2012

BUAD 625-01 Health Industry Law, Regulation and Ethics

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XAVIER UNIVERSITY  
WILLIAMS COLLEGE OF BUSINESS  
SYLLABUS for BUAD 625-01  
Health Industry Law, Regulation and Ethics  
Wednesdays, 6:00 - 8:30 p.m.  
January 11- May 2, 2012  
Location: Smith Hall Rm. 349

Professor Ann Marie Tracey, 228 Smith Hall, Xavier University, 3800 Victory Parkway, Cincinnati, Ohio 45207-1211. Telephone: (513) 745-3129, Fax: 745-4383, e-mail: traceya@xavier.edu.

Office Hours: Monday, 10:00 a.m. – 1 p.m., Tuesdays/ Thursdays 1:30-3 p.m., and by appointment. Prof. Tracey also checks email regularly, and will respond as promptly as possible. She is also available before class in 228 Smith Hall.

Williams College of Business Mission Statement: “We educate students of business, enabling them to improve organizations and society, consistent with the Jesuit tradition.” This tradition includes integrating culture and responsibility, individual accountability and growth, and service to others.

Health Industry Law, Regulation and Ethics

Prerequisite: BUAD 600

This course offers an overview of the legal, and regulatory and ethical environment of the health industry in the U.S. It examines principles and practical applications of the laws that affect the operational decisions of the various players in the health industry including pharmaceutical and biotech companies, health care providers, insurance companies, third parties, and managers, and how health care regulations have an impact on the development of markets for health care products and services. The effects of government policies, regulations and statutory and case law on the health industry are examined, including in the context of federal and state entitlement programs. Students will consider the social, moral, and ethical decision-making opportunities encountered in trying to balance the interests, needs and rights of citizens against those of society. Through interactions with health industry experts and case studies, students will explore the role of government in regulating the health industry and health applications of the law, of torts/malpractice, contracts, government and organizational regulation and administrative law. This course will challenge students and equip them to evaluate and recognize legal and ethical issues in the health environment while managing legal risks in a decision-making framework.

BUAD 625 satisfies the WCB Mission Statement by exposing students to both the legal/ regulatory and ethical aspects of the health industry. Course topics include: health industry ethics overview, health care reform and the health industry, issues facing health care providers challenges and strategies, malpractice and risk allocation, fraud and criminal liability, whistleblowers and false claims, insurance public health and the health industry, medical devices, employment, and issues implicated in clinical research and testing. It is critical for health industry professionals to understand and appreciate these issues in order to best meet their responsibilities as well as to develop proactive strategies to successfully navigate the legal and ethical challenges they will face. Viewing the material through both legal and ethical perspectives is consistent with the Jesuit tradition.
STUDENT LEARNING OUTCOMES FOR THE COURSE ARE FOR STUDENTS TO:

- Explain the legal, regulatory and ethical issues organizations and professionals in the health industry face.
- Demonstrate communication skills related to health industry legal and ethical issues.
- Correlate the legal, regulatory and ethical aspects of issues implicated in health care to the health industry.
- Critically examine health industry laws and regulations.
- Assess proactive strategies to address an ever-changing health industry legal and regulatory landscape.

COURSE DESCRIPTION:

The course is structured to explore and analyze the relationship between law, the regulatory environment and ethics in the health industry. Students will have the opportunity to do so by reviewing current sources in the topics to be examined, engaging with industry experts, analyzing issues with classmates, writing and presenting two research papers on approved topics, and leading a class discussion the students' research.

COURSE MATERIALS:

Professor Tracey will provide the materials through handouts and Blackboard postings under Course Documents and Groups.

COURSE ASSESSMENT:

Evaluation of student comprehension, reflection, and ability to integrate materials is multi-faceted. It is based on the student's evidence of preparedness for class, contributions to in and out of class discussions on class topics. Regular quizzes also gauge the student's understanding of material. Three research papers allow the student to explore and explain a current health industry legal or ethical issue, and reflect the student's ability to correlate the legal and regulatory applications to the health industry and well as to critically examine them. Research presentations further provide the student with the opportunity to demonstrate communication skills related to the health industry and that the student has successfully accomplished the learning outcomes.
TENTATIVE SEMESTER SCHEDULE

Always go to the Blackboard course and open the documents folder for that week’s material. This material (including the web readings and .pdf articles) is “fair game” for quiz questions and class discussion. Discussion Board is available each week under Blackboard.

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Assignments: listed on Blackboard and below</th>
<th>Invitees/ Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/11/12</td>
<td>Introduction to Health Industry Law, Regulation and Ethics</td>
<td>See e-mail / Blackboard</td>
<td></td>
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<tr>
<td>1/18/12</td>
<td>Ethics and the Health Industry</td>
<td></td>
<td>Prof. Mary Beth Shagena</td>
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<td></td>
<td>Bloomberg Health Industry Resources</td>
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<tr>
<td>1/25/12</td>
<td>PHARMA Research and Testing: Legal and Ethical Implications Alt. date</td>
<td>Prepare three questions on topic for speaker</td>
<td>Thomas Todardo, M.D., J.D., MedPace</td>
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<tr>
<td>2/1/12</td>
<td>Quiz #1 Health Care Providers: Regulatory and Compliance Challenges and Strategies</td>
<td>Prepare three questions on topic for speaker</td>
<td>Pamela Popp, Esq. Legal Counsel, HealthSource of Ohio</td>
</tr>
<tr>
<td>2/8/12</td>
<td>Privacy, Electronic Records, and HIPPA</td>
<td>Prepare three questions on topic for speaker</td>
<td>Claudia Allen, J.D.</td>
</tr>
<tr>
<td>2/15/12</td>
<td>Whistleblowers, False Claims and the Health Industry</td>
<td>Prepare three questions on topic for speaker</td>
<td>Glenn V. Whitaker, Esq, The Vorys Firm</td>
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<tr>
<td>2/22/12</td>
<td>Fraud, Criminal Liability and the Health Industry</td>
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<tr>
<td>2/29/12</td>
<td>Health Care Reform and the Health Industry Part I</td>
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<tr>
<td>3/7/12</td>
<td>NO CLASS SPRING BREAK</td>
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<tr>
<td>3/14/12</td>
<td>Health Care Reform, the Health Industry and Business Part II</td>
<td>Paper # 2 due Prepare three questions on topic for speaker</td>
<td>John Sinclair, Mercer, Partner</td>
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<tr>
<td>Date</td>
<td>Topic</td>
<td>Paper Presentations</td>
<td>Speaker</td>
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<td>3/21/12</td>
<td>Medical Devices: Development and Liability</td>
<td>Prepare three questions on topic for speaker</td>
<td>Michael Suffren, Esq.</td>
</tr>
<tr>
<td>3/28/12</td>
<td>Legal and Ethical implications regarding Insurance, Medicare, Medicaid</td>
<td>Prepare three questions on topic for speaker</td>
<td>Amy Renshaw</td>
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<tr>
<td></td>
<td>tentative date</td>
<td></td>
<td>Charlie Perin</td>
</tr>
<tr>
<td>Quiz #4</td>
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<tr>
<td>4/4/12</td>
<td>Paper Presentations</td>
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<tr>
<td>4/11/12</td>
<td>Employment Issues and the Health Industry</td>
<td>Paper # 3 due</td>
<td>Pam Popp, J.D., R.N.</td>
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<td>Prepare three questions on topic for speaker</td>
<td>Legal Counsel, HealthSource of Ohio</td>
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<tr>
<td>4/18/12</td>
<td>Malpractice, Ethics, and Risk Allocation</td>
<td>Prepare three questions on topic for speaker</td>
<td>David Kamp, Esq., White, Getgey &amp; Meyer, LPA</td>
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<td>4/25/12</td>
<td>The Public and the Health Industry</td>
<td>Prepare three questions on topic for speaker</td>
<td>Kevin Flynn, Esq.</td>
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<td>Quiz # 5</td>
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<tr>
<td>5/2/12</td>
<td>Last Class</td>
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**COURSE GUIDELINES:**

Please help us all get the most from the classroom component by:

1. **Attending every class** enables the student to access important material on each topic and to contribute to the learning environment of the entire class. Students who are unable to attend a class should notify Prof. Tracey promptly; missing more than one class falls short of meeting course requirements. By absence the student risks receiving a lower grade, or even a failing grade, depending upon the number of absences, regardless of the student's class participation, paper, team, or quiz scores.

2. **Being prepared** to discuss all assigned readings and cases in class. The best learning occurs by thoroughly preparing the material before class and actively engaging in discussion during class.

3. **Submitting only your own work product, returning tests and keeping them confidential, reporting cheating, plagiarism, or other ethics violations promptly.** (See paper requirements.)
4. As a courtesy to all present, please turn off cell phones and other electronic devices prior to entering the classroom. During class, texting, surfing the web, and unauthorized photographing is inappropriate behavior. When assigning course grades, a grading penalty may be imposed in cases of uncivil behavior stemming from disruptive or distracting classroom conduct.

ASSIGNMENTS: All assignments must be 12-point font, stapled, and bear the class designation and student’s name.

GRADING

Final grade cutoff: A >= 95, A- >= 92, B+ >= 88, B >= 85, B- >= 82, C+ >= 78, C >= 70, F < 70.

Grade weights:

<table>
<thead>
<tr>
<th>Grade weights</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>a. Quizzes</td>
<td>25%</td>
</tr>
<tr>
<td>b. Class contributions</td>
<td>30%</td>
</tr>
<tr>
<td>c. Research Papers</td>
<td>30%</td>
</tr>
<tr>
<td>d. Research Presentations</td>
<td>15%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100%</td>
</tr>
</tbody>
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Prof. Tracey reserves the right to adjust the grade to reflect appropriately student performance in light of the course and WCB standards.

1. **QUIZZES (25% of grade)** begin designated classes. (There is no final examination.) **BRING #2 PENCIL TO CLASS.** Each test will consist of multiple-choice questions, derived from the assigned readings and designated handouts for that class, and the last class presentations and discussions (not previous assigned reading unless discussed in class). Recognizing travel and other demands on students, the lowest quiz score is dropped, in lieu of a makeup exam. No makeup exams are offered.

2. **CLASS CONTRIBUTIONS (30% of grade):** This class will be offered seminar style, and each student is an important member of the class. It is expected that students come to class prepared to discuss the topics presented, and to engage with the instructor(s) and each other in a mature, complex way. Contribution grades reflect the quality of contributions, the depth and sophistication of questions posed in class, volunteering in class (without dominating the discussion), being prepared, relating course materials to organizational and ethical challenges, participating in any blackboard discussions, offering feedback, contributing insight and material (e.g., information about effective policies, sharing articles) and the like. Blackboard discussion questions and/or reflective assignments are posted per topic area each week, and are available until 5 p.m. the following Tuesday. Credit for Blackboard participation is allocated to the week the topic is assigned. Absences, missing parts of class, disruptive behavior, failure to engage in the class and not being prepared will reduce grades. A student can obtain partial credit for contributing on a week she or she misses class through an online contribution.

Outstanding contributions to the class discussion will:
- Display extensive preparation for class
- Bring additional resources and value to the class discussion
- Reflect a desire to add value to classmates, the flow of the class as the professor directs, and to the topic(s) presented
- Reveal critical thinking, that is, demonstrating an insight of issues, distinctions, legal principles, reasoning, and related issues and concepts
- Contribute an understanding of ethical reasoning, embracing stakeholders, values, alternatives, and impact of decision-making.
3. **Health Industry Legal Research Papers (30% of grade):**

In three, 4-5 page original papers on different areas of concentration, on topics designated by Prof. Tracey, students will explore a current business legal, regulatory, and/or ethical issue facing the health industry. The majority of the paper should be research-based; the conclusion should include your reflection on the issue based upon your findings, research, experience, or insight, and incorporating ethical considerations. Professor Tracey must approve the topics. As this is a research paper, sources must be used and cited in footnotes appropriately, using the style sheet provided.

No more than 30% of the paper should be material (directly quoted or paraphrased) from other sources. Rather, include your own thoughts and analysis. Any words of another author must be quoted as well as cited. Failure to cite and quote directly borrowed material, failing to cite indirectly borrowed material, or failing to use quotation marks (“ ”) for another’s words is plagiarism, and may evoke failing the class or expulsion.

Research Papers are graded on:

- meeting and exceeding requirements including topic focus
- the quality of research and writing
- the sophistication and depth of discussion, going beyond course materials and lecture
- integrating course components
- the originality of the work
- the quality of the sources used

Papers which develop an approved topic, interpret and cite cases, regulations/statutes, law and professional journals or other quality works in a sophisticated analysis, properly and frequently cite factual references and integrate a number of authoritative articles, would merit an “A.” Papers which only meet minimal requirements, use vague or simplistic websites or textbooks, contain string citations, exhibit a “cut and paste” approach, and reflect a cursory analysis would receive a “C” grade or lower.

By 6:00 p.m. on the due date, a stapled hard copy of the paper is due in class as well as e-mailed to Turnitin.com. The Turnitin course number is 4677761, the title is Health Industry Law and Ethics, and the case-sensitive password is mbaethics1. Once you get to this web site (available through the Library’s research data base or a simple search), create a user profile, and click “student.” Use the class ID number and password Prof. Tracey provides. Late Papers will lose points.

**SAMPLE AREAS FROM WHICH TO SELECT MORE SPECIFIC PAPER TOPICS:**

- Challenges of Health Care Reform for Health Industry Providers
- Ethics in Pharmaceutical Research and Development
- Learned Intermediary Doctrine and Pharmaceutical Liability
- Strategies to combat Medicare Fraud
- Government Regulation and the Health Industry (pick an aspect)
- Challenges Facing the Whistleblower and the Organization
- Direct To Consumer Marketing

4. **Research Presentations (15% of grade):** Each student will lead the class in an approximate 10-12 minute interactive presentation and discussion of each of his or her papers. Students must provide Prof. Tracey before presenting and at the class and by email with any materials used (e.g., copy of power points, handouts). The presentation should conclude with the student’s own perspective on the topic.

The presentation will be assessed by the quality of the presentation and engaging the class in a discussion about the topic.
Thank you for joining us this semester in BUAD 625. I look forward to exploring with you the legal and ethical challenges the health industry faces.