

Compliance Laws & Regulations Syllabus

Fall 2008

Professor Barbara Colombo
Hamline University School of Law

**NOTE: 1ST DAY OF CLASS – AUGUST 28TH
LAST DAY OF CLASS – DECEMBER 4TH**

General Course Information

Course: Compliance Laws & Regulations
Credits: 3
Classroom: TBD
Days/Times: Thursdays 4:00-6:40pm
Professor: Barbara Colombo
Office Hours: One hour before class and by appointment
Office Phone: Given out first day of class
Cell Phone: 612-306-4655
E-mail: Given out first day of class

Course Description and Objectives

This course is designed to give students a practical understanding of the laws and regulations encountered by compliance professionals in daily practice. Special attention will be given to the federal government's regulatory infrastructure along with a thorough examination of the False Claims Act, Anti-Kickback laws, Physician Self-Referral laws (STARK), EMTALA and access to health care, HIPAA privacy, confidentiality and security, as well as strategies for reducing medical errors, crisis management, liability of health care professionals and entities, and health care provider licensure issues. The key objective of this course is the appropriate application of a range of statutory, regulatory and common law principles to a variety of compliance situations. Students will utilize legal principles and theory through a variety of simulation-based exercises each week.

Course Materials

The required text is GEORGE D. POZGAR, LEGAL ASPECTS OF HEALTH CARE ADMINISTRATION, 10th ed. (Jones and Bartlett 2007). I have also prepared a supplement that you should purchase along with the text. Required reading will be from both the "Pozgar" text and the Supplement (referred to as "Supp.").

Technology Policy:

In order to facilitate an interactive class and small group discussion, there will be occasions when the class will be asked to close their computers and/or turn off technology they have been using. At other times, students may use laptops for note taking. **If a student uses classroom time to read or send email messages, visit web sites or engage in any other online or technology based activities (including cellular telephones) that student will be asked to drop the course and will not receive academic credit for the class.**

Course Evaluation

There are three requirements for the Compliance Laws & Regulations course:

- 1. Class Participation:** This course is designed to be highly interactive with weekly opportunities for simulation-based learning. Students should come to class prepared to discuss the course material and actively participate in class discussions and activities. **Class participation will account for 20% of a student's final grade.** "Participation" is based on attendance, preparedness, and thoughtful classroom commentary.
- 2. Final Exam:** A take-home (open-book) final exam will be given. Final exam date pending. **The exam will account for 65% of a student's final grade.**
- 3. OIG Advisory Opinion Class Presentation:** Students will make a 15 minute presentation on an OIG Advisory Opinion. **This presentation will account for 15% of a student's final grade.**

Course Attendance

At the beginning of each class, I will distribute a class roster for you to sign. If you are absent for more than four classes, your absences will be treated as "excessive" in accordance with Hamline University Academic Rule 1-110 unless you have approval from me in advance.

Course Schedule

August 28, 2008:

- Introductions
- Syllabus and Grading
- "What's New in Compliance?"
- Health Care Jeopardy
- Federal Sentencing Guidelines
- Sarbanes-Oxley Act

Readings:

Pozgar: p. 131

Supp: Tab 1

OIG News

See, <http://www.ussc.gov/index.html>

U.S. v. Caputo, 456 F.Supp.2d 970 (N.D. Ill.2006)

U.S. v. McClatchey, 217 F.3d 823 (10th Cir. 2000)

Corporate Responsibility and Corporate Compliance, A Resource for Health Care Boards of Directors, OIG and AHLA .

September 4, 2008 and September 11, 2008:

- Federal Government's Response to Skyrocketing Health Care Costs
- Regulatory Infrastructure
- Public Health Care Programs Defined
- False Claims Act Laws & Regulations
- Qui Tam Claims
- FCA as a Weapon to Combat Medical Errors
- Issues of Medical Necessity
- FCA and the Implied Certification Theory
- Voluntary Self-disclosure
- Corporate Fraud and Abuse

Readings:

Pozgar: pp 53-58

Supp: Tabs 2 & 3

OIG News

DOJ News

31 USCA Section 3729 (a)-(e)

U.S. v. Krizek, 859 F.Supp. 5 (D.D.C.1994)

U.S. v. Krizek, 111 F.3d 934 (D.C.Cir.1997)

U.S. v.NHC Healthcare Corp., 115 F.Supp.2d 1149 (W.D.Mo.2000)

U.S. ex rel. Aranda v. Community Psychiatric Ctrs., 945 F.Supp. 1485 (W.D. Okla. 1996)

See Generally, <http://www.oig.hhs.gov/publications/semiannual.html>

U.S. ex rel. Mikes v. Straus, 274 F.3d 687 (2nd Cir. 2001)

In re Cardiac Devices Qui Tam Litigation, 221 F.R.D. 318 (D. Conn.2004)

[\(view on Westlaw\)](#)

See Generally, <http://www.oig.hhs.gov/authorities/docs/selfdisclosure.pdf>

September 18, 2008:

- Medicare and Medicaid Fraud and Abuse
- Anti-Kickback Laws
 - Defined
 - Penalties
 - Safe Harbors
- Stark Law (Physician Self-Referral Laws)
 - Designated Health Services
 - Exceptions
- Relationship to Anti-Kickback

Readings:

Pozgar: pp 55-58 (partial repeat of above), p 442

Supp: Tab 4

U.S. v. Greber, 760 F.2d 68 (3rd Cir.1985)

U.S. v. Starks, 157 F.3d 833 (11th Cir.1998)

42 USCA Section 1395nn

See Generally, <http://www.cms.hhs.gov/physiciansselfreferral/>

American Lithotripsy Soc v. Thompson, 215 F.Supp.2d 23 (D.D.C. 2002)

Goodstein v. McLaren Regional Medical Center, 202 F.Supp.2d 671 (E.D. Mich.2002)

September 25, 2008:

- OIG Opinion Presentations

Readings:

Supp: Tab 5

OIG Advisory Opinion Presentations-Assignment

See Generally, <http://www.oig.hhs.gov/fraud/advisoryopinions.html>

October 2, 2008

- Summary/Review Fraud and Abuse
- Compliance Considerations Beyond Fraud and Abuse
- Access/Barriers to Health Care
 - Disparities in Treatment
- The Obligation to Provide Care
 - Common Law
 - EMTALA

Readings:

Pozgar: pp 227-235

Supp: Tab 6

See, <http://www.kff.org/uninsured/upload/The-Cost-of-Care-for-the-Uninsured-What-Do-We-Spend-Who-Pays-and-What-Would-Full-Coverage-Add-to-Medical-Spending.pdf>

Two Examples of government sponsored health care:

1. State Children's Health Insurance (SCHIP) Program Summary
2. MinnesotaCare Program

How Much Would it Cost to Cover the Uninsured in Minnesota? MDH (July 2006)

Williams v. U.S., 242 F.3d 169 (4th Cir.2001)

The Case of Edith Rodriguez (Press Coverage)

See, 42 USCA Section 1395dd

Baber v. Hospital Corporation of America, 977 F.2d 872 (4th Cir.1992)

Lopez-Soto v. Hawayek, 175 F.3d 170 (1st Cir.1999)
EMTALA Checklist

October 9, 2008

- Antitrust Consideration for Compliance Professionals-An Overview
 - Statutes
 - Mergers and Acquisitions
 - Formation of Integrated Systems
 - Private Accreditation and Professional Standard Setting
 - Market Concentration

Readings:

Pozgar: pp 444-447

Supp: Tab 7

FCT News Release-April 28, 2008

Hospital Corporation of America v. FTC, 807 F.2d 1381 (7th Cir. 1986)

U.S. Healthcare v. Healthsource Inc. 986 F.2d 589 (1st Cir. 1993)

Kartell v. Blue Cross of MA, Inc., 749 F.2d 922 (1st Cir. 1984)

October 23, 2008

- Medical Errors-Scope of the Problem
- Legal Reporting Obligations
- Compliance and Mandatory Reporting of Adverse events, near Misses, and Mistakes
- Tort Reform
- Voluntary Reporting Programs

Readings:

Pozgar: pp 297-306, pp 449-459

Supp: Tab 8

Joint Commission Sentinel Event Alert-April 11, 2008

Medical Errors Press Coverage

See, www.healthgrades.com

Adverse Health Reporting Law: Minnesota's 28 Reportable Events, MDH Fact Sheet-October, 2007

Background on MN's Adverse Health Events Reporting

Minnesota Adverse Event Reporting Statutes

See, <http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf>

News Release-Patient Safety and Quality Improvement Act of 2005, July 29, 2005

Statement of Administration Policy, July 27, 2007

See, Pub. L. No. 109-41

Denver Post Article: *Insurer's Plan: Cut Malpractice Suits*

COPIC's 3Rs Program of ADR

See, <http://www.npsf.org/download/Morath.pdf>

States with Apology Laws

October 30, 2008:

- Confidentiality and Disclosure-A Caregiver's Duty/ A Compliance Professional's Role
- Statutory Obligations-Reporting Requirements
- Health Information Management
- HIPAA Privacy

Readings:

Pozgar: pp 272-274

Supp: Tabs 9 & 10

Humphers v. First Interstate Bank of Oregon, 696 P.2d 527 (Or.1985)

Doe v. Medlantic Health Care Group, Inc., 814 A.2d 939 (D.C.2003)

MDH Communicable Disease Rptg Requirements

Communicable Disease Reporting and HIPAA

www.hhs.gov/ocr/hipaa

<http://www.healthprivacy.org>

Health Information Privacy Fact Sheets (2)

Herman v. Kratche, WL 3240680 (Ohio App., 2006)

Acosta v. Byrum, 638 S.E.2d 246 (N.C. App. 2006)

HIPAA Security Rule Summary

November 6, 2008

- HIPAA Privacy Cont.
- HIPAA Security
- New and emerging issues

Readings: See Above

November 13, 2008:

- Crisis Management-The Role of the Compliance Professional
- Pandemic Influenza – A Case Study

Guest Lecturer: Michael Osterholm, Ph.D., M.P.H., Director, Center for Infectious Disease Research & Policy, Associate Director, National Center for Food Protection and Defense, Professor, School of Public Health, University of Minnesota

Readings:

Supp: Tab 11

35W Bridge Collapse and HCMC: Press Coverage

Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers, American Health Lawyers Association (2008)

(Distributed in Advance of Class)

Perspective, Preparing for the Next Pandemic, M. T. Osterholm, N. Engl. J. Med. 352;18, May 5, 2005

November 20, 2008

- Understanding Quality Control Laws and Regulations
 - Acute Care Setting
 - Long Term Care Setting
 - Minnesota Vulnerable Adults Act
- Compliance Considerations in the Long Term Care Setting
- Liability of Health Care Professionals in Acute Care Setting
 - Standard of Care
 - Telemedicine and the Internet
 - Incident Reports and other Hospital-Generated Proceedings
- Compliance Considerations in the Acute Care Setting
- Documentation
- A Word About the “E-Commerce Patient”
- How to Effectively Prevent/Address Liability Issues in the Acute Care Setting
 - Independent Contractors
 - Hospital Direct Liability

Readings:

Pozgar: pp 131-155

Supp: Tab 12

See, <http://www.health.state.mn.us/divs/fpc/fpc.html>

See, <http://www.cms.hhs.gov/NursingHomeQualityInits/>

See, 42 U.S.C.A. Section 1396r (Requirements for Nursing Homes)
Fairfax Nursing Home, Inc., v. U.S. Dept. of Health & Human Services,
300 F. 3d 835 (7th Cir. 2002)

Hall v. Hilbun, 466 So.2d 856 (Miss.1985)

Washington v. Washington Hospital Center, 579 A.2d 177 (1990)

December 4, 2008

- The Role of Compliance in Patient Consent
 - Informed Consent
 - Assessing the Consent Form
 - The Physician’s Obligation
 - The Institution’s Obligation
 - Disclosure of Provider Specific Information
- Licensing of Health Care Professionals
 - Discipline and Due Process
 - Telemedicine
- Alternative and Complementary Medicine

Readings:

Pozgar: pp 277-295, pp 250-251

Supp: Tab 13

Canterbury v. Spencer, 464 F.2d 772 (D.C.Cir.1972)

Johnson v. Kokemoor, 545 N.W.2d 495 (Wis.1996)

See, <http://www.state.mn.us/portal/mn/jsp/home.do?agency=BMP>

Minnesota Board of Medical Practice

See, <http://www.revisor.leg.state.mn.us/stats/147/> (Physicians Practice Act)

Hoover v. The Agency for Health Care Administration, 676 So.2d 1380 (Fl. App. 1996)