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TAANA 2015

Learn Lessons from CIAs: Decode the Documentation Demands

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The way is in sight℠

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WHO IS SIMIONE?

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- Team of home care and hospice experts with focus on solutions
  - Organizational & Compliance
    - 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

PURPOSE OF PRESENTATION

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- The objectives should assist attorneys/others to:
  - →Define a Corporate Integrity Agreement (CIA) and state it's relationship with a Settlement Agreement in a Healthcare fraud matter
  - →Identify at least three requirements of recent CIAs
  - →State at least three practice tips to satisfy provider compliance requirements with clinical and billing documentation

BRIEF HISTORY: FRAUD, ABUSE AND WASTE

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

COMPARE REPORT 2014

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- Nearly 20 years later
- HHS/DOJ Annual Report 2014 Report (Released March 2015)
  - →3.3. Billion recovered from Fraud and Abuse investigations/settlements
  - →734 defendants convicted
  - →957 Civil matters pending at the end of 2014

RESULTS: INCREASED ENFORCEMENT

- Office of Inspector General (OIG) of the U.S. Health and Human Services Department (HHS)
  - Increase in staff, investigations, collaboration with Department of Justice
- State Medicaid Fraud Units Actively Investigating Fraud
  - Many states with multiple Medicaid programs

MANDATORY COMPLIANCE WITH REGULATIONS

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- Affordable Care Act 2010 resulted in *increasing* regulations *annually* for providers
- State Medicaid Fraud Laws
- 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
    - Provider specific case law & Qui Tam actions

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- Investigation and Enforcement of the Laws for preventing Fraud, Abuse and Waste

ANTI-KICKBACK STATUTE

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- 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 (3rd Cir. 1985), cert. denied, 474 US 988 (1985)
    - Established the "one purpose" test

ANTI-KICKBACK SANCTIONS

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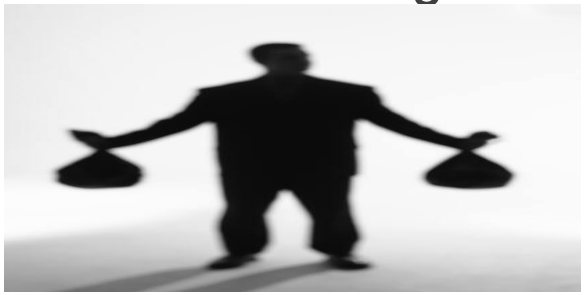
- Federal law sanctions include but may not be limited to:
  - →Single violation can be $25,000 and up to five years in prison, exclusion for certified and Federal programs
  - →Civil sanctions may be applied for treble damages
- Safe Harbors may be applicable
- State Anti-Kickback Statutes
- Stark laws:
  - → Prohibits a physician from making referrals for designated health services to an entity with which he or she ---or immediate family members---have an investment relationship.
  - → Up to $15,000 per claim plus 3 times the claims and/or $100,000 per circumvention scheme.



ANTI-KICKBACK

- Safe Harbors may apply
  - →Bonuses for marketing employees may apply
  - →No bonuses for Independent contractors
- Sales and Marketing Teams
  - →Provide specialized education at hire, annually and at staff meetings through-out the year
  - →Maintain records of agendas, training, education materials
  - →Fair market value

FALSE CLAIMS ACT

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- The FCA has become an important government tool—if not *the* most important tool—for demanding healthcare providers' compliance with the requirements of the federal healthcare programs. (State and Federal FCA)
- Liability for any person who (1) knowingly presents or causes to be presented a false or fraudulent claim for payment; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or (3) conspires to commit a violation.

FEDERAL AND STATE FALSE CLAIMS

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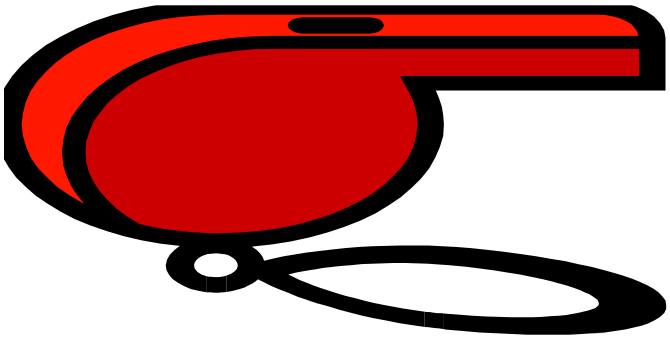
- Federal False Claims Act (FCA)
  - →Statute: 31 U.S.C Sections 3729-3733 (aka Lincoln Law—1863) Amendments 1986 plus 3
  - →1) Actual knowledge; 2)Deliberate ignorance; 3) Reckless disregard
  - →State False Claims laws



- FCA contains provision for Whistleblower (Qui Tam) Actions

WHISTLEBLOWER PROTECTION ACT

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- 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

FALSE CLAIMS ACT

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- FCA liability can impose mandatory treble damages, *and* a civil penalty of $5,500 to $11,000 imposed for each claim for payment that is found to be false or fraudulent.

KEY GOVERNMENT ENFORCERS

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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)

RECENT ENFORCEMENT

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- Documentation
  - → **Res Care Iowa** (February 2015)
    - Agreed to pay $5.63 million to resolve allegations under the FCA that it submitted home healthcare billings to Medicare and Medicaid that were medically unnecessary.
- Medical Necessity
  - → **CareAll Management, LLC (TN)** (November 2014)
    - Agreed to pay $25 million to resolve claims it violated the FCA. Government alleged that between 2006 and 2013, CareAll submitted claims overstating patients' conditions and billed for services that were not medically necessary and rendered to patients who were not homebound.
- Financial Relationship with Referral Source/Medical Necessity
  - → **Other common issues in Fraud and Anti-kickback cases**
    - Company ABC agreed to pay $$$$ million to settle allegations stemming from *qui tams actions*….. The government alleges that the company billed Medicare for services that were not medically necessary, maintained improper financial relationships with referral sources, and pressured staff to provide care based on financial benefits to the company rather than on the needs of patients.

ENFORCEMENT

- Patient Eligibility/Documentation
  - → Creekside Hospice (November 2014)
    - Government intervened in an FCA case and filed a complaint alleging that Creekside companies directed staff to enroll patients in the hospice program regardless of eligibility, sometimes by instructing staff to change records after the hospice submitted claims for payment to indicate that all requirements had been met.

RECENT FCA LITIGATION: HOSPICE

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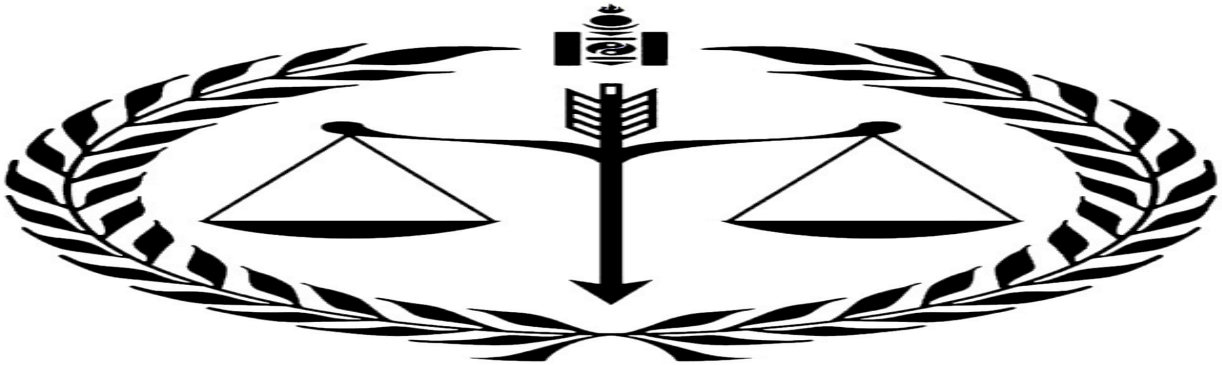
- "[A] physician must use his clinical judgment to determine hospice eligibility, and an FCA complaint about the exercise of that judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of subjective clinical analysis." *U.S. ex rel. Wall v. Vista Hospice Care, Inc*., 778 F. Supp. 2d 709, 718 (N.D. Tex. 2011).

U.S. EX REL. V. ASERACARE INC., ET AL.

- 11th Circuit declined to decide a similar question:

In a FCA case against a hospice provider relating to the eligibility of a patient for the Medicare hospice benefit, for the Government to establish the falsity element under 31 U.S.C. § 3729(a)(1)---must it show that, in light of the patient's clinical information and other documentation, no reasonable physician could have believed, based on his or her clinical judgment, that the patient was eligible for the Medicare Hospice Benefit?



U.S. EX REL. V. ASERACARE INC., ET AL.

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- District Court bifurcated trial into 2 phases:
  1) Phase One on the Falsity Element of Government's False Claims Act claim
  2) Phase Two on the other elements of the Government's FCA Claim

"Falsity cannot be inferred by reference to AseraCare's general corporate practices unrelated to specific patients. A claim is either false or not without evidence of corporate practices unrelated to that claim."

REVERSE FALSE CLAIMS ACT

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- Liability also attaches for Reverse FCA claims:
  - → "Any person who … knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government…"
  - → FCA also applies to a "contractor, grantee, or other recipient, if the money or property is to be spent or used on the government's behalf or to advance a government program or interest."
  - → PPACA establishes **60-day clock** for return of "identified" overpayment (or date of corresponding cost report)

CORPORATE INTEGRITY AGREEMENTS

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- The OIG often offers a contractual agreement (CIA) to a provider who negotiates a settlement with the government
- Separate agreement from the Settlement
- The Provider Agrees to follow the requirements of the CIA for five years----
- In Exchange---the OIG offers NOT to EXCLUDE provider and or owners/C-Suite from the Medicare/Medicaid and other Federal Health care Programs

A CIA MANDATES COMPLIANCE PROGRAM

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- If a provider shows they have a viable compliance program, it may allow them to mitigate risk and negotiate a more favorable outcome in an OIG/DOJ investigation/Settlement
- Corporate Integrity Agreements (CIAs) consistently require/outline the seven elements of an effective compliance program:

  →Use CIA for education/current purposes

CORE ELEMENTS OF A COMPLIANCE PROGRAM

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1. Policy/Procedure/Written Code
2. Compliance Officer/Committee/Governing Board
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

Annual assessment of plan

Governing Board involvement

RECENT ENFORCEMENT: CIA'S

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- See Attached CIAs for review
- CIA Good Shepard (2015)
  - → Agreed to pay $4 million to resolve allegations that the company submitted false claims for hospice patients who did not meet eligibility. Other alleged issues—Medical Director referrals to patients' in Nursing Homes.
- Garden State Cardiovascular Specialists (2015)
- Columbus Regional Healthcare System (2015)
  - → Documentation Review for "arrangements"

A CIA REQUIRES ANNUAL AUDITS

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- CIAs based on allegations of false claims billed and paid and include clinical record and claims audits by an Independent Review Organization (IRO)
- CIAs are based on allegations of violations of Anti-Kickback statute: annual audits re: arrangements
- Reporting Period Annually for five years: Date CIA fully executed through the next year
  - →CIA will identify sample to be audited
  - →Specific issues such as medical necessity or eligibility, coding

DOCUMENTATION

- Individualized Patient Information:
  - →Eligibility
  - →Medical Necessity
  - →Homebound Status
  - →Disease Specific
  - →Plans of Care
  - →Goals, Interventions, Treatments,
  - →Medications
  - →Orders
  - →Therapy

BACK TO BASICS DOCUMENTATION

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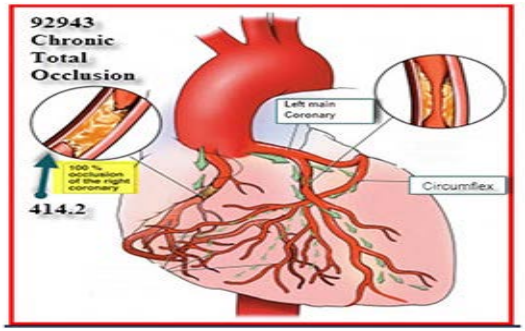
- "Paint" the picture of the patient
- The documentation should tell the patient's story in *measurable* detail
- Measureable data (timeframes);
  - →Patient prior status: tests, labs
  - →Functional status, emotional status
  - →Compared to current…status
  - →Timeframe—dates
  - →BMI, Weight, VS, Respiratory, Cardiac; other
  - →Use Local Coverage Determinations (LCD)

CODING DOCUMENTATION

- ICD-Coding 9 Coding
- ICD-10 Coding effective October 1, 2015
  - →SIGNIFICANT CODING CHANGES
    - – 68,000 codes compared to 13,000 with ICD-9;
    - – Other changes to system
- Providers should ensure all coders are certified and understand the significance of false claims coding



HIRING PRACTICES

- Human Resource practices documentation:
  - →Applications, References Checks
  - →Criminal Background Checks & OIG Exclusions List
  - →Licenses and Certifications
  - →Provide Job Descriptions and acknowledgement thereof
  - →Competency Skills
  - →Annual Performance Reviews
  - →Health Checks: TB, Hep B, Other
  - →Policies & Procedures
  - →Exit Interviews (include attestations annually & terminations)

OFFICE OF INSPECTOR GENERAL (OIG) EXCLUSION CHECKS

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- Medicare Certified Providers *must* conduct OIG Exclusions Checks
- *Exclusion*: an administrative action taken by Department of Health & Human Services (HHS) prohibiting provider participation in Federal Healthcare Program
- The OIG of HHS has authority to exclude
- Mandatory and Permissive Exclusions
- Five year minimum exclusion
- No automatic reinstatement

PROHIBITED PAYMENTS

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- Medicare prohibits payment for items or services that are furnished by an *excluded* individual or entity (See 42 C.F.R. 1003.102(a)(2))
- Payment prohibition includes direct or indirect services (IT, administrative, cleaning), vendors
- Civil Monetary Penalties and Overpayments (FCA)
- Recommend/Best Practice is Monthly Checks (External Screening Vendors)
- **Revenues are at Risk** if excluded provider is hired

COMPLIANCE MEASURES & DOCUMENTATION

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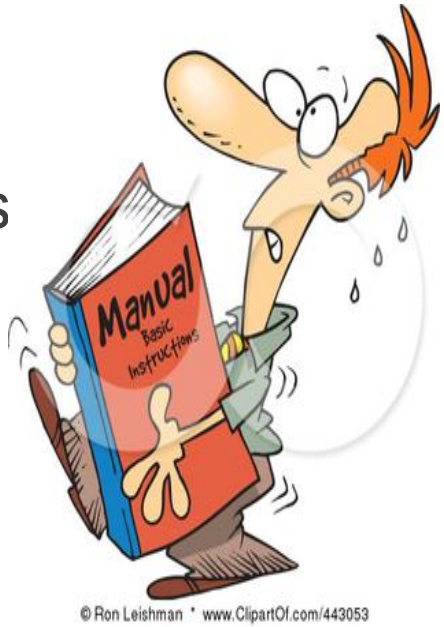
- Assess programs/processes:
  - →Human Resource Function
    - Employee Handbook
    - Standard of Conduct/ Just Culture
    - Written progressive disciplinary procedures all levels management
  - →Marketing Arrangements--Documentation
  - →Internal and External Audits ---Data & Analysis
  - →Clinical & Billing policies and procedures
    - Written manuals or computer accessible
    - Current and up-to-date
    - Accessible to all clinical staff
    - Reviewed/revised annually



QUESTIONS

EDUCATION PURPOSES

- 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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