

Don't Get Caught with Your Compliance Pants Down: Compliance Effectiveness & Role of Counsel

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- Review how compliance programs assist healthcare providers in maintaining ethical conduct and legal compliance
- Examine the US Federal Sentencing Guidelines used by enforcement agencies and courts in determining sanctions for violations of federal criminal laws including reduction factors.....discuss the role of a compliance program in mitigating sentencing
- Determine how an effective ethics and compliance program may help reduce civil/criminal liabilities and regulatory sanctions for healthcare providers (Kathleen & Rose)
- Identify differences between a provider compliance risk assessment and an effectiveness review
- Identify the HCCA-OIG guide specific to the evaluation of compliance effectiveness as well as the DOJ Guidance (Kathleen & Rose)
- State current trends in compliance enforcement (Rose Matricciani)
- Examine the roles of compliance professionals, consultants, and counsel in light of case study/studies. (Rose Matricciani)


- Reduce fraud and abuse; mitigate risk for overpayments for Providers
- May help reduce civil and criminal liabilities and regulatory sanctions
- Required under the Affordable Care Act (ACA). No CMS regulations at this time. NY OMIG requires Compliance Programs. Federal Deficit Reduction Act (DRA): Medicaid providers w/5 Million in annual revenues: See 42 USC 1396a(a)(68); Section 6032
- Best practice standard
- Federal Sentencing Guidelines identify an *effective* compliance and ethics program as a mitigation factor in sentencing
- Increase in Whistleblower Cases (over 24 billion in recovery from whistleblower actions –1987-2012)
- Guide company operations
- Increased enforcement activity by OCR for HIPAA




OIG/DOJ ANNUAL REPORT ON FRAUD 

- HHS/DOJ Annual Report 2017 Report (Released January 2017 for fiscal year 2016)
 - 2.5 Billion recovered from healthcare fraud judgements and settlements (plus administrative remedies)
 - Over 3.3 billion was returned to the Federal Government or paid to private persons
 - Over 31.0 billion returned since formal program started in 1997
 - 2016:DOJ 975 criminal investigations; 480 criminal charges; 658 convictions of defendants;1,422 Civil matters pending at the end of 2016
 - HHS/OIG excluded 3,635 individuals
 - Look for Annual Report for 2017 in early 2018


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GOVERNMENT TOOLS 


- The Governments Tools & Federal Sentencing Guidelines:
 - Federal Anti-Kickback laws (State & Federal)
 - Stark Laws
 - False Claims Act (State and Federal)




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MORE TOOLS OF ENFORCEMENT 

- Civil Monetary Penalties (CMPs) by HHS OIG
 - Self Voluntary Disclosure Regulations
- Other Criminal Provisions
 - Health Care Fraud
 - Mail and Wire Fraud
 - Obstruction
 - False Statements
- See Yates Memo September 2015
- State Department of Health: Surveys can result in CMP




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U.S. SENTENCING COMMISSION 

- **What is the U.S. Sentencing Commission:**
 - An independent agency in the judicial branch of government
 - Created by the Sentencing Reform Act of 1984
 - The Act was enacted by Congress in response to widespread disparity in federal sentencing, ushering in a new era of federal sentencing through the creation of the Commission and the drafting and promulgation of the federal sentencing guidelines
 - www.ussc.gov


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GUIDELINES MANUAL: 11/2016 

- The 2016 Guidelines Manual www.ussc.gov/guidelines/2016
- See Chapter Eight – Sentencing of Organizations
 - Specifically, see Part B – Remedying Harm from Criminal Conduct, and Effective Compliance and Ethics Program
 - (2. Section 8B2.1. effective Compliance and Ethics Program)



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FROM THE SENTENCING GUIDELINES: CHAPTER 8 

- (f) Effective Compliance and Ethics Program
- (1) If the offense occurred even though the organization had in place at the time of the offense an effective compliance and ethics program, as provided in § 8B2.1 (Effective Compliance and Ethics Program), subtract 3 points.
- (2) Subsection (f)(1) shall not apply if, after becoming aware of an offense, the organization unreasonably delayed reporting the offense to appropriate governmental authorities.
- (3) (A) Except as provided in subparagraphs (B) and (C), subsection (f)(1) shall not apply if an individual within high-level personnel of the organization, a person within high-level personnel of the unit of the organization within which the offense was committed where the unit had 200 or more employees, or an individual described in § 8B2.1(b)(2)(B) or (C), participated in, condoned, or was willfully ignorant of the offense.
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OIG GUIDANCE **Simione**
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- Office of Inspector General (OIG) Voluntary Compliance Program Guidance (www.oig.hhs.gov)
 - History of OIG voluntary guidance
 - Hospital: 63 Fed. Reg. 8987; February 23, 1998
 - Supplemental 70 Fed. Reg. 4858; January 31, 2005
 - Home Health Agencies: 63 Fed. Reg. 42410; August 7, 1998
 - Hospice: 64 Fed. Reg. 54031; October 5, 1999
 - Nursing Facilities: 65 Fed. Reg. 14289; March 16, 2000
 - Supplemental Compliance Program Guidance for Nursing Facilities: 73 Fed. Reg. 56832; September 30, 2008
 - Clinical lab; ambulance, physician practices; other...



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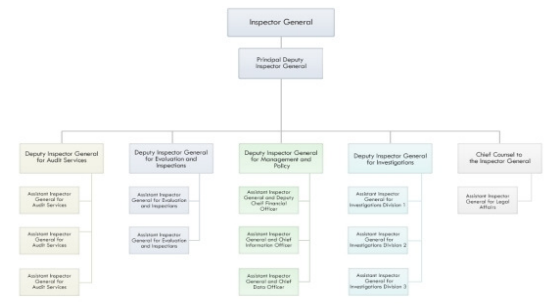
SEVEN ELEMENTS OF A COMPLIANCE PROGRAM **Simione**
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1. Policy/Procedure/Written Code
2. Compliance Officer/Committee
3. Training/Education
4. Communications/Anonymous
5. Auditing Monitoring ---- External monitoring by experts (Attorney Client Privileges issues/ethics)
6. Disciplinary Measures
7. Disclosure /Timely Investigations and Reporting
8. NY OMIG: A Policy of Non-Intimidation and Non-Retaliation



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HEALTH AND HUMAN SERVICES OIG ORG CHART **Simione**
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KEY GOVERNMENT ENFORCERS **Simione**
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- U.S. Department of Justice (DOJ)
 - United States Attorneys' Offices (USAOs)
 - Federal Bureau of Investigations (FBI)
- U.S. Department of Health and Human Services (HHS)
 - Office of Inspector General (OIG)
 - Centers for Medicare and Medicaid Services (CMS)
- State Attorneys' General Offices
 - Assistant U.S. Attorneys in the Medicaid Fraud Control Units (MFCUs)
- Program Integrity Contractors (Auditors)
 - Medicare Administrative Contractors (MACs)
 - Recovery Audit Contractors (RACs)
 - Zone Program Integrity Contractors (ZPICs)
 - Medicaid Integrity Contractors (MICs)



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COMPLIANCE REQUIREMENTS **Simione**
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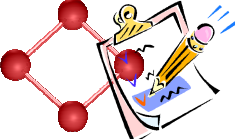
- Medicare and Medicaid Manuals
- CMS Conditions of Participation (CoPs): Cover ethical issues, informed consent, dignity, privacy, resident rights, QAPI, etc
 - Home Health New CoP –New Rules Effective January 13, 2018
- Coding: ICD-9 & ICD-10
- Payment Manuals
- Medicare Administrative Contractors (MACs); Local Coverage Determinations, ZPICs
- CMS Regulations, Notices, Transmittals, other
- State laws regarding background checks/Medicaid fraud
- HIPAA
- Self Disclosure Protocol (revised April 2013); 60-day Rule
- Case Law
 - Jimmo v. Sebelius Settlement
 - Escobar; Aseracare; Brookdale; Tuomey Healthcare
- Other: OIG/State Exclusions List



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IS THERE A TEMPLATE PLAN? **Simione**
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- One size does not fit all
- See HCCA-OIG document released March 27, 2017:
Measuring Compliance Program Effectiveness: A Resource Guide
- Ethics & Compliance plans should *evolve and change*
 - Ethics Committees
 - Compliance Committees



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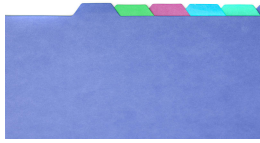
U.S. DEPARTMENT OF JUSTICE



- U.S. Department of Justice, Criminal Division, Fraud Section:

→February 21, 2017:

- *Evaluation of Corporate Compliance Programs*
– Topics and Questions



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CORPORATE INTEGRITY AGREEMENTS



- Medicare/Medicaid Provider entities under investigation for alleged fraud or abuse may enter into a settlement agreement with DHHS OIG
- In addition to the Settlement Agreement, the OIG may require mandatory compliance with a second agreement--Corporate Integrity Agreement (CIA)
- The Provider agrees to the CIA **and** the OIG agrees *not* to exclude Provider entity/C-Suite/owners from Medicare/Medicaid and other Federal programs



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CORPORATE INTEGRITY AGREEMENTS



- Definition
- When is a CIA appropriate?
- Who is subject to a CIA?
- Length of Agreement
- Contents
- Other



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CORPORATE INTEGRITY AGREEMENTS (CIAS) **Simione**
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- **Seven Elements Required in a CIA (OIG & Provider)**
- **Management Certifications:** Training for staff in high risk areas: Human Resources; Marketing (Anti-kickback); Billing (False Claims); Clinical Documentation (Regulations re: eligibility & medical Necessity; care plan goals, therapy).
- **Governing Board Education and Consulting Experts**
- **Annual Audit Plan**
- **Annual Compliance Program Risk/Effectiveness Assessment**
- **Reporting Overpayments**
- **Other**



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WHAT IS A RISK ASSESSMENT? **Simione**
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- A Compliance Risk Assessment is a review of a company's current risk:
 - How to determine a client or company's high risk areas?
 - Review what the OIG identifies as risk areas for service line
 - Assess how your client/company is doing: include other risk areas: HR, Marketing; Billing & Documentation
 - Analyze PEPPER Reports to see where your client/company falls in percentages and percentiles in the state, MAC region and nationally
 - Use other data analytics: EMR reports/QAPI data/ other




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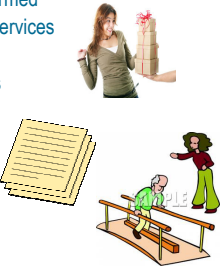
COMPLIANCE EFFECTIVENESS ASSESSMENT? **Simione**
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- A Compliance Effectiveness Assessment is a review of systems and processes as well as outcomes of compliance plan activities:
 - Review seven elements (plus additional recommended elements):
 - Does client/company have a written compliance plan and code of conduct inclusive of the standard seven elements
 - Compare written plan against *current* compliance activities:
 - *Example: Are policies and procedures current and are they reviewed/revised annually? Proof of Findings?*
 - *Recommendations for enhancement or implementation of activities*
 - Compare **achieved** activities/audits/training /complaint resolution logs with annual plan and process improvement
 - Contract Review


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RISK AREAS & RISK MITIGATION 

- Coding & Billing
- Medical Necessity/Services Performed
- Incident to Billing/Unsupervised Services
- Services Not Actually Performed
- Kickbacks/Inappropriate Referrals
- Overbilling/Up-coding
- Therapy Manipulation
- Insufficient Documentation
- Staff Training
- Credentialing/Certification
- Exclusions





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PRACTICE TIPS FOR ATTORNEYS AND CLIENTS 

- Educate clients/employees/vendors/contractors on fraud and abuse laws....compliance & ethics programs... and reeducate
→ Impart the importance of a live and evolving compliance program
- Assist clients in the development and implementation of compliance program; consider collaboration with QAPI programs (or in smaller providers, combining functions)
- Encourage clients to obtain external baseline audits/compliance risk & effectiveness assessments
- Encourage clients to engage their C-Suite and Governing Board in Quality and Compliance initiatives

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QUESTIONS 



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EDUCATION PURPOSES



This presentation is for education purposes only and should not be construed as providing legal advice.



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THANK YOU!



- Thank you for your time and attention
- For additional questions or inquiries please contact:

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