Health Care Compliance Association

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The Art of Ethics in Compliance Activities

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WHO IS SIMIONE?

• Team of home care and hospice experts with focus on solutions
  o Organizational:
    • Operational Assessment, Strategic Planning, Compliance & Risk: Assessments and Audits, Ethics, Mediations and Clinical Operations
  o Financial
    • Cost Reporting, Compliance, Revenue Cycle
  o Sales & Marketing
    • Assessment & Analysis, Referral Management, Training Resources, “Sales Boot Camp”
  o Technology
    • Assessment & Analysis, Guided System Search, Implementation Support, Process Engineering
  o Mergers & Acquisitions
    • Due Diligence & clinical and billing compliance Audits and Assessments, Business Valuation, Market Assessment

• Strategic Planning, Executive Support, Process Engineering, and Simione Financial Monitor offered in all 5 core challenge areas

PURPOSE OF PRESENTATION

• Discussion Points and Objectives
  → Discussion of ethical principles in healthcare & business versus compliance with legal mandates
  → State one difference between an ethical analysis and a legal review
  → Identify at least three practice tips for incorporating ethical principles and activities into a healthcare entity’s ethics & compliance program
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; CPAs, Corporate Standards or Code of Conduct; Other
- 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
  -> Based on values of individual, community, company or society
  -> Values may vary in individuals... cultures...communities...countries
- Laws are often based on a group of people’s ethical values
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

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

CORPORATE/BUSINESS ETHICS

• Compliance Programs require a healthcare entity to have a written Code of Conduct (Standards of Ethics)

• What does this mean:
  → It is about “doing the right” and knowing the right thing to do... and doing it....
  → Avoid appearances of impropriety
  → Disclose conflicts of interest
  → Maintain company proprietary information
  → Maintain patient/customer/client confidentiality
  → Crediting balances/claims adjustments for overpayments
  → Maintaining licenses/certification
  → Patient /Client rights/respect
  → Do no harm/guarding against patient abuse and neglect
  → Appropriate referrals
BUSINESS ETHICS

• Other potential ethical issues:
  • Managing People:
    → Bullying
    → Harassment; gender
    → Disciplinary issues
    → Working environment
    → Training and Education
    → Reporting/Whistleblowing

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) ---- mitigation of accountability and punishment in fraud and abuse matters
### ETHICS AND THE LAW

- Ethical and legal: discussions/decisions flow more easily
- Unethical and illegal: discussions/decisions flow more easily
- Unethical but legal: difficult discussions and decisions
- Ethical and illegal: difficult discussions and decisions

### 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 in our society...
ISSUES W/ LEGAL & ETHICAL CONFLICTS

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

ETHICS, AUTONOMY & CONSENT

- History:
  - Pre-World War II
  - Post World War II
  - Mid-1960’s-1970’s:
    - Abuses in human experimentation exposed
    - 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
  - Supreme Court: “clear and convincing evidence” needed
  - 1990-Missouri courts; 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
HEALTH CARE DECISIONS

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

AFTER THE PATIENT SELF-DETERMINATION ACT

• 1990: Terri Schiavo collapses and falls into a coma—she is 27 years old.
• Coma to unconscious state
• Malpractice case
• 1994: Husband accepts diagnosis of persistent vegetative state (PVS); he limits tx and enters DNR order
• 1998: Petition to discontinue treatment; parents fight petition…
• 2000 Court rules that Terri would want tube removed….multiple appeals/petition—regarding feedings
• 2005, March feeding tube removed… Terri dies…
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
AIDE IN DYING: THE FUTURE?

- Oregon: “Death with Dignity Act” 1997 has allowed terminally ill patients to be prescribed a lethal dose. Brittany Maynard matter.
- 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.
- New Mexico current case.
- Vermont: Common law based on customs and case law.
- Colorado & New York 2015 introduced “Death with Dignity Act”
- California has made attempts to legalize assisted suicide; other

BIOETHICS DISCUSSIONS

- Discussion of 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, 1992 and later editions, McGraw-Hill, Inc.
DOES DOING THE RIGHT THING...

... mean more regulation? Why? Why not?

- Who is subject to more regulations?
  - Medicare certified providers & State Medicaid Programs

- What government oversight and enforcement?
  - CMS COPs, OIG compliance mandates & monitoring; investigations & enforcement actions; MACs, RACs, ZPICs, state laws & Medicaid fraud units (AG offices); DOJ

- Where is the effect being seen?
  - All regions across the United States

- When is this happening?
  - Now---past, present & future

WHY ?

- Why is the Government on watch for fraud, abuse and waste in health care
  - Medicare spends billion of dollars each year on Medicare and Medicaid healthcare services
  - The Government has confirmed many reports of fraud, abuse and waste in provider practices/businesses resulting in settlements for billions of dollars every year...
    - Roadmaps: OIG reports & Work Plans, fraud alert, corporate integrity agreement (CIAs)
  - New regulations dictate new compliance practices
  - See government enforcement actions (Department of Justice)
BRIEF HISTORY: FRAUD, ABUSE AND WASTE

• Operations Restore Trust (ORT) Pilot 1995
  → Successful recoveries in 5 states
    • 42.3 million
  → 35 Criminal convictions & 18 Civil settlements
  → Recovery from Health Care Fraud and Abuse Program (HIPAA 1996)---
  → Fiscal year 2014:
    ➢ HHS/DOJ Annual Report (03/2015) over 3.3 Billion recovered
    ➢ 734 defendants convicted
    ➢ 957 civil matters pending at the end of FY

ANTI-KICKBACK STATUTES

• 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
    • 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
- Safe Harbors may be applicable
- State Anti-Kickback Statutes
- Stark laws:
  - Prohibits physician self-referrals...

FEDERAL AND STATE FALSE CLAIMS

- Federal False Claims Act (FCA)
  - 1) Actual knowledge; 2) Deliberate ignorance; 3) Reckless disregard
  - State False Claims laws
- FCA contains provision for Whistleblower (Qui Tam) Actions
WHISTLEBLOWER PROTECTION ACT 1989

- Seventy percent of FCA actions are initiated by whistleblowers (Discuss ethical issues)
- 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
  → Practice Tip: Employee Attestations

WHY A COMPLIANCE & ETHICS PROGRAM?

- Patient Protection & Affordable Care Act (PPACA) also known as ACA 2010
  → Requires all certified Medicare providers … establish a compliance program that contains…. (Section 6401 (a) (7))
  → History of OIG voluntary guidance
  - Supplemental 70 Fed. Reg. 4858; January 31, 2005
  - Hospice: 64 Fed. Reg. 54031; October 5, 1999
  - Clinical lab; ambulance, physician practices; other…
EVIDENCE FOR COMPLIANCE & ETHICS PLAN

- Programs may allow providers to mitigate risk and negotiate a more favorable outcome if OIG investigation implicates providers or, if provider self-reports
- Corporate Integrity Agreements (CIAs) consistently require/outline the seven elements of an effective compliance program:
  - Use CIA for education/current purposes

MANDATORY COMPLIANCE REQUIREMENTS

- ACA & increasing regulations
- CMS Conditions of Participation (CoPs)
- Medicare Administrative Contractors (MACs) Billing & Payment
- CMS/Medicaid Programs: Regulations, Notices, Transmittals, other
- Case Law
  - Jimmo v. Sebelius Settlement Agreement-Program
- State laws regarding background checks/Medicaid fraud/Other
HOW TO IDENTIFY HIGH RISK COMPLIANCE AREAS

- CMS New Regulations & Rules
- CMS Transmittals & Change Requests
- Review OIG CIAs, Enforcement Actions
- Review OIG Work Plans
  → 2013
  → 2014
  → 2015

CORE ELEMENTS OF AN ETHICS & COMPLIANCE PLAN

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
   Annual assessment of plan
   Governing Board involvement
IS THERE A TEMPLATE PLAN?

• One size does not fit all
• Ethics & Compliance plans evolve and change
  → Ethics Committees
  → Compliance Committees

NO FORMAL PROGRAM? DO NOT DESPAIR

• Take inventory of compliance measures and ethics activities you already have in place.
ASSESS PROVIDER COMPLIANCE MEASURES

- 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?
    - 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?

ASSESS ETHICS & COMPLIANCE MEASURES

- Bioethics/ethics committee? Compliance Committee
- 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
  - Written progressive disciplinary procedures all levels management?
ASSESS, AUDIT, MEASURE & MONITOR & AGAIN

• DO THIS: to AVOID this:

GOVERNMENT RESOURCES

• CMS: www.cms.gov
• MACs
• 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
  → New Materials for Governing Boars/Audit processes (04/2015)
CASE DISCUSSIONS

• Issues arise (bioethics/corporate ethics):
  → clinical, end-of life, quality of care, family, conflict of interest, appearance of impropriety, employee, management

• Convene an ethics consultation or;
• Schedule ethics &/or compliance committee meeting
• Identify individuals, clarify role/interests…, commit to list of important values, align values and actions
• Determine clinical, legal, financial, other issues
• Facilitate discussion to provide information and to seek resolution

QUESTIONS?

The way is in sight
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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