2017 Rocky Mountain Home Care, Home Health & Hospice Conference
Keystone, Colorado
May 17-19, 2017

PRE-CONFERENCE SESSION MAY 17, 2017
Coping with the Chaos: Compliance 2017 & Creating a Culture of Compliance with Everyday Ethics

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LEARNING OBJECTIVES

- Participants will:
  - State at least two laws used by the government to prosecute fraud and abuse cases
  - Identify two areas of current government scrutiny in home health and two for hospice, including current cases
  - State at least two reasons why a formal Ethics & Compliance program is imperative in this climate
  - Name at least three best practices of a formal compliance program
  - Define a Corporate Integrity Agreement (CIA)
  - State at least two elements of Compliance Effectiveness
  - Define ethics and state the difference between a legal review and an ethical analysis

COMPLIANCE CLIMATE 2017

THE WHO, WHAT, WHERE, WHEN & WHY?

- **WHO:** All Medicare and Medicaid Healthcare Providers
- **WHAT:** More Government Oversight/Scrutiny for Compliance with laws and regulations
- **WHERE:** Across the US: Federal and State laws
- **WHEN:** Past, Present and Future
- **WHY:** Increase in Fraud and Abuse in Healthcare and increasing Medicare Beneficiaries resulting in billions of $$$ lost

WHAT IS COMPLIANCE?

- Compliance is an adherence to a set of rules, regulations and law
  - Statutory
  - Regulations
  - Case Law
  - Codes of Conduct
  - Other: Advisory Opinions, Fraud Alerts, Compliance Guidance, Policy and Procedures and Human Resources Requirements
    - HIPAA, CoPs, ACA, CMS OIG Guidance
COMPLIANCE FOR PROVIDERS

- Federal Laws & Regulations
  - Social Security Act: Social Security Administration (SSA)
  - Affordable Care Act: Center for Medicare Services (CMS) of DHHS. See also State Department of Human Services (DHS) for Medicaid programs
    - Medicare Conditions of Participation (CoPs): (Home Health 2014 pending); Hospice (2008)
  - HIPAA: Office of Civil Rights (OCR)
- OSHA -- Agency in the Department of Labor (DOL)
- State Law & Regulations (Licensing, Background checks, other)
- Case Law (State Courts, Circuit Courts, Supreme Courts)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

- Multiple Federal Agencies and Offices come under the Department of Health and Human Services (HHS): some examples below--
  - Centers for Medicare & Medicaid Services (CMS)
  - Centers for Disease Control (CDC)
  - Food and Drug Administration (FDA)
  - Office of Civil Rights (OCR)
  - Indian Health Services (HIS)
  - National Institutes of Health (NIH)
  - Departmental Appeals Board (DAB)
  - Office of the Inspector General (OIG)
OFFICE OF INSPECTOR GENERAL (OIG) OF HHS

- Since 1976, the OIG of the U.S. Department of Health and Human Services (HHS) has been at the forefront of the Nation’s efforts to fight waste, fraud, and abuse in Medicare, Medicaid and other HHS programs
- www.oig.hhs.gov
- Responsibilities of the OIG (Offices across the country)
  - Investigations
  - Audit Services
  - Evaluations and Inspections
  - Management and Policy
- See Reports and Publications/work plans/ACA Reviews
SO WHY A COMPLIANCE & ETHICS PROGRAM?

• Patient Protection & Affordable Care Act (PPACA) also known as ACA 2010 requires providers to establish compliance programs
• Office of Inspector General (OIG) Voluntary Compliance 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
    • Clinical lab, ambulance, physician practices; other...

GOVERNMENT FRAUD PREVENTION METHODS

• Office of Inspector General (OIG) Voluntary Compliance Guidance (www.oig.hhs.gov)
  → OIG voluntary guidance for Home Health and Hospice
    • Home Health Agencies: 63 Fed. Reg. 42410; August 7, 1998
    • Hospice: 64 Fed. Reg. 54031; October 5, 1999
  → OIG Work Plans
  → Increase in Audits
  → Use of Data Analytics
  → OIG Teams with Department of Justice on Investigations
  → State Audits for Medicaid
  → Involvement from State Offices of Attorney Generals
**BRIEF HISTORY OF FRAUD AND ABUSE**

- Anti-Fraud Initiative---Operations Restore Trust (ORT) Pilot 1995
  - Successful recoveries in 5 states (Texas, CA, NY, Illinois and Florida)
    - 42.3 million ($10 in recoveries for each $1 spent)
  - 35 Criminal convictions
  - 18 Civil settlements

**COMPARE OIG/DOJ ANNUAL REPORTS**

- Over 20 years later
  - 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
**KEY GOVERNMENT ENFORCERS**

- 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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**THE LAWS: STATUTES, REGULATIONS, CASE LAW**

- The Laws --- aka:
  - The Government’s Tools of Investigation and Enforcement of the Laws for preventing Fraud, Abuse and Waste

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ANTI-KICKBACK STATUTE (AKS)

- Focus on Federal Anti-Kickback Statute (Criminal)
  - Broadly prohibits offering or providing anything of value (remuneration) in return for referrals for goods, services, or items paid for by a federal health care program. Liability for AKS includes fines, civil penalties, and imprisonment.
  - 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
    - Established the "one purpose" test

ANTI-KICKBACK SANCTIONS

- 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
- Must review State Anti-Kickback Statutes
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

STARK LAWS

- 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. Other arrangements/referrals…may also be illegal
  - Up to $15,000 per claim plus 3 times (treble damages) the claims and/or $100,000 per circumvention scheme.
FALSE CLAIMS ACT (FCA)

- 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. (Federal FCA as well as State False Claims Acts) —Also known as the “Lincoln Law”

→ 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.

FALSE CLAIMS ACT DAMAGES

- 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.
FALSE CLAIMS & QUI TAM

• Federal False Claims Act (FCA)
  → 1) Actual knowledge; 2) Deliberate ignorance; 3) Reckless disregard

• FCA contains provision for Whistleblower (Qui Tam) Actions

• See also State False Claims Acts

WHISTLEBLOWER PROTECTION ACT

• Approximately 70% percent of FCA actions have been initiated by whistleblowers in the past
• Person can file an action on behalf of government
• 15-30% of recovered claims go to person who brought action (Government decides each case); See State laws
• Government can opt out but claim can go forward
• 35 Billion has been recovered under FCA between 1987-2012;
  → 24 billion by qui tam actions
  → 2016: 2.9 B recovered from Qui Tam /FCA (all industries)
ADDITIONAL 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

REVERSE FALSE CLAIMS AND THE 60-DAY RULE

- 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...”
- PPACA establishes 60-day clock for return of “identified” overpayment (or date of corresponding cost report)
- See Updated OIG’s Self-Disclosure Protocol:
  April 17, 2013 (prior protocol was published in 1999)
- New Regulations February 12, 2016 for the 60 day rule (Medicare Parts A & B) (81 Fed. Reg. 7654)
  - Clarification on when an overpayment is identified
  - Establishes a six-year lookback
  - Describes options for reporting and returning identified overpayments.
THE 60 DAY RULE

• The 60-day time period for returning/reporting overpayments begins when either:
  → Reasonable diligence is complete or;
  → On the day the provider received credible information of a potential overpayment (if the provider fails to conduct reasonable diligence)

• Conduct investigations in a “timely” manner:
  → Providers must complete the investigation within 6 months from the receipt of credible information indicating there may be an overpayment (may be extended); 8 months generally the maximum

• Maintain documentation of “reasonable diligence”

MANDATORY COMPLIANCE REQUIREMENTS

• HH & HOS CMS Conditions of Participation (CoPs): Cover ethical issues, informed consent, dignity, privacy, resident rights, QAPI, etc
  → Home Health New CoP Rules Effective January 13, 2018

• Coding: ICD-9 & ICD-10

• Payment: CTI/Face-to-Face; Attestations; Notice of Election; HH Medical Necessity and Homebound status/POC /485

• Medicare Administrative Contractors (MACs); Local Coverage Determinations, ZPICS looking at Eligibility, LOS; live discharges;

• Hospice: NOE

• CMS Regulations, Notices, Transmittals, other

• Self Disclosure Protocol (revised April 2013); 60-day Rule

• Case Law
  • Jimmo v. Sebelius Settlement
  • Escobar; Aseracare; other

• State laws regarding background checks/Medicaid fraud

• Other: OIG/State Exclusions List

• HIPAA
GOVERNMENT FOCUSED AUDITING

• MAC/ZPIC: Claims Oversight & Data Analytics
  → Pre-Bill claims monitoring
  → ZPIC letters requesting clinical records for claims billed and paid:
    • **Focus on Hospice:** Eligibility, Long Length of Stays, Face to Face, Election of Benefit, Notice of Election, Revocation; Live Discharges, Routine Home Care (RHC); General Inpatient Care (GIP); Continuous Home Care (CHC); other
    • **Focus Home Health:** Face to Face; therapy evaluation and assessments; medical necessity, home bound status, Plan of Care (POC), other

USE YOUR PEPPER REPORTS—the Contractors are….

WHY THE FOCUS ON HOSPICE?

• **MEDPAC REPORT 2014**
  • In 2012—more than 1.27 million Medicare beneficiaries received hospice services from over 3700 hospice providers. Medicare expenditures total about $15.1 billion
  • Approximately 46.7 percent of Medicare Beneficiaries who died in 2012 used hospice
  • Growth nearly 4% of for-profit hospices
  • Average length of stay increased between 2000 and 2011 from 54 to 86 days in 2012
  • **2013:** 1.3 Million Beneficiaries; 3900 Hospices; Over 15 Billion paid in Medicare
  • Increase in Use of Hospice for Non-Cancer Diagnosis
    → 68% of Medicare decedents who used hospice had a non-cancer diagnosis

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ANNUAL OIG WORK PLANS: HOSPICE

• 2013-2014 OIG Work Plan (www.oig.hhs.gov/reports)
  → Marketing practices
  → Financial relationships with nursing facilities
    • Mandatory contract language
  → 2014-15: Hospice in Assisted Living Facilities
  → 2015-2016 Hospice General Inpatient Care
    • Services billed but not received
    • Increase utilization
    • Is level of care appropriate?
  → 2016 Hospice GIP, POC, Revocation, other
  → 2017: Hospice RN Visits; HOS overall requirements

OIG HOSPICE INITIATIVES

• OIG will continue to review the use of hospice general inpatient care:
  - OIG will assess the appropriateness of hospices’ general
    inpatient care claims and the content of election statements
    for hospice beneficiaries who receive general inpatient care.
    OIG will also review medical records to address concerns
    that this level of hospice care is being misused.

  - Alabama Hospice paid $3.92 million to settle allegations
    that the company submitted false reimbursement claims to
    the government for patients treated at its facilities. The
    government alleged that the Hospice agency was submitting
    false claims for hospice care for patients who were not
    eligible (i.e., did not have a prognosis of six months or less
    to live).
**OIG HOSPICE INITIATIVES**

- In FY 2015 Work Plan (ongoing), the OIG states it will review hospices that serve Medicare beneficiaries who reside in assisted living facilities (ALFs):
  - Specifically, the OIG focused on length of stay, levels of care received and the common terminal illnesses of beneficiaries who receive hospice care in ALFs.
  - Pursuant to the Affordable Care Act, CMS must reform the hospice payment system, collect data relevant to revising hospice payments, and develop quality measures for hospices.

**HOSPICE KEY RISK AREAS**

- Facility/Hospice Relationships – more scrutiny
  - Overlap of services
  - Appropriateness of services
- Documentation and F2F continues to present challenges
- Recent Activity–
  - Pre-Payment Review through the ZPICS
  - Continued focus on eligibility
    - Diagnosis specific audits
    - Secondary diagnoses
    - Documentation of related or un-relatedness of other conditions
  - Continued focus on Long Length of Stays – over 180 days
  - New focus on internal audits – requests for all of a company’s records pertaining to any internal audits or reviews of claims
  - Continued focus on Medical Director/Physician Relationships
ENFORCEMENT

• Patient Eligibility/Documentation/See also CIAs
  →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.

INDIVIDUAL MEDICAL DIRECTOR LIABILITY

• Dr. Eugene Goldman was convicted in June 2013 of one count of conspiring to violate the AKS and four counts of violating the AKS arising from his work as medical director at Home Care Hospice Inc. (HCH) in Philadelphia. He regularly referred Medicare and Medicaid patients to HCH between December 2000 and July 2011 in exchange for more than $263,000 in kickbacks.
HOSPICE KEY RISK AREAS:
WORTHLESS SERVICES

• Increase in worthless services cases
• These are quality of care cases
  → In a recent case, court opined that when proceeding under a worthless services theory, it is not necessary to show that the services were completely lacking; rather, it is also sufficient to show that patients were not provided with the quality of care that meets the statutory standard.
  • Low staffing, missed visits
  → But other courts have said need to show that services are so inadequate, deficient or substandard that a reasonable person would understand that any services provided were worthless.
• Most egregious cases being handled criminally but we are seeing an increase in civil claims as well
  → Typically brought by employees who are alleging agency understaffed, allegations of missed visits, forged records.

RECENT FCA LITIGATION: HOSPICE

• “[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...

• Update on the ASERACARE Case

WHY THE FOCUS ON HOME HEALTH?

• In 2013, 3.5 million Medicare beneficiaries received home health services costing around $18 billion, from more than 12,000 Home Health Agencies (HHAs).
• Medicare spending for home health care has doubled since 2001.
• According to OIG, since 2010, nearly $1 billion in improper Medicare payments and fraud has been identified relating to the home health benefit.
GOVERNMENT OVERSIGHT FOR HOME HEALTH

- 2013-2014 OIG Work Plan (www.oig.hhs.gov/reports)
  - Face to face encounters
  - 2014-2015 Employment of home health aides (HHA) with criminal convictions
  - OASIS
  - MAC: Claims oversight
- 2014-2015 Home health PPS requirements
  - Trends in expenses and revenues--cost report analysis
- 2016: Home Health PPS: documentation; are claims in accordance with laws and regulations
- 2017: Overall requirements for documentation and claims

OIG HOME HEALTH SERVICES INITIATIVE

- OIG will review compliance with the home health prospective payment system (PPS), including the documentation required in support of the claims paid by Medicare.
  - Prior OIG report found that one in four home health agencies had questionable billing. Since 2010, nearly $1 billion in improper Medicare payments and fraud has been identified relating to the home health benefit.
  - OIG will determine whether claims were paid in accordance with federal laws and regulations.
  - Probe and Educate Audits
  - Pre-Payment Audits: Illinois
REVIEW: HOME HEALTH KEY RISK AREAS

• Medical necessity, and eligibility for home health benefit
  → Medically unnecessary skilled services
  → Services provided to patients who are not homebound

• Documentation sufficiency and compliance with CMS requirements
  → Face-to-Face Requirements
  → Placement of Signatures
  → Plans of Care

• ICD-10---Coding/OASIS

• Financial relationships with referral source

• Marketing practices

• Home health aide certification and training

• Patient Safety and Quality of Care

• Therapy Threshold Manipulation

EXAMPLES RECENT ENFORCEMENT

• Documentation:
  → Many cases re: eligibility and level of service; homebound status and Medical Necessity

• 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

• Universal Health Services, Inc. v. United States et al., EX REL. ESCOBAR et.al.

• Relator vs. Brookdale Senior Living (6th Circuit): August 2016
  → 485 Signatures and dates prior to billing: what length of time is reasonable?
QUESTIONS

2017 COMPLIANCE CLIMATE

The Seven Elements and More: OIG Guidance & Building Blocks to Best Practices
**ELEMENTS OF AN ETHICS & COMPLIANCE PLAN**

**WHAT SHOULD YOU NAME YOUR PROGRAM?**

1. Written policies and procedures to include written standards/code of conduct:
   - Policies must cover high risk areas of practice; include Anti-kickback Laws, False Claims Act, billing, conflicts of interest, billing, ICD-Coding, Face-to-Face, CTI, clinical documentation for hospice eligibility and physician diagnoses, care plans, 485, homebound status; medical necessity; physician, other

2. Effective oversight by provider/company compliance officer & governing body & compliance committee

**ELEMENTS OF A PLAN/PROGRAM**

3. Effective development and implementation of regular, applicable education and training for all affected employees, independent contractors and vendors

4. An effective reporting system such as a hotline
   - Anonymity
   - Email
   - Lock-Box

5. Use of audits and or other systemic practices to monitor compliance, identify problem, and implement corrective action: i.e. contracts; pre-billing checks; revenue cycle processes; clinical documentation audits; effective EMR edits; use PEPPER Reports to identify patterns...
ELEMENTS OF A ...PROGRAM

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

7. Implement effective policies that ensure prompt investigations, reporting and corrective actions

• Other
  → Annual assessment of plan and draft of annual audit plan
  → Governing Board Involvement
  → Management Certifications
  → Compliance Board Expert

IS THERE A TEMPLATE PLAN?

• One size does not fit all


• Ethics & Compliance plans should evolve and change
  → Ethics Committees
  → Compliance Committees
U.S DEPARTMENT OF JUSTICE DOCUMENT

• U.S. Department of Justice, Criminal Division, Fraud Section:
  → February 21, 2017:
    • Evaluation of Corporate Compliance Programs
      – Topics and Questions

OTHER CONSIDERATIONS

• Do you have a regulatory compliance expert who monitors regulations, CMS and OIG guidance, payment requirements? Is this person a clinician? Does your EMR vendor understand the clinical and billing regulations/documentation?

• Consider the size of your organization/agency
  → Multiple Provider Numbers?
  → Multiple Lines of Service?
BEST PRACTICES

• Governing Board
• Executive Team: CEO, COO, CFO, CCO
• Marketing Team
• Clinical Management and Staff
• Revenue Cycle and Billing
• Human Resources
• Other

REVIEW: LAWS WITH IMPACT ON COMPLIANCE

C-Suite/Board should have knowledge of the following laws:
• Coverage / COP / Licensure / Provider Enrollment / HIPAA
• Patient Freedom of Choice, SSA § 1802
• Stark II, Phase III, SSA § 1877
• Anti-kickback laws, SSA § 1128B
• Civil Monetary Penalties, SSA § 1128(a)(5)
• False Claims Act, 31 U.S.C. § 3730
  → Includes failure to report and refund known overpayments
• State and Federal fraud laws
• Various state referral laws
C- LEVEL SCREENING RE: REFERRALS

- QUERY: Where are the referrals coming from?
- Has there been a change in referral patterns?
- Is there any financial relationship with any referral source?
- Does the staff compensation method create any risk; Independent Contractor arrangements?
- Do third parties contribute to referrals?
- Do staff have any family or personal relationship with referral sources?

CLAIMS RISK AREAS

C-Suite: Know what Questions/Inquires to make of your Managers and other Staff

- Utilization Risk Areas
- Coding and Billing
- Authorization of Care
- COMPLIANCE/CONSISTENCY with approved Plan of Care/Treatment
- DOCUMENTATION
- Technical Requirements for Payments
EDUCATE GOVERNING BOARD

- Private or Public: The government is looking to provider governing Boards for effective oversight of healthcare providers --- and to monitor company quality and compliance:
  → See “Practical Guidance for Health Care Governing Boards on Compliance Oversight” – attached to materials
  → See also: “A toolkit for Health Care Board:
  → Go to: www.oig/hhs/gov for additional resources and guidance for compliance related issues

BEST PRACTICES CONTINUED

- Human Resources
- Marketing
  → Training and Education; role playing; Agendas & Sign-in Sheets
- Clinical/Documentation
  → Practical hands on training; education on payment requirements re: technical and narrative documentation
  → Physicians and Nurses, nurse practitioners
- Revenue Cycle and Billing
  → EMR education on edits; pre-bill review
2017 COMPLIANCE CLIMATE

Federal Sentencing Guidelines & Lessons Learned from Corporate Integrity Agreements

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.usssc.gov
The 2016 Guidelines Manual
www.uscc.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)

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.

- .........................
CORPORATE INTEGRITY AGREEMENTS

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

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.
CURRENT REQUIREMENTS OF A CIA

• Similar to OIG voluntary guidance for Compliance Programs
• Requires the provider(s) to establish a formal compliance program complete with the Seven Elements of a Compliance Program PLUS
• Selection of an Independent Review Organization (IRO)
  → Annual Claims Review by the IRO & Annual Reports

Newer CIAs:
• Require upfront training and education
• Involvement from the Governing Board
• Certifications from Management
• Overpayment Reporting & Refunding
• Quality Monitors and Annual Risk Assessment
• Board Compliance Expert

A CIA REQUIRES ANNUAL AUDITS

• CIAs based on allegations of false claims billed and paid will require annual clinical record and claims audits by an Independent Review Organization (IRO)
• CIAs based on allegations of violations of Anti-Kickback statute: require annual audits of contracts and “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
WHAT IS AN IRO?

• Definition: Independent Review Organization (IRO)
  → A consulting, auditing or accounting firm that provides independent and objective reviews and analyses
  → Provides services to Medicare/ Medicaid Provider entities who are mandated to comply with a Corporate Integrity Agreement (CIA)
  → May also provide consulting and other services to covered and non-covered entities when not acting as an IRO

EXAMPLE OF A CIA & APPLICATION OF IRO

• CIAs are listed on the OIG website alphabetically
• All provider types: Physicians, Ambulance, Hospitals, Home Health, Hospice, other
• Discussion of a CIA and Application of IRO Responsibilities
HOME HEALTH AND HOSPICE CIA

- Corporate Integrity Agreement Between The Office of Inspector General of the Department of Health and Human Services and St Joseph’s Hospice, LLC; et al.
- Corporate Integrity Agreement Between The Office of Inspector General of the Department of Health and Human Services and Friendship Home Health, Inc. et al.

QUESTIONS
ETHICS DEFINED

- The word ethics comes from the Greek word ethos which means “custom” or “character”
- Principle of “right” or “wrong” conduct
- A set of rules or conduct governing a profession or business: ABA Model Rules of Professional Conduct for lawyers; ANA Code of Ethics for Nurses; AMA; Corporate Standards or Code of Conduct
- Set of social or religious norms and a way of life
### WHO DECIDES?

- Ethical principles or judgments are closely related to moral judgments or principles; morals are a **value**
  - Ethics: based on values of individual, community or society
  - Values may differ in people… cultures….communities…countries

Laws are often based on a group of people’s ethical values ---- Example: U.S. Democracy

### VALUES DEFINED

- A principle, quality or standard considered desirable and important
- Many types of values:
  - Social: i.e. social programs, security...
  - Religious: charity, sanctity of life…
  - Legal: order, justice, equality, freedom
  - Economic: frugality, financial security…
  - Cultural: sanctity of land, caring for elderly
  - Environmental: clean air, carpooling, other
VALUES … CONTINUED

→ Corporation/Agency/Providers: quality, leadership, teamwork
→ Self Determination: autonomy, respect, responsibility, right to consent/refuse medical/health care
→ Aid-in-Dying, Other...

ETHICAL PRINCIPLES HEALTHCARE

• Principles:
  → Respect for Autonomy
  → Non-maleficence: do no harm
  → Beneficence: do good, duty to help
  → Distribution of Justice

Beneficence / Nonmaleficence
- **Beneficence**: The duty to do and to maximize good
- **Nonmaleficence**: the duty to do no harm or to minimize harm in pursuing a greater good
THE LAW

- In our society, laws are written:
  - statutory,
  - regulatory
  - common law (case law)
- Alleged violation of laws are dependent on facts
- Accountability and punishment
- Corporate Integrity Agreements (CIA)

ETHICAL VERSUS LEGAL

- Difficult issues:
  - What is ethical may be illegal
  - What is legal may be unethical
- Less complicated issues:
  - Legal and ethical
  - Illegal and unethical
- Examples
ISSUES W/ LEGAL & ETHICAL CONFLICTS

- ACA: birth control
- Abortion
- Gun Control
- Medical Marijuana
- Gay Rights/Marriage
- End-of life:
  - Informed Consent
  - Autonomy
  - Withdrawing & withholding treatment
  - Assisted Suicide
  - Aid-in-Dying

ETHICS & INFORMED CONSENT

- History: Case 1914
  - Pre-World War II
  - Post World Was II
  - Mid-1960’s-1970’s:
    - Abuses in human experimentation exposed
    - Karen Ann Quinlan Case, 1976
    - 1976-1988: by one count, there were 54 reported decisions involving the right to refuse life-sustaining treatment
LANDMARK CASE: CRUZAN

- Right to consent and right to refuse treatment evolves…
- Cruzan case: 1980’s
  - Car Accident: coma to persistent vegetative state
  - Feeding tube inserted for hydration and nutrition
  - Parents claim a “somewhat serious conversation” with Nancy in which she stated that she did not want to be kept alive unless she could have a halfway normal life
  - U. S. Supreme Court: “clear and convincing evidence” needed; Missouri to decide
  - 1990-Missouri courts: friends testified re: Nancy’s wishes; Nancy allowed to die

COMPLIANCE WITH THE PATIENT SELF-DETERMINATION ACT

- State laws follow:
  - Living Wills, Health Care POA’s, also known as advance directives—(Legal/ethical resolution? Allows for decision-making based on values)
HEALTH CARE DECISIONS

• State Law
  → Patient has capacity
  → Legal or natural guardian
  → Appointed agent
  → Health care surrogate based on state law—order of priority
  → Health care provider based on futility issues…

ETHICS OF INFORMED CONSENT

• Consent: Informed and Implied
• Informed Consent and Refusal of Care
  → Capacity
  → Competency
SURROGATE DECISION-MAKING

• Surrogate decision-makers have an obligation to make decisions based on:
  → Substituted Judgment
  → Best Interests
  → Informed Refusal of Care

THE FUTURE?

• Oregon: "Death with Dignity Act" 1997 allowed terminally ill patients to be prescribed a lethal dose. Brittany Maynard. Supreme Court Ruling in 2006 affirmed.
• Montana Note 3: 12/31/09 State’s living will act permits forms a basis for aid-in-dying. Consent of patient can be used as a defense
• The Washington Death with Dignity Act: the prior crime of assisted suicide is a medical treatment if the assistance is provided by a physician
• Vermont: Common law based on customs and case law
• California: Fifth State
• Colorado
• Washington D.C.
• New Mexico case and 2017 Legislation
• Other states introducing legislation—over 20... (Terminally ill, competent, two MD, capable admin meds)
BIOETHICS DISCUSSIONS

- May discuss values in light of:
  → **Medical issues**: current condition, prognosis,
  → **Patient wishes/preferences**: Surrogate decision-maker’s knowledge of patient wishes, or if unknown, best interests
  → **Patient quality of life issues**
  → **Outside issues**: financial resources, legal, family, other
  → See Albert Jonsen’s Clinical Ethics, All editions; Eighth Edition 2015, McGraw-Hill, Inc.

CORPORATE/BUSINESS ETHICS

- Do you have a Corporate Code of Conduct?
  → Ethical issues include but are not limited to:
    - Conflicts of Interest Disclosure
    - Confidentiality: Patient, Business, Employee
    - Appearances of impropriety
    - Managing people
      - Bullying; harassment; gender
    - Disciplinary issues
    - Working environment
    - Billing and Coding/Licenses/Certifications
    - Referrals /Kickback issues/Abuse and Neglect
DOES DOING THE RIGHT THING MEAN MORE REGULATION? WHY? WHY NOT?

- **Who is subject to more regulations?**
  All Medicare Certified providers/Medicaid
  → Home Health & Hospice Agency Providers

- **What: Government oversight and enforcement**
  → DHHS Centers for Medicare (CMS) and Office of Inspector General (OIG) compliance mandates & monitoring; investigations & enforcement actions; MACs, RACs, ZPICS, state laws & state Medicaid fraud units; Department of Justice (DOJ)

- **Where: Everywhere**
  → All regions across the United States

- **When: Past, present & future**

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ETHICAL AND LEGAL HIGH RISK AREAS

- **Common areas for high risk for Medicare Providers:**
  → Marketing, Billing, Documentation, Human Resources
  (Exclusions, Competence, License, Certifications...)

- **Take inventory of what is in place in your organization:**
  → Establish Compliance Committee/Plan
  → Bioethics Committee—Advance Directive & Aid-in—Dying issues;
  → QAPI & Compliance Auditing
  → Monitor, Measure
CORPORATE & BIOETHICS DISCUSSIONS

Review: Facilitate discussion of values with all parties involved.

May use outside mediator or internal bioethics/corporate ethics consultants.

PROVIDERS MUST:

ASSESS, AUDIT, MEASURE & MONITOR ...

Again and again...

DO THIS:  

TO AVOID THIS:
QUESTIONS /COMMENTS

EDUCATION ONLY

All sessions are for educational purposes & should not be construed as providing legal advice.

THANK YOU!

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