

October 10, 2014

## TAANA 2014

### Reel in Regulatory Risk: Avoid a Government Catch

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*The way is in sight*™

**Simione**™  
HEALTHCARE CONSULTANTS

# WHO IS SIMIONE?

- Team of home care and hospice experts with focus on solutions
  - Organizational
    - Operational Assessment, Strategic Planning, Interim Management, Clinical Operations, **Compliance & Risk: Assessments, Audits, Ethics Consulting and Compliance Program Development**
  - Financial
    - Cost Reporting, Compliance, Revenue Cycle
  - Sales & Marketing
    - Assessment & Analysis, Referral Management, Training Resources, "Sales Boot Camp"
  - Technology
    - Assessment & Analysis, Guided System Search, Implementation Support, Process Engineering
  - Mergers & Acquisitions
    - Due Diligence & **Compliance** Audits, Business Valuation, Market Assess
- Strategic Planning, Executive Support, Process Engineering, and Simione Financial Monitor offered in all 5 core challenge areas

- The objectives should assist attorneys/others to:
  - Identify laws and initiatives applicable to the government's fight against fraud and abuse in the healthcare industry
  - State at least three practice tips for assisting your clients in developing and maintaining an effective Compliance and Ethics Program
  - State at least two lessons learned from a CIA

- **Who:** All Medicare Certified & Medicaid providers
  - Hospitals, Physician Offices, DME, Home Health & Hospice Agency Providers, Skilled Nursing Facilities, Ambulance, Pharmacies, Clinical Laboratories, other
- **What:** More government oversight and enforcement
  - HHS Centers for Medicare (CMS) and Office of Inspector General (OIG) compliance mandates & monitoring; investigations & enforcement actions; MACs, RACs, ZPICs state laws & Medicaid fraud units; Department of Justice (DOJ)
- **Where:** Everywhere
  - All regions across the United States
- **When:** Past, Present & Future

- **Why:** Government is on watch for fraud, abuse and waste in health care
  - Medicare spends billions of dollars each year paying health care providers
  - The Government has confirmed many reports of fraud, abuse and waste in all areas of healthcare resulting in settlements for millions of dollars every year...
    - Roadmaps: OIG reports & Work Plans, fraud alerts, Corporate Integrity Agreement (CIAs)
  - New regulations dictate new compliance practices
  - Media on healthcare government spending
  - See government enforcement actions (Department of Justice)

- Operations Restore Trust (ORT) Pilot 1995
  - Successful recoveries in 5 states
    - 42.3 million
  - 35 Criminal convictions
  - 18 Civil settlements



- Focus on Federal Anti-Kickback Statute (Criminal)
  - Statute: 42 U.S.C. Sec. 1320a-7b: “Whoever knowingly and willingly solicits or receives any remuneration directly or indirectly, overtly or covertly, in cash or in kind, ...”
    - Kickbacks, bribes, rebates, gifts, other
  - Landmark Case: United States v. Greber, 760 F.2d 68,69 (3<sup>rd</sup> Cir. 1985), cert. denied, 474 US 988 (1985)
    - Established the “one purpose” test



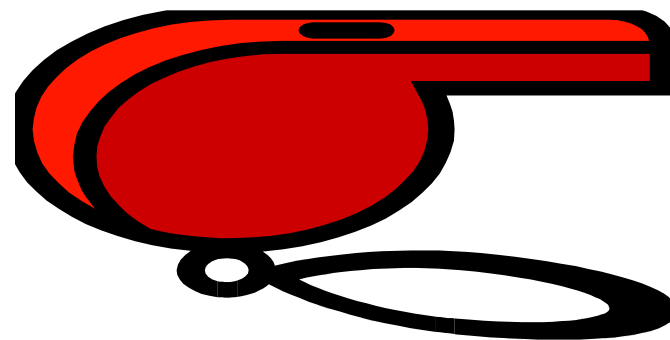


- Federal law sanctions include but may not be limited to:
  - Single violation can be \$25,000 and up to five years in prison, exclusion for certified and Federal programs
  - Civil sanctions may be applied for treble damages
- Safe Harbors may be applicable
- State Anti-Kickback Statutes
- Stark laws:
  - Prohibits physician self-referrals...





- Federal False Claims Act (FCA)
  - Statute: 31 U.S.C Sections 3729-3733 (aka Lincoln Law—1863) Amendments 1986 plus 3
  - 1) Actual knowledge; 2) Deliberate ignorance; 3) Reckless disregard
  - State False Claims laws
- FCA contains provision for Whistleblower (Qui Tam) Actions



- Seventy percent of FCA actions are initiated by whistleblowers
- Person can file an action on behalf of government
- 15-25% of recovered claims go to person who brought action (Government decides each case)
- 35 Billion has been recovered under FCA between 1987-2012;
  - 24 billion by qui tam actions

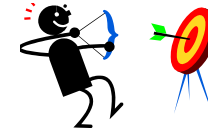
- Patient Protection & Affordable Care Act (PPACA) also known as ACA 2010 (Obama Care)
  - Requires all certified Medicare providers to establish and implement a compliance program that contains....core elements established by...HHS CMS (Section 6401 (a) (7))
- CMS is charged with drafting and implementing regulations
  - waiting for CMS... but likely modeled after voluntary guidance and Corporate Integrity Agreement (CIA) content and structure

- Office of Inspector General (OIG) Voluntary Compliance Program Guidance ([www.oig.hhs.gov](http://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...

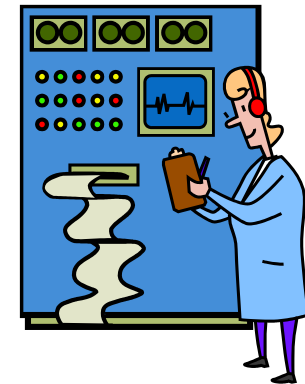
- Programs may allow providers to mitigate risk and negotiate a more favorable outcome if OIG investigation implicates providers or provider self-reports
- Corporate Integrity Agreements (CIA) mandate compliance plan (See handouts)
  - Elements of CIAs (see [www.oig.hhs.gov](http://www.oig.hhs.gov))
    - Common elements
    - Five year requirements for Independent Review Organizations (IRO)
    - Must establish a company compliance and ethics plan or enhance plan
    - Annual Audits

- CMS Conditions of Participation (CoPs)
- Medicare Administrative Contractors (MACs)
- ZPIC (Zone Program Integrity Contractors)
- CMS Regulations, Notices, Transmittals, other
- Self Disclosure Protocol (revised April 2013)
- Case Law
  - Jimmo v. Sebelius Settlement Agreement-Program Manual Clarifications (Fact Sheet)
- State laws regarding background checks/Medicaid fraud/Other

- Common areas for high risk:



→ Marketing, Billing, Human Resources, Quality  
→ Management/QAP





- Each Medicare provider type has its own high risk areas that must be addressed
- CMS New Regulations & Rules
- CMS Transmittals & Change Requests
- Regularly review CMS/OIG websites, CIAs, Enforcement Actions
- Annually review OIG Work Plans
  - 2013
  - 2014

- 2013-2014 OIG Work Plan ([www.oig.hhs.gov/reports](http://www.oig.hhs.gov/reports))
  - Face to face encounters
  - Employment of home health aides (HHA) with criminal convictions
  - OASIS
  - MAC: Claims oversight
  - Home health PPS requirements
  - State survey and Certification/Quality
  - Trends in expenses and revenues
    - Cost report analysis



- 2013-2014 OIG Work Plan ([www.oig.hhs.gov/reports](http://www.oig.hhs.gov/reports))
  - Marketing practices
  - Financial relationships with nursing facilities
    - Mandatory contract language
  - Hospice in Assisted Living Facilities
  - General Inpatient Care (GIP) services
    - Services billed but not received
    - Increase utilization

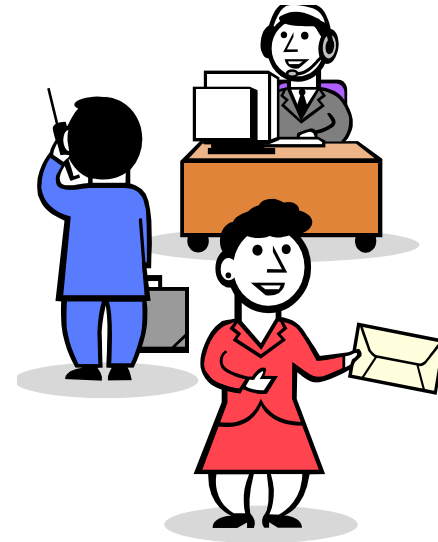


1. Written policies and procedures to include written standards/code of conduct; **policies must cover high risk areas of practice; include anti-kickback, conflicts...**
2. Effective oversight by provider/company compliance officer & governing body & compliance committee
3. Effective development and implementation of regular, applicable education and training for all affected employees;



4. An effective reporting system such as a hotline to receive complaints and to ensure effective communication between the compliance officer and employees. Option for anonymity.

- Most Common: Telephone
- Other:
  - Email
  - Mail

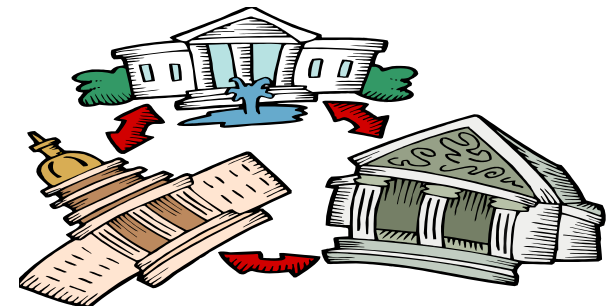


5. Use of audits and or other systemic practices to monitor compliance, identify problem areas, and implement corrective action measures: contracts; pre-billing checks, high risk areas per provider type, internal & external compliance audits, etc.;

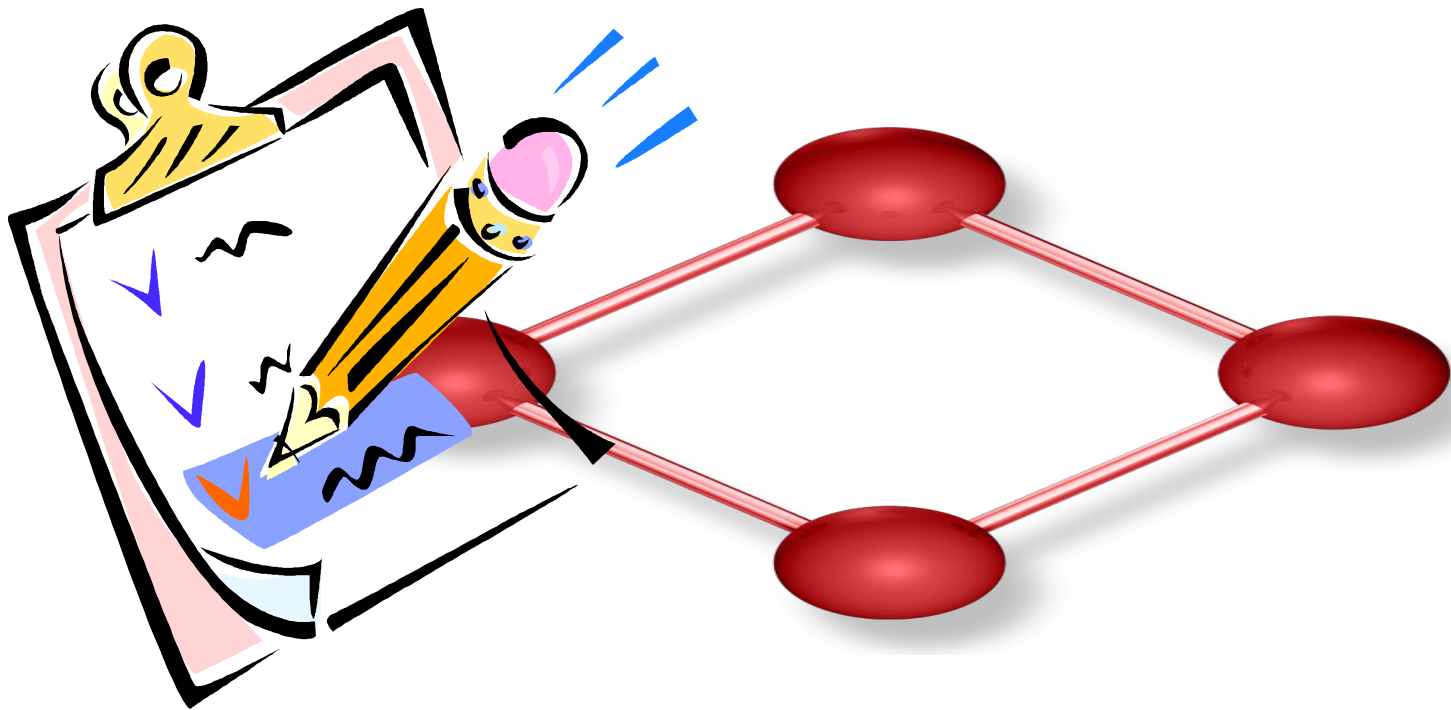
6. Establish disciplinary measures to enforce standards of conduct, address violation and apply applicable sanctions;

7. Effective policies that ensure prompt investigations, reporting and corrective actions;

8. Annual assessment of plan.



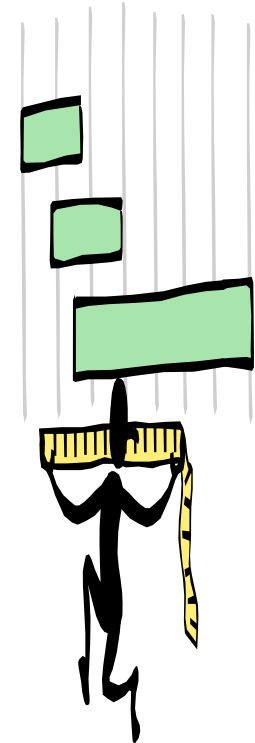
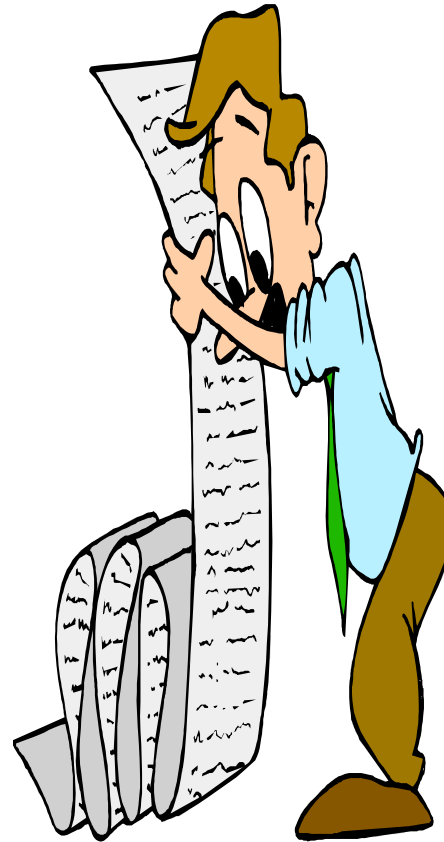
- One size does not fit all
- Compliance plans evolve and change





# CLIENT HAS NO COMPLIANCE PROGRAM? DO NOT DESPAIR

- Take inventory of compliance measures your clients already have in place



- Assess programs/processes already in place:
  - Clinical policies and procedures
    - Written manuals or computer accessible?
    - Current and up-to-date?
    - Accessible to all clinical staff/other staff?
    - Reviewed/revised annually?
  - Billing and Claims submission policies/processes
    - Written manuals or computer accessible
    - Pre-billing checks
    - Special training and education for billing personnel: on-hire and annually?

→ Effective Quality Assessment and Performance Improvement (QAPI) Committee?

- Dashboard? Agency management team put together for what your agency wants to measure.
- Analysis of data? Action Plans?
- Ongoing auditing and monitoring?

→ Electronic Medical Records

- Compliance measures in place to capture regulatory requirements? Clinical people working w/vendor?

→ Human Resource Function

- Employee Handbook? Standard of Conduct?
- Written progressive disciplinary procedures all levels management? Just culture? Use term "Ethics" in title

- DO THIS:



to AVOID this:



# EXAMPLE: ENFORCEMENT ACTION

- **Department of Justice**
  - Office of Public Affairs
  - FOR IMMEDIATE RELEASE
  - Tuesday, January 7, 2014
  - Medical Clinic Owner and Other Patient Recruiters Plead Guilty in Miami for Roles in \$8 Million Health Care Fraud Scheme
- Several patient recruiters, including a medical clinic owner, pleaded guilty today in connection with a health care fraud scheme involving Flores Home Health Care Inc., a defunct home health care company.

Acting Assistant Attorney General Mythili Raman of the Justice Department's Criminal Division, U.S. Attorney Wifredo A. Ferrer of the Southern District of Florida, Special Agent in Charge Michael B. Steinbach of the FBI's Miami Field Office, and Special Agent in Charge Christopher B. Dennis of the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), Office of Investigations Miami Office made the announcement.

At a hearing held before U.S. District Judge Ursula Ungaro of the Southern District of Florida, Lerida Labrada, 59, of Miami, pleaded guilty to conspiracy to commit health care fraud, which carries a maximum penalty of 10 years in prison, and Mayra Flores, 49, and German Martinez, 36, both of Miami, pleaded guilty to conspiracy to defraud the United States and receive health care kickbacks, which carries a maximum penalty of five years in prison. Sentencing has been scheduled for March 14, 2014.

According to court documents, the defendants worked as patient recruiters for the owners and operators of Flores Home Health, a Miami home health care agency that purported to provide home health and physical therapy services to Medicare beneficiaries. Labrada also owned and operated a Miami medical clinic that provided fraudulent prescriptions to patient recruiters and to the owners and operators of Flores Home Health.

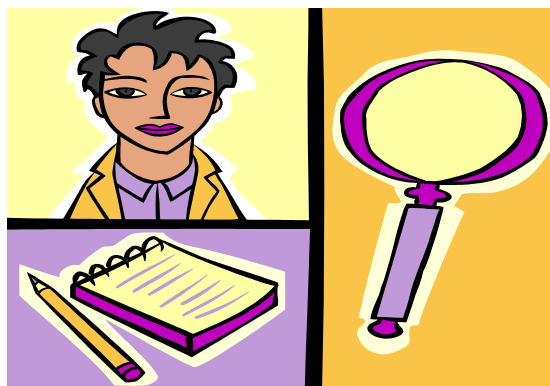
Flores Home Health was operated for the purpose of billing the Medicare program for, among other things, expensive physical therapy and home health care services that were not medically necessary and/or were not provided.

The defendants would recruit patients for Flores Home Health and would solicit and receive kickbacks and bribes from the owners and operators of Flores Home Health in return for allowing the agency to bill the Medicare program on behalf of the recruited Medicare patients. These Medicare beneficiaries were billed for home health care and therapy services that were not medically necessary and/or not provided.

- Read CIAs ([www.oig.hhs.gov](http://www.oig.hhs.gov))
  - A good approach to learning what government is investigating and penalizing



- Example provided of Home Health CIA & Other
  - CIA False Claims Act Activity
  - More criminal charges in home health activity than hospice
  - Medicaid Enforcement increasing
    - December 2013 NY AG Fraud Unit: 2.5 million settlement included false billings and uncertified HH aides...
  - Other





- KAI Heart, Inc. D/B/A Kai Heart Home Health Care

→ Highlights of CIA

- Board Obligations
- Implement written policies and procedures reimbursement requirements for home health services
- Training and Education on: medical necessity, accurate coding, timely assessments, OASIS data collection, other
- IRO Claims review

- [MAC websites](#)
- [www.cms.gov](#)
  - Medicare
  - Provider Type
    - Date
    - Transmittals
    - Regulations and Notices



- [www.oig.hhs.gov](http://www.oig.hhs.gov)
  - Compliance Guidance
  - Compliance Tool Kits (toolkit for Boards)
  - OIG Compliance Audit Tool for Hospice
  - Corporate Integrity Agreements (CIA)
  - Latest enforcement actions with link to the Department of Justice (DOJ)
  - Self Disclosure Protocol (SDP)—April 17, 2013
  - Internal Review Organizations (IRO)



# QUESTIONS ?



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



# THANK YOU!

- Thank you for your time and attention; we know you are busy!
- For additional questions or inquiries please contact:

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