

THE FUTURE OF THE
COMPLIANCE
PROFESSION: LEARNING FROM
MANDATORY COMPLIANCE

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WHAT MANDATORY COMPLIANCE
CAN TELL US ABOUT THE FUTURE
OF THE COMPLIANCE PROFESSION

- COMPLIANCE PROFESSIONALS AS
PROCESS EXPERTS
- WHERE ARE EACH OF YOUR COMPLIANCE
PROCESSES?
- MEASURING COMPLIANCE AND
IMPROVING OUTCOMES-FUTURE OF
COMPLIANCE?
- SHOULD YOU ACCEPT THIS JOB?

HIGHER EDUCATION-THE NEXT AREAS FOR MANDATORY COMPLIANCE

- CRIME ON CAMPUS US DOJ and EDUCATION
- STUDENT LOAN PROGRAMS NY AG
- UNIVERSITY HEALTH PROGRAMS-NY AG
- RESEARCH AND PATIENT PROTECTION-THE HAVASUPAI SETTLEMENT, GELSINGER
- DISCLOSURE OF DRUG INDUSTRY PAYMENTS-HARVARD CHILD PSYCHIATRISTS
- PRIVACY BREACHES (HIPAA, FINANCIAL, IDENTITY THEFT)

EARLY MANDATED COMPLIANCE:

- SEC MANDATED DISCLOSURES OF INVESTMENT RISKS (since 1930's) 10b-5
- FDA MANDATED DISCLOSURE OF FOOD CONTENTS (1930's methyl alcohol)
- FDA MANDATED DISCLOSURE OF SIGNIFICANT ADVERSE EVENTS BY MANUFACTURERS (since 1960s) (thalidomide)
 - CRIME IN FAILURE TO REPORT, REGARDLESS OF INTENT

EARLY MANDATED COMPLIANCE: FDA MANDATED REPORTING OF PRODUCT ADVERSE EVENTS

- Endovascular Technologies-failure to report serious adverse events (2002).
- In Re Grand Jury Subpoena 220 F.R.D. 130(D. Mass. 2004) –if you knew the product was likely to fail more frequently than disclosed in your labelling, and you do not disclose to FDA, product is misbranded (a federal crime)
- United States v. Caputo 374 F. Supp. 2d 632(N.D. Ill. 2005)-evidence allowed that “defendant intentionally avoided information about potential safety hazards.” (compliance officer given 7 year sentence)

PREDICTABLE EVENTS IN GOVT. COMPLIANCE MANDATES (apologies to Donabedian)

- 1) PERSONAL AND PROFESSIONAL ETHICS (fraud=intentional failure to meet standard of good faith and fair dealing)
- 2) MANDATED DISCLOSURE AND REPORTING
- 3) MANDATED STRUCTURE (7 elements)
- 4) MANDATED PROCESS (must investigate, must conduct audits, must conduct training, must meet with Board)
- 5) MANDATED OUTCOMES “*reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations*”
- 6) MEASUREMENTS

PREDICTABLE EVENTS IN GOVT. COMPLIANCE MANDATES

- WHAT MOVES THE MANDATED COMPLIANCE REGIME TO THE NEXT LEVEL?
- 1)PERSONAL AND PROFESSIONAL ETHICS-NOT MY JOB
- 2)REPORTING AND DISCLOSURE-SIGNIFICANT REGULATORY FAILURE DUE TO LACK OF INFORMATION
- 3)STRUCTURE-FAILURES OF REPORTING AND DISCLOSURE BY PRIVATE ENTITIES, GOVERNMENT NEVER ORGANIZED OR USED INFORMATION
- 4)PROCESS-STRUCTURE EXISTED, NEVER EFFECTIVELY IMPLEMENTED
- 5)OUTCOMES-STRUCTURE AND PROCESS MANDATES ARE EXPENSIVE, CAN LIMIT INNOVATION, SEPARATE COMPLIANCE FROM CORE MISSION, FAILED TO WORK
- 6)MEASUREMENT-WHAT EXACTLY WERE WE TRYING TO ACHIEVE HERE? WHAT DO OUTCOMES REALLY TELL US?

PREDICTABLE PROFESSIONAL ROLES IN RESPONSE TO GOVT. COMPLIANCE MANDATES-

- 1)PERSONAL AND PROFESSIONAL ETHICS-LICENSING BOARDS, PROFESSIONAL SOCIETIES
- 2) MANDATED DISCLOSURE AND REPORTING-ATTORNEYS
- 3) MANDATED STRUCTURE (7 elements)-AUDITORS AND CONSULTANTS
- 4) MANDATED PROCESS (must investigate, must conduct audits, must conduct training, must meet with Board)-COMPLIANCE OFFICERS
- 5) MANDATED OUTCOMES-NOT YET CLEAR
- 6) MEASUREMENT-ALL

THE CURRENT STATE OF MANDATED COMPLIANCE

- CORPORATE INTEGRITY AGREEMENTS (US HHS-OIG)-early 1990s
- STATE CORPORATE LAW-CAREMARK DECISION
- DEFERRED PROSECUTION AGREEMENTS (US DOJ-early 2000s-Bristol-Myers)
- MANDATED COMPLIANCE DISCLOSURES FOR NON-PROFITS ON IRS 990 (2008)
- MANDATED COMPLIANCE PROGRAMS FOR MEDICARE ADVANTAGE AND PART D (CMS-2009) (72 FR 68700 and program memos)
- MANDATED COMPLIANCE PROGRAMS FOR FEDERAL CONTRACTORS (2009)
- MANDATED "EFFECTIVE" COMPLIANCE PROGRAMS FOR NY MEDICAID PROVIDERS-(New York OMIG 2009) (18 NYCRR 521)
- MANDATED COMPLIANCE PROGRAMS FOR NURSING HOMES AND SOME OTHER HEALTH PROVIDERS-Patient Protection and Affordable Care Act Sections 6102, 6401 (2013)

Patient Protection and Affordable Care Act (PPACA) Section 6102

- *REQUIREMENT.—“On or after the date (March 22, 2013). . . a (snf or nursing)facility shall . . . have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care . . .*
- *Regs by March 2012, evaluation by March 2015*

"compliance and ethics program" means, with respect to a facility, a program of the operating organization that

- *"has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care; and*
- “(B) includes at least the required components specified in paragraph (4).*

HOW IS A MANDATED COMPLIANCE PROGRAM DIFFERENT?

- VERY BIG NEW DEAL-
 - COMPLIANCE REQUIRED BY GOVT
 - COMPLIANCE PROGRAMS FORMALLY EVALUATED BY GOVT
 - COMPLIANCE MEASURED BY GOVT
 - COMPLIANCE SELDOM TESTED BY GOVT
 - CONSEQUENCES OF INEFFECTIVE COMPLIANCE NEVER ARTICULATED EXCEPT IN SENTENCING GUIDELINES AND IN SPECIFIC CIAS
 - THINK OF AN ORGANIZATION'S FIRST ACCREDITATION REVIEW, OR JCAHO REVIEW

MODELS FOR MANDATED COMPLIANCE IN EDUCATION

- GELSINGER AGREEMENT
- CRIME ON CAMPUS AGREEMENTS
- AG CUOMO LOAN PROGRAM AGREEMENTS

FREE STUFF FROM OMIG

- OMIG website-WWW.OMIG.State.ny.us
- Mandatory compliance program-hospitals, managed care, all providers over \$500,000/year
- Over 1300 provider audit reports, detailing findings in specific industry
- 66 page work plan issued 4/20/09-shared with other states and CMS, OIG (new one coming in April)
- Listserv (put your name in, get emailed updates)
- Updates on Medicaid Integrity Contractors IPRO and Thomson-Reuters
- New York excluded provider list