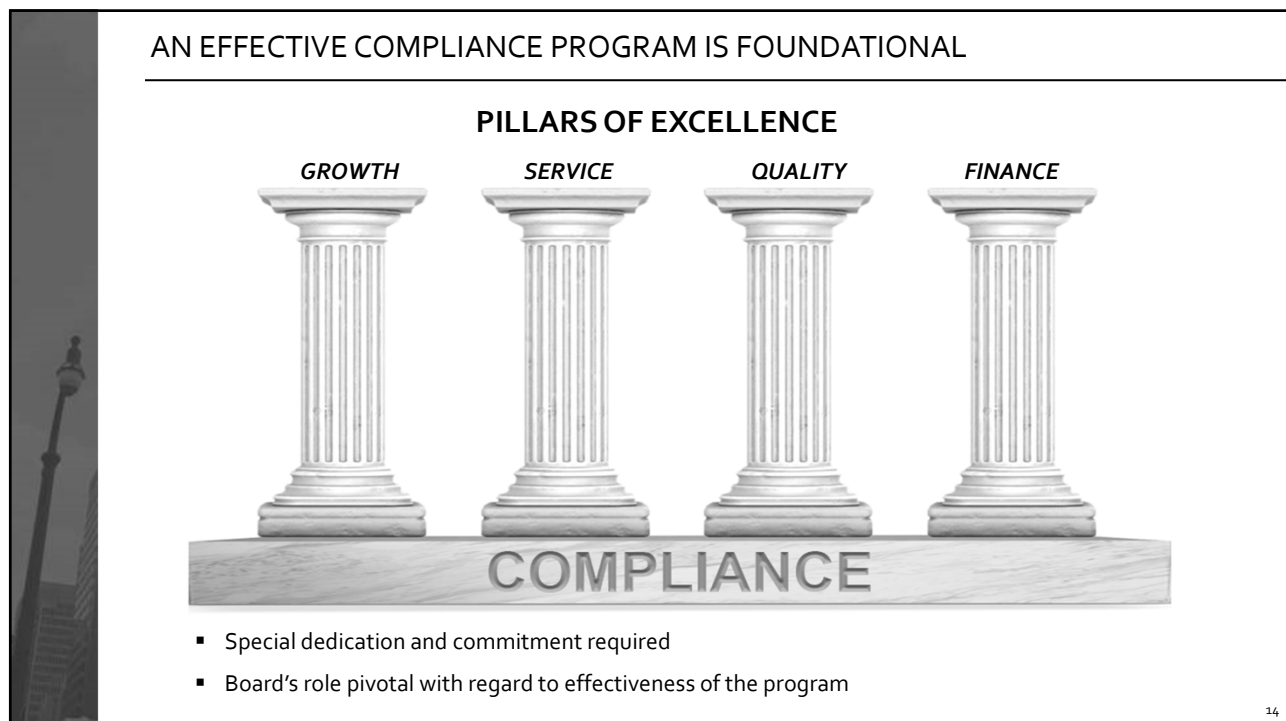
BOARD OVERSIGHT OF COMPLIANCE

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FUNDAMENTAL DUTIES OF DIRECTORS

- A director has three basic duties:
 - *Duty of Loyalty*
 - *Duty of Care*
 - *Duty of Obedience*
- This means a director must perform his/her duties:
 - In *good faith*
 - In a manner he/she reasonably believes to be in the *best interests of the corporation*, and
 - With the *care an ordinarily prudent person would exercise* under similar circumstances
- A director can reasonably rely on information presented by officers, employees, legal counsel, accountants and other experts, unless he/she knows such reliance is unwarranted

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BUSINESS JUDGEMENT RULE

- Courts will not second-guess board decisions (no matter how wrong) if directors are
 - Disinterested,
 - Reasonably informed, and
 - Rationally believe the decision to be in the company's best interest
- Presumption of good faith absent "reckless indifference or deliberate disregard"
- Reasonably informed requires reasonable inquiry, not "roving reporter"

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Pertinent Duty of Care Opinions



- *In Re Caremark (1996)*
 - Shareholder derivative suit
 - “[A] director’s obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists.”
 - Business judgment rule applied
- *Walt Disney Co. (2005)*
 - Shareholder derivative suit
 - Presumption that directors acted in good faith unless plaintiff presents evidence of “reckless indifference or deliberate disregard”
 - Director’s adherence to reasonable process is key
 - Strong affirmation of the business judgment rule



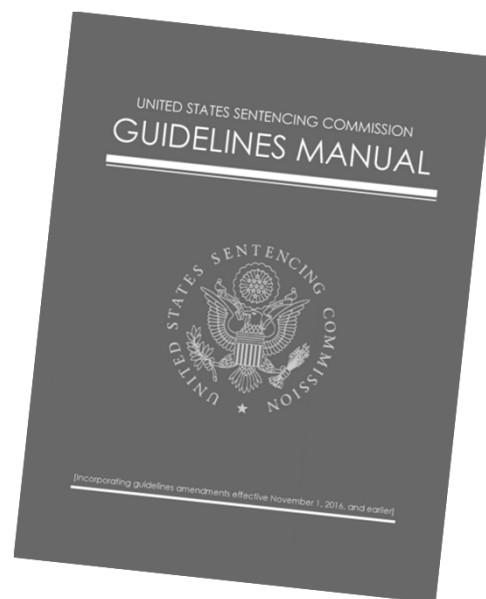
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FEDERAL SENTENCING GUIDELINES

“The organization’s governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program.”

- *Federal Sentencing Guidelines*, “Sentencing of Organizations”
at Sec. 8B2.1(b)(2)(A).



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OIG GUIDANCE FOR DIRECTORS

CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE:

*A Resource for Health Care
Boards of Directors*



THE OFFICE OF INSPECTOR GENERAL OF THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE AMERICAN HEALTH LAWYERS ASSOCIATION

AN INTEGRATED APPROACH TO CORPORATE COMPLIANCE

A Resource For Health Care Organization Boards of Directors



United States Department of Health and Human Services
Office of Inspector General
American Health Lawyers Association

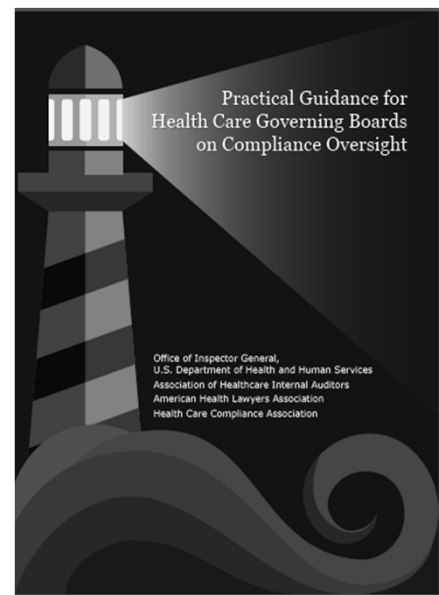
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2015 PRACTICAL GUIDANCE FOR HEALTHCARE GOVERNING BOARDS

- Addresses issues relating to the Board's oversight and review of compliance
 - Expectations
 - Roles and responsibilities
 - Issue reporting
 - Regulatory risk
 - Accountability

"A critical element of effective oversight is the process of asking the right questions of management to determine the adequacy and effectiveness of the organization's compliance program, as well as the performance of those who develop and execute that program, and to make compliance a responsibility for all levels of management."



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BOARD HEALTHCARE QUALITY OVERSIGHT

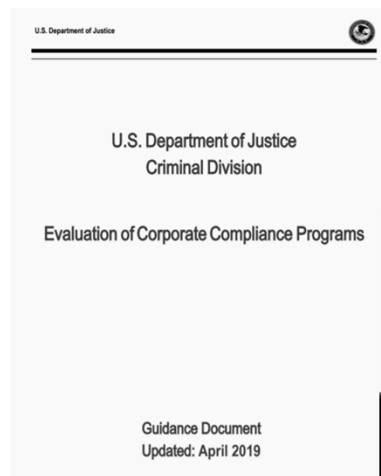
- Quality of care required by Medicare conditions of participation
- Increasingly payment tied to quality data submission
- Governmental enforcement agencies increasingly focused on care provided to beneficiaries and billed to governmental payors
 - Substandard care
 - Medically unnecessary care



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2017-2019: FOCUS ON COMPLIANCE PROGRAM EFFECTIVENESS



Measuring Compliance Program Effectiveness: A Resource Guide

ISSUE DATE: MARCH 27, 2017

HCCA-OIG Compliance Effectiveness Roundtable
Roundtable Meeting: January 17, 2017 / Washington, DC



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DEPARTMENT OF JUSTICE GUIDANCE

3 Fundamental Questions

1. Is the Program Well-Designed?
2. Is the Program Being Implemented Effectively?
3. Does the Program Work in Practice?

"[A critical factor] in evaluating any program are whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is tacitly encouraging or pressuring employees to engage in misconduct."

JM 9-28.800

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RISK ASSESSMENT PROCESS

▪ Risk Management Process

- Methodology used to identify, analyze, and address particular risks?
- Information or metrics collected and used to help detect the type of misconduct in question

▪ Risk-Tailored Resource Allocation

- Does the company devote a disproportionate amount of time to policing low-risk areas instead of high-risk areas?
- Does the company give greater scrutiny, as warranted, to high-risk transactions (for instance, a large-dollar contract with a government agency in a high-risk country) than more modest and routine hospitality and entertainment?

▪ Updates and Revisions

- Is the risk assessment current and subject to periodic review?
- Have there been any updates to policies and procedures in light of lessons learned?
- Do these updates account for risks discovered through misconduct or other problems with the compliance program?

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COMMITMENT BY SENIOR & MIDDLE MANAGEMENT

▪ Conduct at the Top

- How have senior leaders, through their words and actions, encouraged or discouraged compliance?
- What concrete actions have they taken to demonstrate leadership in the company's compliance and remediation efforts?
- How have they modelled proper behavior to subordinates?
- Have managers tolerated greater compliance risks in pursuit of new business or greater revenues?
- Have managers encouraged employees to act unethically to achieve a business objective, or impeded compliance personnel from effectively implementing their duties?

▪ Shared Commitment

- What actions have senior leaders and middle-management stakeholders taken to demonstrate their commitment to compliance or compliance personnel, including their remediation efforts?
- Have they persisted in that commitment in the face of competing interests or business objectives?

▪ Oversight

- What compliance expertise has been available on the board of directors?
- Have the board of directors and/or external auditors held executive or private sessions with the compliance and control functions?
- What types of information have the board of directors and senior management examined in their exercise of oversight in the area in which the misconduct occurred?

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DOES THE PROGRAM WORK IN PRACTICE?

▪ Continuous improvement and sustainability

- Actual implementation of controls in practice will necessarily reveal areas of risk and potential adjustment
- Survey of employees to gauge the compliance culture and evaluate the strength of controls
- Conducting periodic audits to ensure that controls are functioning well

▪ Periodic Testing

- Internal Audit
- Control Testing
- Evolving Updates
 - How often has the company updated its risk assessments and reviewed its compliance policies, procedures, and practices?
 - Has the company undertaken a gap analysis to determine if particular areas of risk are not sufficiently addressed in its policies, controls, or training?
 - What steps has the company taken to determine whether policies/procedures/practices make sense for particular business segments/subsidiaries?
- Culture of Compliance

▪ Analysis & Remediation

- Root Cause Analysis
- How does this relate to your company's risk profile

"In evaluating whether a particular compliance program works in practice, prosecutors should consider "revisions to corporate compliance programs in light of lessons learned."

JM 9-28.800

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HEALTHCARE COMPLIANCE RISKS "IN THE NEWS"

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JUSTICE NEWS

Department of Justice
Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, August 8, 2019

Medicare Advantage Provider and Physician to Pay \$5 Million to Settle False Claims Act Allegations

Beaver Medical Group L.P. (Beaver) and one of its physicians, Dr. Sherif Khalil, have agreed to pay a total of \$5,039,180 to resolve allegations that they reported invalid diagnoses to Medicare Advantage plans and thereby caused those plans to receive inflated payments from Medicare, the Justice Department announced. Beaver is headquartered in Redlands, California.

"The United States relies on healthcare providers to submit accurate diagnosis data to Medicare Advantage plans to ensure those plans receive the appropriate compensation from Medicare," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "We will pursue those who undermine the integrity of the Medicare program and the data it relies upon."

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, November 15, 2019

California Health System and Surgical Group Agree to Settle Claims Arising from Improper Compensation Arrangements

Several hospitals owned and operated by Sutter Health (Sutter), a California-based healthcare services provider, and Sacramento Cardiovascular Surgeons Medical Group Inc. (Sac Cardio), a practice group of three cardiovascular surgeons, have agreed to pay the United States a total of \$46,123,516 to resolve allegations arising from claims they submitted to the Medicare program, the Department of Justice announced today.

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, September 25, 2018

Hospital Chain Will Pay Over \$260 Million to Resolve False Billing and Kickback Allegations; One Subsidiary Agrees to Plead Guilty

Health Management Associates, LLC (HMA), formerly a U.S. hospital chain headquartered in Naples, Florida, will pay over \$260 million to resolve criminal charges and civil claims relating to a scheme to defraud the United States. The government alleged that HMA knowingly billed government health care programs for inpatient services that should have been billed as outpatient or observation services, paid remuneration to physicians in return for patient referrals, and submitted inflated claims for emergency department facility fees.

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

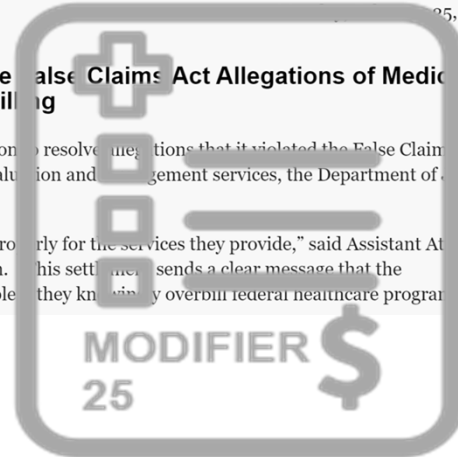
FOR IMMEDIATE RELEASE

December 11, 2019

Skyline Urology to Pay \$1.85 Million to Settle False Claims Act Allegations of Medicare Overbilling

Skyline Urology has agreed to pay the United States \$1.85 million to resolve allegations that it violated the False Claims Act by submitting improper claims to the Medicare program for evaluation and management services, the Department of Justice announced today.

"Physicians and practice groups are expected to bill Medicare properly for the services they provide," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "This settlement sends a clear message that the Department of Justice will hold healthcare providers accountable if they knowingly overbill federal healthcare programs."



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Department of Justice

U.S. Attorney's Office

Eastern District of Pennsylvania

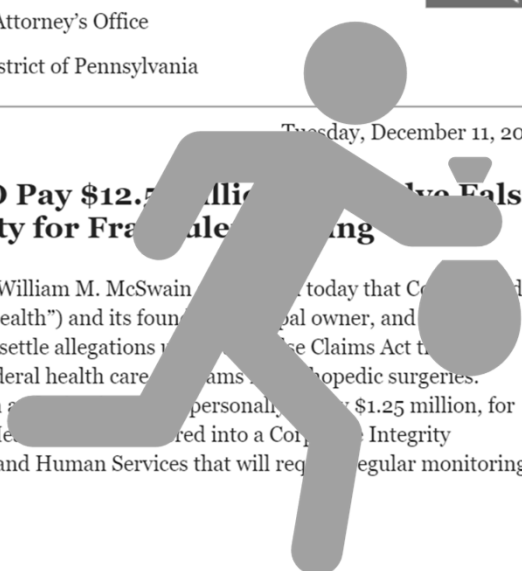
SHARE

FOR IMMEDIATE RELEASE

Tuesday, December 11, 2018

Coordinated Health and CEO Pay \$12.5 Million to Resolve False Claims Act Liability for Fraudulent Billing

PHILADELPHIA, PA – United States Attorney William M. McSwain announced today that Coordinated Health Holding Company, LLC ("Coordinated Health") and its founder, legal owner, and Executive Officer, Emil DiIorio, M.D., agreed to settle allegations under the False Claims Act that they submitted false claims to Medicare and other federal health care programs for orthopedic surgeries. Coordinated Health agreed to pay \$11.25 million and personally pay \$1.25 million, for total settlement of \$12.5 million. Coordinated Health entered into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services that will require regular monitoring of its billing practices for five years.



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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

January 17, 2016

Fifty-One Hospitals Pay United States \$23.5 Million to Settle Medicare Claims Act Allegations Related to Billing of Cardiac Catheterization

The Department of Justice has reached settlements with 51 hospitals in 15 states for more than \$23.5 million related to cardiac devices that were implanted in Medicare patients in violation of Medicare coverage requirements. The Department of Justice announced today. These settlements represent the final stage of an investigation into the billing practices of hundreds of hospitals improperly billing Medicare for these devices. With these settlements, the Justice Department's investigation has now yielded settlements with more than 500 hospitals for more than \$1 billion.

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JUSTICE NEWS

Department of Justice

FOR IMMEDIATE RELEASE

Friday, January 18, 2015

Ohio Cardiologist Sentenced to 20 Years in Prison for Unnecessary Catheterization Procedures and Others of \$5.7 Million for Unnecessary Catheterization Procedures

A Westlake, Ohio, cardiologist was sentenced to 20 years in prison for performing unnecessary catheterization procedures, tests, stent insertions and causing unnecessary coronary artery disease as part of a scheme to defraud Medicare and other insurers by \$29 million, law enforcement officials said.

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U.S. AND THE STATE OF INDIANA, EX. REL. THOMAS P. FISCHER v.
COMMUNITY HEALTH NETWORK, INC.

- Allegation – illegal and improper payments to its employed and affiliated physicians to ensure that they refer all, or substantially all, of their patients to CHN
- High base salaries
- Generous performance and retention bonuses
- Lump sum payments
- Inflated purchase of assets owned by the physicians
- Surgical center investment opportunities
- Access to lucrative payer contracts
- Lucrative medical director positions

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U.S. AND THE STATE OF INDIANA, EX. REL. THOMAS P. FISCHER v.
COMMUNITY HEALTH NETWORK, INC.

- Overcompensation so extreme that the CHN physician group has lost tens of millions of dollars per year; for the last two years, losses have topped \$100 M each year
- Employment agreements pay physicians “far in excess of what they made in private practice”
- Losses of approximately \$393,000 per physician; loss of \$55/WRVU
- Specialists paid substantially above the 90th percentile even though revenue substantially below the benchmark
- When CHN analyzes financial performance of physicians it includes downstream referrals

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HOW DOES THE ORGANIZATION DOCUMENT AND MANAGE RISK?

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RISK ASSESSMENT METHODOLOGY

- Policy & Procedure
- Develop potential audit list
 - Employee feedback
 - OIG Workplan
 - DOJ Settlements
 - OIG Guidance
 - OIG Special Fraud Alerts
 - CIAs
 - Industry News
 - Hotline submissions
 - Prior audit results
 - Results of root cause analyses
 - Payer audit letters
 - Overpayment determinations
 - Denials



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RISK PRIORITIZATION

- Vulnerability
 - Likelihood of risk
 - Detectability
 - Existing controls
- Risk Impact
 - Mission
 - Financial
 - Legal
 - Reputation



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RISK MATRIX

RISK MATRIX			
Item	Risk Elements		Risk Rating
	Impact (1-5)	Vulnerability (1-5)	
ICD-10 coding accuracy MA Plans	5	2	7
Medical Director Agreements	4	5	9
Modifier 25 Urology	4	1	5
Modifier 59	4	3	7
Medical Necessity of Cardiac Stents	5	4	9
Duplicate Billing	1	1	2
Appropriateness of Inpatient Status	3	2	4

Risk Rating Key	
High	(7-10)
Medium	(4-6)
Low	(0-3)

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SUMMARY

- Healthcare laws and regulations are numerous and complicated
- Risk is inherent
- Compliance Program is foundational to managing that risk
- Governing Body role is pivotal
 - Setting the tone
 - Management accountability
- Risk Assessment is the core of a solid compliance program structure
- Ensure policies/procedures/processes are employed around identifying, prioritizing and documenting the risk that guides your audit and monitoring activity

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THANK YOU

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ABOUT ROZ CORDINI, JD, MSN, RN, CHC, CHPC

Rosalind "Roz" Cordini is senior vice president with Coker. She is certified in healthcare compliance, healthcare privacy compliance, and experienced as a healthcare regulatory attorney with a solid clinical and healthcare leadership background.

Before joining Coker, Ms. Cordini was vice president of legal services/chief compliance officer with Owensboro Health (Owensboro, KY) where she functioned as the health system's Chief Compliance Officer and provided support to the chief legal officer in managing the daily functions of the legal services division (legal services, privacy and security, compliance and internal audit, and risk management). Prior to her tenure with Owensboro Health, Ms. Cordini practiced healthcare law with Wyatt, Tarrant & Combs (Louisville, KY), advising and counseling clients in a broad range of healthcare regulatory and compliance matters, including EMTALA, HIPAA, physician contracting, corporate compliance, clinical laboratory, audits, fraud and abuse, licensing and certification, Medicare reimbursement, end-of-life decisions, medical staff matters and patient care/operations advice.



Ms. Cordini obtained her juris doctor degree from the University of Louisville, *magna cum laude*. She is a registered nurse, earning a Bachelor of Science in Nursing from the University of San Francisco and a Master of Science in Nursing from the University of California at San Francisco. Ms. Cordini is a frequent speaker on a myriad of areas relating to healthcare compliance and associated areas. At Coker, Ms. Cordini leads the Coding & Compliance service line which focuses on coding, clinical documentation and OIG compliance services for hospitals, health systems and physician practices. Given her background, she is especially qualified to help organizations develop or update their compliance programs, establish remote compliance officer services for smaller facilities without the internal resources to support this area of great importance, providing ongoing compliance advisory services and assist acquiring organizations with mergers and acquisitions compliance due diligence.

In addition, Ms. Cordini's legal experience helps organizations, who are developing novel structures such as clinically integrated networks, understand the statutory and regulatory environment surrounding such entities. While not providing legal advice to clients in these matters, she can nevertheless provide invaluable guidance and advisory services that ensure innovative integration of clinical providers is done in a compliant fashion.

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