Med_Inf 407-DL Syllabus

Karin Lindgren, Esq.

Legal, Ethical & Social Issues in Medical Informatics
Winter 2011

Contact Information:
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Instructor's Office Hours and Availability:
Office hours will be held by prior appointment only. There also will be an Instructor's Q&A Forum on the Blackboard Discussion Board for easy access to the Instructor for questions or concerns of general interest to the class. Otherwise, feel free to call or email the Instructor directly with more individual student questions or concerns.

Course Description: This course will present the legal and regulatory requirements applicable to healthcare data and information management systems, and stimulate critical thinking around selected topics related to the ethical and social impacts of information technology as they interface with the current healthcare regulatory environment. Some topics include HIPAA, medical ethics, fraud & abuse, data privacy and confidentiality, antitrust law, intellectual property issues, The Joint Commission, disclosure, transparency and accountability, compliance programs, including clinical research data compliance, healthcare data privacy and security regulations, and conflicts of interest.
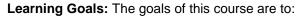
Course Readings:
There is no textbook for the MMI 407 course; however, students are expected to have read certain materials in advance of the first class (to be posted by Instructor prior to the start of the quarter), with further required readings to be assigned as the course moves forward.

Teaching Method:
The 407 course content will be delivered in a combination of interactive Adobe Connect lectures with PowerPoint presentations; faculty-led class discussions; required and optional readings; class issue-spotting exercises; student presentations; student-led online debates on Blackboard's Discussion Board; and conversations with guest speakers.

The Instructor makes extensive use of the NU Blackboard for distributing class reading assignments, copies of PowerPoints, communicating with students, class participation evaluation (Discussion Board), grades, student work submissions, and more.

Prerequisites: No previous background in law or medical ethics is necessary.

Learning Goals: The goals of this course are to:

- Identify Protected Health Information (PHI) and understand the range of permissible uses and disclosures allowed by HIPAA
- Develop ability to analyze, criticize and construct rigorous policy-oriented arguments for the appropriate handling of healthcare data
- Explain basic government regulations and legal principles applicable to healthcare data management, i.e. how to keep your CIO out of jail
- Summarize The Joint Commission's accreditation interest in medical informatics and data handling
- Identify the key components of an effective compliance program, including a demonstration of regulatory informatics
- Demonstrate critical thinking and thought leadership regarding future legal and ethical regulation of medical informatics in the U.S. social landscape.
- Basic facility with legal terminology to be in position to know when, and how, to consult effectively with corporate legal counsel

Evaluation: Students will be evaluated by:

- Projects: 70%
- Class participation, including Discussion Board, issue-spotting exercises and in-class: 30%

Discussion Board Etiquette: The purpose of Discussion Boards is to allow students to freely exchange ideas and participation is highly encouraged. It is important that we always remain respectful of one another's viewpoints and positions and, when necessary, agree to disagree, respectfully. While active and frequent participation is encouraged, cluttering a Discussion Board with inappropriate, irrelevant, or insignificant material will not earn additional points and may result in receiving less than full credit. Although frequency is not unimportant, content of the message is paramount. Please remember to cite all sources – when relevant – in order to avoid plagiarism.

Proctored Assessment: There is no proctored assessment requirement in this course.

Grading Scale:

A   95-100
A-   90-94
B+   88-89
B   83-87
B-   80-82

        <u>MMI Acceptable</u>

C+   78-79
C   73-77
C-   70-72
F   below 70

Attendance: For the online MMI 407 course, all scheduled synchronous sessions (i.e. Adobe Connect) will be held on Wednesday nights, unless otherwise indicated.

Late Work: Assignments will be accepted after the due date, but only with Instructor permission. If you will be turning in an assignment after the due date, points will be deducted; however, fewer points will be deducted for late work with advance notice to the Instructor, and with legitimate excuse for the delay.

Projects: Each student will be assigned three (3) projects during the course, with more details to be provided at the first class:

1. Group Case Study:
Participate in a group case study project, selected from a series of case studies provided to students, to be summarized in writing and presented to the class as if you were making a group presentation to a C-level executive (25%);

2. Criticism Project:
Read an older journal article relating to medical informatics (selected from a list to be provided), and write a thoughtful response to the article, including a rigorous critique and update of the author's premise/conclusions by applying the legal, ethical and social concerns learned in class (20%); and

3. Research Paper:
Write a research paper that presents a detailed forward-thinking proposal to improve upon some aspect of the legal regulation of healthcare data and/or information management systems, including taking a critical look at the relevant history of that legal issue, the current state, and most importantly the future state as envisioned by the student (25%).

Academic Integrity at Northwestern: Students are required to comply with University regulations regarding academic integrity. If you are in doubt about what constitutes academic dishonesty, speak with your instructor or graduate coordinator before the assignment is due and/or examine the University web site. Academic dishonesty includes, but is not limited to, cheating on an exam, obtaining an unfair advantage, and plagiarism (e.g., taking material from readings without citation or copying another student's paper). Failure to maintain academic integrity will result in a grade sanction, possibly as severe as failing and being required to retake the course, and could lead to a suspension or expulsion from the program. Further penalties may apply. For more information, visit:
http://www.scs.northwestern.edu/student/issues/academic_integrity.cfm

Plagiarism is one form of academic dishonesty. Students can familiarize themselves with the definition and examples of plagiarism, by visiting the site http://www.northwestern.edu/uacc/plagiar.html. Myriad other sources can be found online, as well.

Some assignments in this course may be required to be submitted through SafeAssign, a plagiarism detection and education tool. You can find an explanation of the tool here. In brief, SafeAssign compares the submitted assignment to millions of documents in very large databases. It then generates a report showing the extent to which text within a paper is very similar or identical to pre-existing sources. The user can then see how or whether the flagged text is cited appropriately, if at all. SafeAssign also returns a percentage score, indicating the percentage of the submitted paper that is similar or identical to pre-existing sources. High scores are not necessarily bad, nor do they necessarily indicate plagiarism, since the score doesn't take into account how or whether material is cited. (If a paper consisted of just one long quote that was cited appropriately, the score would be 100%. This wouldn't be plagiarism, due to the appropriate citation. However, just submitting one long quote would probably be a pretty bad paper.) Low scores are not necessarily good, nor do they necessarily indicate a lack of plagiarism. (If a 50-page paper had all original material, except for one short quote that was not cited, the score might be around 1%. But, not citing a quotation would still be plagiarism.)

If SafeAssign is used, it includes an option in which the student can submit a paper and see the resultant report before submitting it to the instructor as a final copy. This ideally will help students better understand and avoid plagiarism.

Other Processes and Policies: Please refer to your SCS student handbook at
http://www.scs.northwestern.edu/grad/information/handbook.cfm for additional course and program processes and policies.

Course Schedule

Important Notes:

Changes may occur to the syllabus at the instructor's discretion. When changes are made, students will be notified via an announcement in Blackboard.

All times noted on the Course Calendar are in U.S. Central Time (Chicago).

Red font color means there is a mandatory student deadline or student participation expected.

Links to all Readings (articles and websites) can be found in the Course Content section for the session in which they're assigned.

Issue Spotting exercises will be discussed during Sync sessions at the beginning of the course and can be found posted in the Discussion Board forums later in the course.

Each Session you are required to participate in Discussion Board forums. Your participation in both posting and responding to other students' comments is part of your class participation grade.

All .ppt presentations will be posted on Blackboard, and will remain there for the rest of the quarter.

We use no textbook in 407, so there are extensive weekly Required Reading… a friendly word of caution not to get too far behind, but note that the course is front-loaded with content, so there is time later in the quarter to catch up if you fall behind!

Effective Fall 2008, no Final Exam is required for MMI 407.   NOTE: If there were, the Study Guide posted on Blackboard by the Instructor would contain the key concepts covered in this course and which students are expected to know upon completion of the course.

Please refer to the following pages for the course schedule and outline of each course Session.

<u>Session 1</u>: Week of January 3, 2011
Introduction to the American Legal System and Key Government Players in Medical Informatics

Learning Objectives:
After this session, the student will be able to:
- Identify the instructor expectations of this course and state student expectations
- Recognize the basic components and structure of the American legal system
- Identify the governmental regulatory players in medical informatics
- Understand the concept of issue-spotting

Course Content:
Required Readings – Please read these documents posted on Blackboard:
- History and Organization of State Judicial System
- Federal Judicial System
- Chapter Introduction to Outline of US Legal System
- HIPAA Patient Identifiers
- Privacy, Security and the Regional Health Information Organization
- The HIPAA Paradox

Optional Readings -
- Public Policy Analysis
- Homeland Security and HIM (AHIMA)
- Summary of the HIPAA Privacy Rule
- Toward a National Framework for the Secondary Use of Health Data

Sync Session: Wednesday, January 5th from 7-9pm (central time)
Agenda:
- Introduction to Instructor; Course Overview and Expectations; Review Course Calendar
- <u>Introduce Project #1</u>: Group Case Study Project (with Peer Assessment) (Due week of Oct 4th)
- Assign weekly Discussion Board Leaders
- Class Issue-Spotting Exercise: An Introduction
- The American Legal System and Foundations of Law and Ethics
- Who are the Key Governmental Regulatory Players in Medical Informatics Today?

Session 2: Week of January 10, 2011
Healthcare Data: Privacy and Security Issues for Medical Informaticists

Learning Objectives:
After this session, the student will be able to:
- Identify data privacy, confidentiality and security issues in healthcare, and especially in relation to The Health Insurance Portability and Accountability Act (HIPAA)
- Recognize when and how to consult effectively with legal counsel on data privacy/security issues
- Discuss a short case study to demonstrate various HIPAA compliance issues and suggest alternative approaches to HIPAA compliance, including a review of penalties for non-compliance
- Understand the five parts of the federal HIPAA law, with focus on Title II regarding medical data privacy and security
- Use HIPAA and other course Resources (found as the 2nd item listed in the Course Content tab) to research and work on Project #1.

Course Content:
Required Readings – Please read these documents posted on Blackboard:
- How to Approach the Final HIPAA Security Regulations
- Research Under HIPAA

Optional Readings -
- JAMA Reforming HIPAA Privacy Rule
- Top 10 Ways to Protect From Data Security Threats
- First HIPAA Covered Entity Settles with Government
- Are Troublesome HIPAA Changes of the Way?
- Employees Have Right to Privacy in Text messages
- Remote Use of ePHI
- Report from the Health Information Protection Taskforce to the State Alliance for e-Health

Sync Session: Wednesday, January 12 from 7-9pm (central time)
Agenda:
- Healthcare Data: Privacy and Security issues for Informaticists, especially HIPAA Regs (.ppt)
- **Class Issue-Spotting Exercise**

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<u>Session 3</u>: Week of January 17, 2011
Group Case Study Presentations

Learning Objectives:
After this session, the student will be able to:
- Present Group case studies
- Analyze the presentations given by your Group, as well as your classmates' Groups, on the Peer Assessment Form
- Gain greater facility with HIPAA regulations and the language of the privacy rule
- Develop the ability to make a business case for change to your CEO/CIO

Course Content:
Required Readings – Please read these documents posted on Blackboard:
- How to Launch a Data Governance Program (INFORMATICA)
- The State of RHIOs

Optional Readings -
- Securing eHealth records Without Impeding Flow of Information
- The Role of Ethics in IT Decisions

Assignment(s):
For more information, click *Assignments* on the left navigation bar in Blackboard, and scroll to this assignment's item:
- **Individual Case Study Paper……………………………………………Due Monday, January 17th**
- **Individual Peer Assessment on Group Case Studies…………..…………..Due Friday, January 21st**

Sync Session: Wednesday, January 19th from 7-9pm (central time)
Agenda:
- **Group Presentations of Case Studies to Class**
- Introduce Project #3: Research Paper (Due Friday, March 11)

Session 4: Week of January 24, 2011

Fraud and Abuse Issues and Compliance Issues

Learning Objectives:
After this session, the student will be able to:
- Evaluate fraud and abuse issues
- Determine how conflicts of interest can be avoided
- Identify key components of an effective compliance program
- Identify when and how to consult effectively with a corporate compliance officer on compliance issues
- Understand the concept of the session's issue-spotting exercise

Course Content:
Required Readings – Please read these documents posted on Blackboard:
- Conflicts of Interest in Human Subject Research
- Health Data Access, Use, and Control (AHIMA)
- Hospitals Cautious About Subsidizing EMR Adoption Despite Relaxed Federal Rules
- Overview of Organizational Sentencing Guidelines

Optional Readings -
- Current Issues Under the Civil False Claims Act
- Healthcare Fraud & Abuse 101

Sync Session: Wednesday, January 26th from 7-9pm (central time)
Agenda:
- SESSION 3 FraudAbuseCompli IssueSpot Combo1.ppt
- **Class Issue-Spotting Exercise**
- Introduce Project #2: Criticism Paper (Friday, February 18th)

REMINDER: **CLEAR YOUR CHOICE AND SCOPE OF RESEARCH TOPIC WITH THE INSTRUCTOR WITHIN THE NEXT WEEK… 6 WEEKS TO DEADLINE.**

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<u>Session 5</u>: Week of January 31, 2011
Intellectual Property Issues in Informatics

Learning Objectives:
After this session, the student will be able to:
- Identify various intellectual property (IP) issues in medical informatics
- Understand what you can do to protect IP you are creating
- Learn key triggers or red flags which require action to protect IP assets
- Know how to document "first use"
- Be able to analyze and discuss Fair Use of copyrighted works
- Understand the concepts of intellectual property in the class issue-spotting exercise

Course Content:
Required Readings – Please read these documents posted on Blackboard:
- "Fair Use" of Copyrighted Works
- Summary of IP Protections
- Understanding the importance of Derivative Works

Optional Readings -
- Advanced Copyright Issues on the Internet
- Clean Rooms are Not Just for Kids: How to demonstrate independent development to avoid a trade secret lawsuit

Sync Session: NO SYNCH SESSION THIS WEEK
See class materials posted on Blackboard:
- Intellectual Property Issues in Medical Informatics (.ppt)
- **Class Issue-Spotting Exercise**

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Session 6: Week of February 7, 2011
Ethical and Social Issues for Medical Informaticists and
Interactive Class Discussion of Ethics Case Studies

Learning Objectives:
After this session, the student will be able to:
- Recognize key common medical ethics and social issues
- Analyze several medical ethics case studies
- Discuss social issues arising from medical informatics
- Discuss ethical issues for professional medical informaticists
- Have new tools to evaluate the ethics of reporting medical data

Course Content:
Required Readings – Please read these documents posted on Blackboard:
- The Principle of Autonomy
- Beneficence
- Bioethics and Health Informatics
- Ethics and EHRs
- Ethical Dimensions in Public Reporting of Clinical Performance Data
- Justice
- Non-Maleficence

Optional Readings -
- AHRQ National Health Data Stewardship
- Forms of Ethical Reflection

Sync Session: Wednesday, February 9th from 7-9pm (central time)
Agenda:
- Ethical and Social issues of Concern to Informaticists: An Interactive Class Discussion of Ethics Case Studies (.ppt)
- Guest Speaker (Ethicist):
  - Mark Waymack, PhD, Associate Professor of Philosophy and Co-Director of Graduate Programs in Health Care Ethics at Loyola University - Chicago
- See Readings for this week, **including advance preparation of short Ethics Case Studies for discussion at this synch session Wednesday night.**

<u>Session 7</u>: Week of February 14, 2011
The Joint Commission's Accreditation and Regulatory Interests in Informatics

Learning Objectives:
After this session, the student will be able to:
- Understand what is the function of TJC
- Explore how a medical informaticist may interact with The Joint Commission
- Explain TJC's accreditation process
- Understand TJC's interest in collecting and analyzing clinical data

Course Content:
Required Readings – Please read these documents posted on Blackboard:
- Summary Rewarding Provider Performance
- TJC Measurement Data

Optional Readings -
- Rewarding Provider Performance
- TJC Data Activities Chronology

Assignment(s):
For more information, click *Assignments* on the left navigation bar in Blackboard, and scroll to this assignment's item:
- **Criticism Paper……………………………………………………………..Due Friday, February 18th**

Sync Session: NO SYNCH SESSION THIS WEEK
See class materials posted on Blackboard:
- TJC and Medical Informatics: The Joint Commission's Accreditation Interest in Data (.ppt)

<u>Session 8</u>: Week of February 21, 2011
Antitrust Issues Arising from Data Handling

Learning Objectives:
After this session, the student will be able to:
- Understand the various types and forms of anti-competitive conduct which violate antitrust laws
- Identify the antitrust issues that may result from the work of professional medical informaticists
- Learn to spot the triggers or red flags that should alert you to an antitrust issue
- Reinforce the antitrust concepts with a class issue-spotting exercise

Course Content:
Required Readings – Please read these documents posted on Blackboard:
- Legal Process and Electronic Health Records
- Maintaining a Legally Sound Health Record
- Antitrust Watch on Standard Setting Organizations (SSOs): Fox in the Henhouse?

Optional Readings -
- EHR Guidelines to Prevent Fraud
- Legal Issues and eHealth in the EU
- Legal Obstacles to eHealth

Sync Session: Wednesday, February 23rd from 7-9pm (central time)
Agenda:
- Antitrust Issues Arising from Data Handling (.ppt)
- **Class Issue-Spotting Exercise**

Session 9: Week of February 28, 2011
Regulatory Informatics: An Overview and Live Interactive Regulatory Informatics Demonstration

Learning Objectives:
After this session, the student will be able to:
- Understand the regulatory demands on medical informaticists applicable to clinical data collection.
- Explore a massive clinical database and understand the basic information architecture of the database.
- Recognize important legal and ethical issues arising from use of a clinical database as a tool for clinical and operational improvement.

Course Content:
Required Readings – There are no required readings during this session

Optional Readings -
- Cloud Computing Security Risks
- Legal Issues with Cloud Computing

Sync Session: Wednesday, March 2nd from 7-9pm (central time)
Agenda:
- Overview of Regulatory Informatics: A Live Interactive Regulatory Informatics Demonstration (.ppt)
- Guest Speaker (Regulatory Informaticist):
  - Leslie Prellwitz, MBA, Senior Director, Clinical Data & Informatics, University HealthSystem Consortium

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<u>Session 10</u>: Week of March 7, 2011
Research Paper

Learning Objectives:
- The focus of Week 10, the final week of the quarter, is completion of the students' 407 final project, the Research Paper.
- As always, feel free to reach out to the Instructor if you need to brainstorm issues relating to your Research Paper, need direction for further research resources, or just get stuck!

Course Content:
There are no readings for Session 10, in order to allow students maximum time to complete their 407 Research Papers, due on Friday of this week.

Assignment(s):
For more information, click *Assignments* on the left navigation bar in Blackboard, and scroll to this assignment's item:
- **Research Paper…………………………………………….…………..Due Friday, March 11, 2011**

Sync Session: NO SYNCH SESSION THIS WEEK