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
  - Organizational
    - Operational Assessment, Strategic Planning, Compliance & Risk: Assessments and Audits, Ethics Mediations and Clinical Operations
  - 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 and Assessments, Business Valuation, Market Assessment
- Strategic Planning, Executive Support, Process Engineering, and Simione Financial Monitor offered in all 5 core challenge areas

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PURPOSE OF PRESENTATION

• After this presentation participants should be able to:
  ➔ State one difference between an ethical analysis and a legal review
  ➔ Name at least two laws that are intended to deter fraud and abuse in healthcare
  ➔ State at least three core elements of a corporate Ethics and Compliance Program framework
  ➔ Identify several benefits of effective auditing in Ethics and 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; 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
  ➔ 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
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
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
- Gay Rights/Marriage
- End-of-life:
  - Informed Consent
  - Autonomy
  - Withdrawing & withholding treatment
  - Assisted Suicide
  - Aid-in-Dying
ETHICS & INFORMED 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

• Federal Patient Self-Determination Act 1991
• 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
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...

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.

CORPORATE/BUSINESS ETHICS

- Ethical principles applicable to corporate and business dealings:
  - Ethical issues include but are not limited to:
    - Conflict of Interest
    - Appearances of impropriety
    - Managing people
      - Bullying; harassment; gender
    - Disciplinary issues
    - Working environment
    - Billing and coding
    - Referrals / Kickback issues
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

And Why?

- Why: Government is on watch for fraud, abuse and waste in health care
  → Medicare spends billion of dollars each year on health care services
  → The Government has confirmed many reports of fraud, abuse and waste in hospital, physician, DME, home health & hospice provider practices resulting in settlements for millions 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)
    • Enforcement actions include "worthless: services"

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

- HIPAA 1996 established Health Care Fraud and Abuse Control Program—implemented 1997

- Focus on Anti-kickback Statute (Criminal)
  → Statute: 42 U.S.C. Sec. 1320a-7b(b)
    • Whoever knowingly ...offers or accepts remuneration for ...referrals...

- False claims
  → Statute: 31 U.S.C Sections 3729-3733
    • Knowingly, deliberate ignorance, reckless disregard
  → Other federal statutes & State Laws
COMPARE ANNUAL REPORT 2014

- 20 (plus) years later
  → 3.3 Billion recovered from Fraud and Abuse judgements/settlements/administrative impositions
  → 734 defendants convicted
  → 957 Civil matters pending at the end of 2014
  → 2015 --nearly 250 Corporate Integrity Agreements (CIA) signed;
  → See also DOJ Press Release Dec 3, 2015

SO WHY A COMPLIANCE & ETHICS PROGRAM?

- Patient Protection & Affordable Care Act (PPACA) also known as ACA 2010 requires providers to establish compliance programs
  → 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)
MANDATORY COMPLIANCE REQUIREMENTS

- CMS Conditions of Participation (CoPs)
  - Oct 06, 2014: proposed rule for changes to Home Health CoPs
- Medicare Administrative Contractors (MACs)
- ZPIC (Zone Program Integrity Contractors)
- CMS Regulations, Notices, Transmittals, other
- Case Law
  - Jimmo v. Sebelius Settlement Agreement-Program Manual Clarifications (Fact Sheet)
- 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
  - 2016

CORE 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, conflicts...Billing, ICD-Coding, CPT, HH & HOS: Face-to-Face, CTI, Clinical documentation, care plans, 485, other; Medical Necessity; Physician Diagnoses Doc
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
ELEMENTS OF AN ETHICS & COMPLIANCE PLAN

4. An effective reporting system such as a hotline
5. Use of audits and or other systemic practices to monitor compliance, identify problem, and implement corrective action: i.e., contracts; pre-billing checks;
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

Annual assessment of plan
Governing Board involvement

IS THERE A TEMPLATE PLAN?

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

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, values
• Determine clinical, legal, financial, other issues
• Facilitate discussion to provide information and to seek resolution
ETHICS PROCESS

- Clarify & Comprehend: Points of View of all individuals
  → Patient, providers (nurse, physician, therapist), family, healthcare facility, employee, other
- Commit: to a list of most important values
- Choose: Align values and actions (see company Code of Conduct)
- Communicate: Communication of the decision Facilitate discussion
- See: A Field Guide to Good Decisions, Values in Action, 2006; Bennett and McIver Gibson

QUESTIONS /COMMENTS

EDUCATION

- This session is for education purposes & 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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