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2015

HESA 581 Legal Aspects of Health Care

William Freedman

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Xavier University
Graduate Program in Health Services Administration
College of Social Sciences, Health, and Education

**HESA 581:
LEGAL ASPECTS OF HEALTH CARE**

Number of credit hours	3 Graduate Credit hours
Semester	Fall 2015
Classroom	Alumni Center B13
Instructor name:	William M. Freedman, J.D. Richard L. Schuster, J.D., Ph.D.

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Course Description (from the University Catalogue)

Describes the legal climate within which the health care institution operates with an emphasis on the legal concepts that influence the activities of health care administrators.

Objectives/Domains/Competencies

Although this course will touch on many aspects of healthcare, there are a number of competencies that you will be expected to achieve during this semester. Below are listed the competencies that you are expected to master:

Competencies/Student Learning Outcomes for Clinical Processes (HESA 561)			
Course Objectives	Competency/ Student Learning Outcome	Minimum expected level of competence	Method of assessment
Be able to write papers that have correct grammar and spelling. Writing should be compelling and easy to understand.	#18 Be able to write in an effective, concise business style	Competent- writing shows correct grammar and writing skills and these are applied consistently. There is generally good organization of thoughts.	Written Assignments
Be able to use basic technology and presentation skills to deliver a presentation and deliver information to the audience.	#19 Be able to present information using appropriate oral skills and technology.	Competent- oral presentations get the point across and the speaker displays comfort in speaking.	Class Participation and presentations
-Be able to discuss how the legal system in the United States affects the deliver of healthcare. -Be able to discuss how the constitutional, statutory, regulatory and common law processes and mechanics that result in the development and interpretation of court-created rights (torts), privately created rights (contracts), and rights created by legislative branches of state and federal governments in the form of statutes and which are then interpreted and enforced by the executive branches of federal and state governments in the form of regulations, as they affect the organization and delivery of health care.	#23 Develop familiarity with, and the ability to identify and analyze, court-created legal rights and remedies and the principal statutes and regulations that affect the delivery of health care.	Competent- able to identify many legal rights and remedies, and the principal statutes and regulations that affect the delivery of healthcare in such a manner that suggests familiarity. Able to analyze and apply such information accurately, but application suggests some minor gaps in understanding.	Written assignments, classroom participation and classroom presentations; mid-term and final exams
-Be able to discuss how the current statutes and regulations directly affect the role of the patient's participation in the delivery of health care. These include an understanding of statutes and regulations affecting patients' rights and privileges with respect to (a) the security and use of their	#24 Be able to integrate legal considerations with financial, ethical and policy issues that arise in the course of the provision of health care services.	Competent- Able to recognize legal considerations that need to integrate with financial, ethical, or policy issues in the course of the provision of healthcare services. Able to integrate such legal considerations, but	Written assignments, classroom participation and classroom presentations; mid-term and final exams

<p>health information; (b) their ability to consent and withhold consent for themselves and others for treatment; (c) access to emergency care and other specific types of health services.</p> <p>- Be able to discuss how the various statutes and regulations that directly govern the manner in which health care providers may permissibly structure relationships between and among themselves. These include an understanding of statutes and regulations affecting financial relationships between health care providers that involve patients enrolled in regulated health care delivery systems, both governmental and nongovernmental.</p>		<p>integration suggests minor gaps in understanding how they are integrated.</p>	
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We will focus on current issues, recently decided cases and the latest developments affecting the application of the significant federal and state statutes to learn these principles and master these skills.

Course Requirements and Methodology

- **Requirements**
 - Prerequisites: Graduate level, HESA 571 with a minimum grade of C
- **Methodology**
 - **Learning**
 - You will learn in this course using a variety of learning and teaching methods. On an average week, you will spend approximately 10 hours learning in this course:
 - In Class Student Presentations 25%
 - Case Studies 25%
 - Team Activities 10%
 - Lectures 10%
 - Readings 15%
 - Class Discussion 15%
 - Exams: There are two assessments in true-false, multiple-choice, essay and short answer format. The first assessment occurs during Session 8 and will cover material from the beginning of the course through the end

of Session 8. The second assessment will take place as the final examination and will cover material from Session 1 through the end of the course. Each assessment will be timed. **Emphasis will be placed on questions that require decision-making, problem solving or application, not recall of a fact.** The student will have approximately 60 minutes to complete the mid-term assessment during Session 8 and will have the entire session to complete the final examination. Some questions may take less time; some questions may take a bit more time. Tests will cover the objectives from the respective sessions.

- A variety of learning activities are designed to support the course objectives, facilitate different learning styles, and build a community of learners. Learning activities for the sessions include the following:
 - Reading textbook assignments
 - Reading other articles as assigned
 - Participating in classroom discussions by responding to assigned topics/questions both individually and as a member of a group
 - Completing writing assignments by individualized exploration of topics

- **Evaluation**

- Performance for this course will generally be based upon these factors, in the proportions indicated:
 - Class attendance and participation: 20%
 - Midterm and other interim examinations: 20%
 - Written assignments: 20%
 - In-class presentation(s): 10%
 - Final examination 30%
- These are general guides. They are not final and binding upon the instructor, whose ultimate weighting of the factors, as well as the evaluation of each student's performance, are solely within the discretion of the instructor, and are final.
- Class attendance is expected and failure to attend will be reflected in the "class attendance and participation" grade. If you have a valid reason for missing class, contact your instructor prior to the class in question. Late assignments will result in deductions of up to 10% of the total points for the assignment.

Grading Scale:

This is the official scale of the Department

A: 94+	A-: 90-93
B+: 86-89	B: 82-85
B-: 80-81	C+: 75-79
C: 70-74	F: <69

Here is the Department's description of the letter grades:

- "A-" or above represents academic performance that is exceptional or significantly above

- expectations.
- “B” or above represents academic performance that meets or is somewhat above expectations.
 - “B-” or lower represents academic performance that is somewhat to significantly lower than expectations

Accommodations

Qualified students with disabilities who will require disability accommodations in this class are encouraged to make their requests to me by sharing their Accommodation Letters with me at the beginning of the semester either during office hours or by appointment. Disability related information is confidential. If you have not previously contacted Disability Services, I encourage you to do so by phone at 513-745-3280, in person on the Fifth Floor of the Conaton Learning Commons, Room 514, or via e-mail to Cassandra Jones at jonesc20@xavier.edu , to coordinate reasonable accommodations as soon as possible as accommodations are not retroactive.

It is my goal that this class be an accessible and welcoming experience for all students. If you are a student with a disability who may have trouble participating or effectively demonstrating learning in this course, contact me to arrange an appointment to share your Accommodation Letters from Disability Services and to discuss your needs. Disability related information is confidential. If you have not contacted Disability Services (located in the Learning Assistance Center) to arrange accommodations, I encourage you to do so by contacting Cassandra Jones, by phone at 513-745-3280, in person on the Fifth Floor of the Conaton Learning Commons, Room 514, or via e-mail at jonesc20@xavier.edu as soon as possible as accommodations are not retroactive.

Required Readings:

J. Stuart Showalter, *The Law of Healthcare Administration, Seventh Edition (2014)* ISBN 978-1-56793-644-5

For each of the class weeks during the semester, there are (1) assigned readings from the textbook, and (2) additional readings, which include the texts of decisions in reported cases, statutes, regulations, and articles.

Additional Resources:

All students should have a student Lexis-Nexis subscription to enable them to search the Lexis federal and state court databases to locate the texts of court opinions, statutes, and regulations. In addition, students will be provided with a vetted list of websites they can use for these same purposes with assurance that the results will be accurate and unbiased.

Academic Honesty (Xavier University Policy)

The pursuit of truth demands high standards of personal honesty. Academic and professional life requires a trust based upon integrity of the written and spoken word. Accordingly, violations of certain standards of ethical behavior will not be tolerated at Xavier University. These include theft, cheating, plagiarism, unauthorized assistance in assignments and tests, unauthorized copying of computer software, the falsification of results and material submitted in reports or admission documents, and the falsification of any academic record including letters of recommendation. All work submitted for academic evaluation must be the student's own. Certainly, the activities of other scholars will influence all students. However, the direct and unattributed use of another's efforts is prohibited as is the use of any work untruthfully submitted as one's own. Penalties for violations of this policy may include one or more of the following: a zero for that assignment or test, an "F" in the course, and expulsion from the University. The dean of the college in which the student is enrolled is to be informed in writing of all such incidents, though the teacher has full authority to assign the grade for the assignment, test, or course. If disputes of interpretation arise, the student, faculty member, and chair should attempt to resolve the difficulty. If this is unsatisfactory, the dean will rule in the matter. As a final appeal, the academic vice president will call a committee of tenured faculty for the purpose of making a final determination.

FACULTY NOTE

In addition to the above (taken directly from the University Catalog), please be aware that cutting and pasting from the Internet without attribution is unacceptable. If you use more than three words written by someone else, those words should be enclosed in quotation marks and appropriately noted.

This syllabus and course outline are subject to change.

Methodology for Grading Written Assignments

The following rubric will be utilized to determine your grade for each written assignment and class presentation you submit or present for this course:

Criteria	A Outstanding	B Proficient	C Basic	D-F Below Expectations
Critical Thinking	Rich in content Full of thought, insight, and analysis	Substantial information Thought, insight, and analysis has taken place	Generally competent Information has minimal depth	Rudimentary and superficial Minimal analysis or insight is displayed

Criteria	A Outstanding	B Proficient	C Basic	D-F Below Expectations
Connections	Clear connections to previous or current assigned readings and optional research	Some new ideas or connections Moderate depth and/or detail	Limited, if any connections Vague generalities	No connections are made Unfocused and off topic
Uniqueness	High creativity and innovative observations High level of depth and detail	Moderate creative thinking Moderate depth and detail	Few, if any new ideas or creativity Restatement or summarization of textbook or other materials	No new ideas Submission of a paper that simply repeats the words used in the textbook, the descriptive material accompanying the additional course materials, or simply copies material from the Internet or other third party source
Stylistics	Few grammatical or stylistic errors	Several grammatical or stylistic errors	Obvious grammatical or stylistic errors Errors interfere with content	Obvious grammatical or stylistic errors Makes understanding difficult

Methodology for Grading In-Class Presentations and Participation in Class Discussions

The following rubric will be utilized to determine your grade for your participation in class discussions:

Criteria	A Outstanding	B Proficient	C Basic	D-F Below Expectations
Critical Thinking	Rich in content Full of thought, insight, and analysis	Substantial information Thought, insight, and analysis has taken place	Generally competent Information has minimal depth	Rudimentary and superficial Minimal analysis or insight is displayed
Connections	Clear connections to previous or current assigned readings and optional research	Some new ideas or connections Moderate depth and/or detail	Limited, if any connections Vague generalities	No connections are made Unfocused and off topic

Criteria	A Outstanding	B Proficient	C Basic	D-F Below Expectations
Uniqueness	High creativity and innovative observations High level of depth and detail	Moderate creative thinking Moderate depth and detail	Few, if any new ideas or creativity Restatement or summarization of other textbook or other handouts	No new ideas Responding with an "I agree with..." statement
Stylistics	Few grammatical or stylistic errors Thorough and clear presentation Engaging delivery Substantive presentation completed within allotted time	Several grammatical or stylistic errors Presentation delivered with moderate persuasion Mostly clear in thought process	Obvious grammatical or stylistic errors Errors interfere with content	Obvious grammatical or stylistic errors Makes understanding difficult

Course Schedule

Dates/Sessions	Required Reading and Reference Material	Assigned Student-Led Class Presentations	Writing Assignment	Class Discussion Assignments
<p>Week 1</p> <p>August 25 2015</p> <p>Introduction to the Course; Sources of Law and the American Legal System</p>	<p>See Week 1 for readings</p>	<p>None</p>	<p>An in-class cooperative practice session: learn how to prepare a digest of a case.</p>	<p>Be prepared to discuss these topics:</p> <ol style="list-style-type: none"> 1. The order of precedence of court decisions and the choices litigants possess in choosing a forum -- and why that is important 2. The process of legislation and regulation writing: what materials will be generated? How should health care decision makers interpret these materials? What nuggets of information or guidance must health care decision be prepared to spot? 3. The mechanics of litigation and the importance of motions to dismiss, motions for summary judgment, and discovery. 4. Work with your classmates to see how judges write opinions and learn how to boil down primary source material to the essential elements that health care decision makers need to know. 5. Analyze several scenarios in which class members will apply the lessons in this week's material to actual fact patterns
<p>Week 2</p> <p>September 1 2015</p> <p>Contracts Continued--How They are Made, Interpreted and Enforced; Intentional Torts--An Introduction to the Basic Concepts of the One of the</p>	<p>See Week 2 for readings</p>	<p>See Week 2 for assigned student-led class presentations</p>	<p>Required: Analysis of <i>Kaplan v. Mayo Clinic</i>. See Week 2 for details of the assignment. Due at 6:00 p.m. on the day before this week's class.</p>	<p>Be prepared to discuss these topics:</p> <ol style="list-style-type: none"> 1. Lessons to be learned from <i>Millcreek Community Hospital v. Fairview Radiology, P.C.</i>-a case that illustrates the creation of a privately created right – a contract; the court's role as the arbiter of disputes involving privately created rights; the court's creation of rules to interpret a right; and an

Dates/Sessions	Required Reading and Reference Material	Assigned Student-Led Class Presentations	Writing Assignment	Class Discussion Assignments
Two Fundamental Types of Torts				<p>introduction to the steps in the litigation process</p> <p>2. Compare and contrast Hayes v. Oakridge Home to Brown v. Genesis Healthcare Corp: how can two courts in two states reach opposite conclusions on the same issue?</p> <p>3. Legislatures create rights and duties - and courts then interpret the scope and meaning of those rights and duties, using a variety of rules (developed by the courts) to determine what the legislature intended and how to interpret the text of the legislature's handiwork. Read Wainscott v. Centura Health Corp. (Colo. Ct. App. Aug. 14, 2014) to see how one court applied these principles. What lessons can we learn when attempting to craft policies and procedures for a health care provider or health plan?</p>
<p>Week 3</p> <p>September 8, 2015</p> <p>The Evolution of the Concept of Negligence from Two People Who Deal Directly with One Another to an Expanding Concept of Vicarious Liability: From "Control" to "I Thought She Controlled Him"</p>	See Week 3 for readings	See Week 3 for assigned student-led class presentations	<p>Analysis of <i>McCorry v. Evangelical Hospitals Corp.</i> and <i>Rawlins v. Daughters of Charity</i>. See Week 3 for details of the assignment. Due at 6:00 p.m. on the day before this week's class.</p>	<p>Read <i>Simineri et al. v. LifeCell Corp.</i>, No. L-5972-11 (Super. Ct. N.J., 5-8-2015). Be prepared to discuss these topics:</p> <ol style="list-style-type: none"> 1. What is the "learned intermediary" doctrine? 2. Who benefits from the application of the "learned intermediary" doctrine? Who shoulders additional risk as a result of the "learned intermediary" doctrine? 3. The U.S. Supreme Court has held that, since under the Food, Drug & Cosmetic Act, generic drug manufacturers must use the same label that the FDA approved when authorizing the sale of the branded version by the brand name manufacturer, generic drug manufacturers cannot be held liable for a failure to warn arising

Dates/Sessions	Required Reading and Reference Material	Assigned Student-Led Class Presentations	Writing Assignment	Class Discussion Assignments
				<p>out of hazards discovered after the original label was approved but before the FDA approves changes to the label for the brand name manufacturer. Does this produce differences in liability between brand-name manufacturers and generic manufacturers for the same product? What possible claims might a plaintiff attempt to bring against the prescribing physician of a generic drug? Use your research skills: see if you can find discussions of this legal principle, the Supreme Court decisions, and what happened when plaintiffs did seek to bring claims using other theories.</p>
<p>Week 4 September 16, 2015 (3:30 p.m.- 6:00 p.m.) Developing Areas of Negligence-Wrongful Birth and Wrongful Life; Issues in the Admission and Discharge of Patients</p>	<p>See Week 4 for readings</p>	<p>See Week 4 for assigned student-led class presentations</p>	<p>Analysis of “non-delegable duty” and <i>Albain v. Flower Hospital</i>. See Week 4 for details of the assignment <i>Due at 6:00 p.m. on the day before this week’s class.</i></p>	<p>Review the three articles that are included in this week’s materials, Be prepared to discuss these issues:</p> <ol style="list-style-type: none"> 1. How do the evolving standards and recommendations for tests and screenings designed to identify what can be catastrophic conditions potentially affect health care providers’ liability for breach of the standard of care? 2. How, if at all, should health care decision makers factor the effects that introducing innovative or leading edge tests may have on the cost of health care and potential liability -- not only for failure to perform a test but also for performing a test that is known, for example to have a material incidence of false positives? 3. How should health care institutions best manage the evaluation and potential inclusion of screening options and manage the flow of information to patients?

Dates/Sessions	Required Reading and Reference Material	Assigned Student-Led Class Presentations	Writing Assignment	Class Discussion Assignments
<p>Week 5</p> <p>September 22, 2015</p> <p>Consent for Treatment, Withholding Consent</p>	<p>See Week 5 for readings</p>	<p>See Week 5 for assigned student-led class presentations.</p>	<p>Prepare a one page consent form. See Week 5 for details. <i>Due at 6:00 p.m. on the day before this week's class.</i></p>	<p>Participate in a review of the lessons to be learned from the assigned student-led class presentation and the writing assignment.</p>
<p>Week 6</p> <p>September 29, 2015</p> <p>Medical Staff Issues: Money, Self-Interest and Risk Intersect: Granting, Denying, and Terminating Medical Staff Privileges; Exclusive Agreements; Economic Credentialing</p>	<p>See Week 6 for readings</p>	<p>See Week 6 for assigned student-led class presentations.</p>	<p>Analyze the effects on originating site hospital of CMS CoP Regulation on Telemedicine Credentialing. See Week 6 for details. <i>Due at 6:00 p.m. on the day before this week's class.</i></p>	<p>1. Having read the synopsis of the court's decision in <i>Murphy v. Baptist Hospital System</i>, what economically motivated maneuvering room do you think integrated health care delivery systems continue to possess -- and how should they tailor their desire to deal with competitors who happen to need access to the system's facilities?</p> <p>2. After you prepare your written assignment on the effect of the CMS final regulation on telemedicine credentialing on the "originating hospital," discuss in class, the potential magnitude of the risks the "originating" hospital faces. Do they outweigh the costs the "originating hospital" will incur if it does not adopt the policy in the CMS final regulation? Are there alternatives the originating hospital may deploy to shift the risk?</p>
<p>Week 7</p> <p>October 6, 2015</p> <p>Emergency Care and the Emergency Medical Treatment and Active Labor Act (EMTALA)</p>	<p>See Week 7 for readings</p>	<p>See Week 7 for assigned student-led class presentations</p>	<p>Read <i>Thomas v. St. Joseph Healthcare</i> and answer this question: Why did the court conclude that the hospital had a duty to stabilize an emergency condition even though the hospital argued that its screening failed to reveal an emergency condition? See Week 7 for details. <i>Due at 6:00 p.m. on the day before this week's class.</i></p>	<p>Participate in a review of the lessons to be learned from the assigned student-led class presentation s, the assigned readings, and the writing assignment.</p>

Dates/Sessions	Required Reading and Reference Material	Assigned Student-Led Class Presentations	Writing Assignment	Class Discussion Assignments
<p>Week 8</p> <p>October 13, 2015</p> <p>Conducting a Health Care Business to Minimize Exposure to Liability</p>	<p>See Week 8 for readings</p>	<p>None</p>	<p>None</p>	<p>Participate in a review of the lessons to be learned from the assigned readings.</p> <p>Take the quiz. See the Syllabus for details.</p>
<p>Week 9</p> <p>October 20, 2015</p> <p>The Wide World of Taxation: Conducting a Health Care Business to Minimize Exposure to Taxation, Especially When Partnering With Other Players</p>	<p>See Week 9 for readings</p>	<p>See Week 9 for assigned student-led class presentations</p>	<p>Prepare a one page analysis of the IRS's recent guidance on what tax-exempt entities must do to make sure their participation in an accountable care organization won't imperil their exempt status -- and the one area in which the IRS has refused to provide guidance or solace. See Week 9 for details. <i>Due at 6:00 p.m. on the day before this week's class.</i></p>	<p>Read IRS PLR 201533018 (denial of application for tax-exempt status as a Section 501(e) cooperative hospital service organization due to failure to allocate net profits and failure to perform any of the specified & required cooperative services on a centralized basis). We'll discuss these issues:</p> <ul style="list-style-type: none"> ●What business objectives did the hospitals seek to achieve? Were they realistic? ●What lessons can we learn about the IRS's approach to interpretation of the provisions of the Internal Revenue Code governing attempts by health care providers to characterize their operations as tax-free? <p>Then, read PLR 201436050 (healthcare organization established to reduce hospital readmissions denied 501(c)(3) status--organization's noncharitable founders controlled board and operations, allowing for inurement and private benefit; reducing readmissions benefited noncharitable founder thereby precluding existence of charitable purpose).</p> <ul style="list-style-type: none"> ● How seriously does the IRS treat possible inurement? ●What lessons can we learn about the IRS's approach to avoid the bad result the taxpayers suffered

Dates/Sessions	Required Reading and Reference Material	Assigned Student-Led Class Presentations	Writing Assignment	Class Discussion Assignments
				in this request for a ruling?
<p>Week 10 October 27, 2015 Fraud and Abuse Antikickback</p>	<p>See Week 10 for readings</p>	<p>None</p>	<p>Prepare your answers to the questions posed about Ducati Medical Center’s proposed cardiac emergency telemedicine arrangement with area community hospitals. See Week 10 for details. <i>Due at 6:00 p.m. on the day before this week’s class..</i></p>	<p>Using the resources for this week and your exploration of OIG advisory opinions and articles that you can retrieve using your student Lexis subscription, Google Scholar, and internet resources, review the scenarios described in “An Exercise in Hospital-Physician Joint Ventures” in the Course Materials for Week 10 and answer the questions that are posed at the end. We will review the scenarios and collaborate to reach answers to the questions.</p>
<p>Week 11 November 3, 2015 Stark II Physician Self-Referral</p>	<p>See Week 11 for readings</p>	<p>See Week 11 for assigned student-led class presentations.</p>	<p>Submit answers to the questions about the proposed joint venture between Home Health Services Company and Parent Physician Company in the Course Materials for Week 11. See Week 11 for details. <i>Due at 6:00 p.m. on the day before this week’s class.</i></p>	<p>Review the synopsis of the September 28, 2012 GAO Imaging Self-Referral Study and the CMS-OIG November 2, 2011 Interim Final Rule--Waiver of Stark-Antikickback for Certain ACOs and discuss topics listed in Week 11 Class Discussion. See Week 11 for details.</p>
<p>Week 12 November 10, 2015 False Claims Act; ERISA, Health Plans, and Health Care Providers</p>	<p>See Week 12 for readings.</p>	<p>See Week 12 for assigned student-led class presentations.</p>	<p>Read the text of <i>Advanced Orthopedics & Sports Medicine v. Blue Cross Blue Shield of Mass.-Health Plan’s Anti-Assignment Clause Deprived Out-of-Network Provider Standing to Sue the Plan Under ERISA for Failure to Make Adequate Payment</i>. Write a synopsis of the decision See Week 12 for details. . <i>Due at 6:00 p.m. on the day before this week’s class</i></p>	<p>Participate in a review of the lessons to be learned from the <i>False Claims Act written assignment</i> and the assigned reading on <i>ERISA preemption, ERISA remedies, and the in- and out-of-network provider</i>. See Week 12 for details.</p>

Dates/Sessions	Required Reading and Reference Material	Assigned Student-Led Class Presentations	Writing Assignment	Class Discussion Assignments
<p>Week 13</p> <p>November 17, 2015</p> <p>Rights and Responsibilities of Health Care Providers to Secure the Privacy of Patients' Health Information; Regulation of Health Care Facts- A Case Study</p>	<p>See Week 13 for readings</p>	<p>See Week 12 for assigned student-led class presentations.</p>	<p>Using the materials for this week's session, your student Lexis-Nexis subscription, and the internet resources supplied to you, answer the questions about the security requirements and restrictions that affect a health care provider's ability to use or disclose "protected health information" under HIPAA that appear in the document titled, <i>HIPAA Privacy and Security Scenarios.</i>"</p>	<p>We will discuss the questions about the security requirements and restrictions that affect a health care provider's ability to use or disclose "protected health information" under HIPAA that appear in the document titled, <i>HIPAA Privacy and Security Scenarios.</i></p> <p>Read the text of <i>Amarin Pharma, Inc. v. FDA</i> and "<i>Kardashian Promotes a Pill, and the F.D.A. Strikes-- F.D.A. Warns Company Over Kardashian Instagram Marketing</i>" (New York Times, 8-12-13-2015. We will discuss another aspect of "privacy": when and under what circumstances may the [federal] government regulate speech in the pursuit of health care safety and efficacy?</p>
<p>Week 14</p> <p>November 24, 2015</p>	<p>No class-Thanksgiving Holiday.</p>	<p>No class-Thanksgiving Holiday</p>	<p>No class-Thanksgiving Holiday</p>	<p>No class-Thanksgiving Holiday</p>
<p>Week 15</p> <p>December 1, 2015</p> <p>Antitrust</p>	<p>See Week 15 for readings.</p>	<p>See Week 13 for assigned student-led class presentations.</p>	<p>Read the FTC-DOJ October 2011 Guidelines for ACOs and answer this question: how do the final guidelines affect a health care system that wishes to form an accountable care organization all of whose physician participants will consist of physicians employed by the system? <i>Due at 6:00 p.m. on the day before this week's class.</i></p>	<p>We will discuss the issues raised in <i>Signature MD, Inc. v. MDVIP, Methodist Home Services Corp. v. OSF Healthcare System, St. Alphonsus Med. Ctr. v. St. Luke's</i>, and the complaint in <i>U.S. v. Hillsdale</i>. Prepare a one paragraph synopsis and participate in a discussion of these decisions and their implications.</p>

Dates/Sessions	Required Reading and Reference Material	Assigned Student-Led Class Presentations	Writing Assignment	Class Discussion Assignments
Week 16 December 8, 2015 Health Care Reform: Emerging Issues in the Delivery and Consumption of Health Care	See Week 16 for reference material.	See Week 16 for assigned student-led class presentations.	None	Using the reference materials for this Week, your textbook, and additional material you can retrieve using your student Lexis subscription, Google Scholar, and internet resources, meet with your team members and prepare written materials for your classmates to accompany your team's presentation on the topic to which you are assigned. See Week 16 for details..
Week 17 December 16, 2015 Final Exam	None	None	None	Take the final exam.

Week 1

Introduction to the Course; Sources of Law and the American Legal System; Introduction to Contracts August 25, 2015

Learning Objectives

1. Examine and understand the steps and rules by which litigation progresses and its implications for decision makers charged with formulating policies and procedures for the delivery of health care.
2. Examine and understand the steps by which legislation and regulations are published and codified so as to be able to locate and intelligently analyze these documents.
3. Master the elements of a valid and enforceable contract, how a people can find themselves to be deemed to have entered into a contract, and the applications of contract law to the delivery of health care.

Learning Activities and Assignments

Required Reading:

1. Chapters 1 and 2 and pages 103-109 of 7th Edition J. Stuart Showalter, **The Law of Healthcare Administration**
2. PowerPoint Presentation: An Introduction to the Course
3. PowerPoint Presentation: Introduction to the Legal System
4. Text of *Moore v. Clarian Health Partners (Indiana Supreme Court, 2012)*
5. The Standard a Judge Uses to Determine Whether to Grant or Deny a Party's Motion for Summary Judgment or a Motion to Dismiss for Failure to State a Claim (Excerpts from Cases Describing the Standard)
6. Text of *Wainscott v. Centura Health Corp.* (Colo. Ct. App. Aug. 14. 2014)-- An Example of a Statutorily Created Right or Duty-Hospital's Substantial Compliance With Hospital Lien Statute Sufficient To Preserve Hospital's Rights To Share Of Patient's Award In Subsequent Litigation Against Third Party For Injuries Treated By Hospital
7. OSMA 2007 Billing and Collection Practices for Health Care Providers
8. Scenarios To Practice Applying This Session's Key Points

Assignments to Bring to Class for Discussion:

Read the text of *Moore v. Clarian Health Partners (Indiana Supreme Court, 2012)*. Be prepared to participate in a class discussion of these questions:

1. The facts of the case: what are the salient facts of this case? The salient facts consist of two types of facts: what happened that led to the filing of the lawsuit? In what posture

was the case when the trial or intermediate appeals courts What happened in the trial or intermediate court of appeals? Remember: courts do two things: they set the procedural ground rules and they make substantive decisions of law.

2. What did the court whose opinion you are reading decide?
3. What lessons should we learn from this decision?

Read “Scenarios To Practice Applying This Session’s Key Points.” Review the questions posed for each of the scenarios. Be prepared to analyze each scenario in light of those questions.

Classroom Discussion:

Be prepared to discuss these topics:

1. The order of precedence of court decisions and the choices litigants possess in choosing a forum -- and why that is important
2. The process of legislation and regulation writing: what materials will be generated? How should health care decision makers interpret these materials? What nuggets of information or guidance must health care decision be prepared to spot?
3. The mechanics of litigation and the importance of motions to dismiss, motions for summary judgment, and discovery.
4. Work with your classmates to see how judges write opinions and learn how to boil down decisions to the essential elements that health care decision makers need to know - *Moore v. Clarian Health Partners*.
5. Analyze scenarios to learn how to apply the lessons in this week’s material to actual fact patterns.

Week 2

Contracts Continued--How They are Made, Interpreted and Enforced; Intentional Torts--An Introduction to the Basic Concepts of the One of the Two Fundamental Types of Torts September 1, 2015

Learning Objectives

1. Practice the art of reading statutory or case law material and extracting the key facts, the key procedural issues, the nub of the court's decision (in the case of a court opinion), and distilling the lessons to be learned for health care decision makers
2. Understand basic elements of one of the two traditional types of "torts" -- intentional conduct --: the elements of each cause of action that a plaintiff must prove in order to avoid dismissal, and the affirmative defenses a defendant may possess even if the plaintiff can sustain the plaintiff's burden of proof as to each of the elements of the cause of action.
3. Evaluate steps health care providers can take to evaluate and control exposure to liability for alleged intentional conduct.

Learning Activities and Assignments

Required Reading:

1. Pages 103-123 of Chapter 4 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**
2. Session 2 Lecture Handout--*Background on Contracts*
3. Text of *Millcreek Community Hospital v. Fairview Radiology, P.C.*
4. Text of *Hayes v. Oakridge Home*, 122 Ohio St.3d 63, 2009-Ohio-2054
5. Text of *Kaplan v. Mayo Clinic*, 653 F. 3d 720 (8th Cir. 2011)
6. Text of *Hogue v ProPath Lab*--A case that illustrates how statutes of limitation operate.
7. Text of *Tener v. Cremer* (N.Y. Sup. Ct., 8/1/12)--The Internet and Patient Dissatisfaction: What Can Patients Say Without Committing the Intentional Tort of Defamation (and Libel in Particular)?
8. Text of *Ginn v. Stonecreek Dental Care* (OH 12th Dist. Ct. App. 4-27-15)-- Trial Court Mistakenly Granted Directed Verdict Against Plaintiff-Dentist In Favor of Employer of Dentist Who Sold Practice to Plaintiff with a Restrictive Covenant on Claim of Tortious Interference with Contract and Correctly Granted Directed Verdict To Employer on Claim For Tortious Interference With Business Relationship Between Plaintiff And Patients Of The Purchased Practice
9. Text of *Javorsky v. Sterling Medical* (OH Ct. App. 7th Dis. 5-27-15)-Court Denies Motion to Dismiss Plaintiff Physician's Breach of Contract Complaint-Contract Plus

Email Adequately Demonstrates Contract Renewal and Possible Breach by Employer for Failure to Give Notice of Termination Required in the Contract

10. Synopsis of *Wayt v. Community Health Sys., Inc.*, Ohio Ct. C.P., No. 2012CV03479, verdict 2/6/15)--Jury Awards Ohio Nurse \$2 Million (Including \$750,000 Punitive Damages) For Defamation for Pretextual Firing in Retaliation for Union Activity
11. Text of *Wainscott v. Centura Health Corp.* (Colo. Ct. App. Aug. 14. 2014)-- Hospital's substantial compliance with hospital lien statute sufficient to preserve hospital's rights to share of patient's award in subsequent litigation against third party for injuries treated by hospital

NB: Please note that ALL students are expected to read and be familiar with all cases and articles, including the cases or articles assigned to a fellow student for presentation. ALL students should prepare a written synopsis of each case as a study guide and as a means of mastering the principles to be learned from the case. You may be asked to supplement a class member's presentation. Be prepared.

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK'S CLASS.

Read the text of *Kaplan v. Mayo Clinic*, 653 F. 3d 720 (8th Cir. 2011)

Write a synopsis of the decision. Your synopsis should follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. "The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff's name] appealed.

Part Three: The Court's Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Part Four: Assume that you are charged with supervision of risk management at Mayo Clinic. Based on the answer you and your classmates posted to Step 1, what choices does the Clinic possess at this point -- and what would you advise the Clinic's executives to do?

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences. Remember: Your instructors will stop reading after one page.

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of one of these cases:

1. Text of *Hogue v ProPath Lab*--A case that illustrates how statutes of limitation operate.
2. Text of *Tener v. Cremer* (N.Y. Sup. Ct., 8/1/12)--The Internet and Patient Dissatisfaction: What Can Patients Say Without Committing the Intentional Tort of Defamation (and Libel in Particular)?
3. Text of *Ginn v. Stonecreek Dental Care* (OH 12th Dist. Ct. App. 4-27-15)-- Trial Court Mistakenly Granted Directed Verdict Against Plaintiff-Dentist In Favor of Employer of Dentist Who Sold Practice to Plaintiff with a Restrictive Covenant on Claim of Tortious Interference with Contract and Correctly Granted Directed Verdict To Employer on Claim For Tortious Interference With Business Relationship Between Plaintiff And Patients Of The Purchased Practice
4. Text of *Javorsky v. Sterling Medical* (OH Ct. App. 7th Dis. 5-27-15)-Court Denies Motion to Dismiss Plaintiff Physician's Breach of Contract Complaint-Contract Plus Email Adequately Demonstrates Contract Renewal and Possible Breach by Employer for Failure to Give Notice of Termination Required in the Contract

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the

judge's decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. "The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff's name] appealed.

Part Three: The Court's Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court's decision, and the implications of the court's decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court's final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Students who have been assigned an article or case to present in class must submit their written synopses BY 6:00 P.M. ON THE DAY BEFORE THE CLASS FOR WHICH THE STUDENT WAS INITIALLY ASSIGNED TO PRESENT.

Classroom Discussion:

Be prepared to discuss these topics:

1. Lessons to be learned from *Millcreek Community Hospital v. Fairview Radiology, P.C.* - a case that illustrates the creation of a privately created right – a contract; the court's role as the arbiter of disputes involving privately created rights; the court's creation of rules to interpret a right; and a review of the steps in the litigation process

2. Compare and contrast *Hayes v. Oakridge Home* to *Brown v. Genesis Healthcare Corp.*: how can two courts in two states reach opposite conclusions on the same issue?
3. Legislatures create rights and duties - and courts then interpret the scope and meaning of those rights and duties, using a variety of rules (developed by the courts) to determine what the legislature intended and how to interpret the text of the legislature's handiwork. Read *Wainscott v. Centura Health Corp.* (Colo. Ct. App. Aug. 14. 2014) to see how one court applied these principles. What lessons can we learn when attempting to craft policies and procedures for a health care provider or health plan?

Week 3

Negligence: The Evolution of the Concept of Negligence from Two People Who Deal Directly with One Another to an Expanding Concept of Vicarious Liability--From "Control" to "I Thought She Controlled Him" **September 8, 2015**

Learning Objectives

1. Understand basic elements of negligence: the elements of the cause of action of negligence that a plaintiff must prove in order to avoid dismissal, and the affirmative defenses a defendant may possess even if the plaintiff can sustain the plaintiff's burden of proof as to each of the elements of the cause of action.
2. Learn how the concept of negligence has expanded to expose defendants -- health care providers in particular -- to liability for the conduct of an expanding universe of people.
3. Evaluate steps health care providers can take to evaluate and control exposure to liability for alleged negligent conduct
4. Evaluate the options (and their drawbacks) that health care providers might deploy to either minimize or shift responsibility in the expanding universe of potential liability.

Learning Activities and Assignments

Required Reading:

1. Chapter 5 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**
2. Session 3 Lecture Handout: *Negligence*.
3. Edited Text of *Simineri et al. v. LifeCell Corp.*, No. L-5972-11 (Super. Ct. N.J., 5-8-2015): Learned Intermediary Doctrine Applies to a Distributor-Manufacturer's Supply of Tissue Implants Prescribed by Physicians-Manufacturer's Duty to Warn Satisfied by Notifying Physician
4. Text of *Matsuyama v. Birnbaum*--a case that explores liability for "loss of chance" as a separate claim of negligence even when the pre-incident chance of survival is less than 50%.
5. Text of *Mackey v. Sarroca* (Ill. App. Ct. 4/27/15): can a telephone conversation create the first element of the tort of negligence (the physician-patient relationship in which a physician owes a duty of care to the patient)?
6. Text of *McCorry v. Evangelical Hospitals Corp.*, 771 N.E.2d 1067, 331 Ill. App.3d 668, 265 Ill. Dec. 108 (2002)--a case involving the potential liability of a hospital for the conduct of a third party -- a community-based physician.
7. Text of *Estate of Cordero v. Christ Hospital*---- a case involving the potential liability of a hospital for the conduct of a third party -- a hospital-based physician.
8. Text of *Olson v Wrenshall*, 822 NW 2d 336 (Neb Sup Ct 2012) --do the physicians transplanting a kidney in the donee owe a duty to the kidney donor?

9. Text of *Rawlins v. Daughters of Charity*, No. 03-10-00092-CV, (Court of Appeals of Texas, Third District, August 26, 2011)-- a case involving the potential liability of a hospital for the conduct of a third party -- a hospital-based physician.

NB: Please note that ALL students are expected to read and be familiar with all cases and articles, including the cases or articles assigned to a fellow student for presentation. ALL students should prepare a written synopsis of each case, including the cases assigned to your classmates for an in-class presentation, as a study guide and as a means of mastering the principles to be learned from the case. You may be asked to supplement a class member's presentation. Be prepared.

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 PM ON THE DAY BEFORE THIS WEEK'S CLASS

Prepare a written paper in which you:

- Part One: In not more than two paragraphs, **describe** the decisions of the court in *McCorry v. Evangelical Hospitals Corp.* and the decision of the court in *Rawlins v. Daughters of Charity*
- Part Two: **Identify** one significant factual similarity, and one factual difference, between *Rawlins* and *McCorry* which you think may explain the difference in outcomes in these two cases.
- Part Three: Given the facts you thought were significant, **discuss** why you think these courts reached opposite conclusions.
- Part Four: **Identify** at least one lesson you think health care decision makers should learn (and how health care facilities might practically deliver health care) so as to minimize their exposure to liability in fact patterns like those in *Rawlins* and *McCorry* (i.e., liability for the conduct of physicians who are not employed by the facility). Remember to address the fact that one of the cases involved a *hospital-based* independent physician and the other case involved a *community-based* independent physician.

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences. Remember: Your instructors will stop reading after one page.

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of one of these cases:

1. Text of *Mackey v. Sarroca* (Ill. App. Ct. 4/27/15): can a telephone conversation create the first element of the tort of negligence (the physician-patient relationship in which a physician owes a duty of care to the patient)?
2. Text of *Matsuyama v. Birnbaum*--a case that explores liability for “loss of chance” as a separate claim of negligence even when the pre-incident chance of survival is less than 50%
3. Text of *Estate of Cordero v. Christ Hospital*---- a case involving the potential liability of a hospital for the conduct of a third party -- a hospital-based physician.
4. Text of *Olson v Wrenshall*, 822 NW 2d 336 (*Neb Sup Ct 2012*) --do the physicians transplanting a kidney in the donee owe a duty to the kidney donor?

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court’s decision: “The court held that.... because....” Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don’t copy and paste the court’s recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge’s decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. “The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff’s name] appealed.

Part Three: The Court’s Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1” left and right margins; a header and footer each at least .5”; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court's decision, and the implications of the court's decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court's final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Each student who has been assigned an article or case to present in class must submit the student's written synopsis to the student's instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Classroom Discussion:

Read *Simineri et al. v. LifeCell Corp.*, No. L-5972-11 (Super. Ct. N.J., 5-8-2015). Be prepared to discuss these topics:

1. What is the "learned intermediary" doctrine?
2. Who benefits from the application of the "learned intermediary" doctrine? Who shoulders additional risk as a result of the "learned intermediary" doctrine?
3. The U.S. Supreme Court has held that, since under the Food, Drug & Cosmetic Act, generic drug manufacturers must use the same label that the FDA approved when authorizing the sale of the branded version by the brand name manufacturer, generic drug manufacturers cannot be held liable for a failure to warn arising out of hazards discovered after the original label was approved but before the FDA approves changes to the label for the brand name manufacturer. Does this produce differences in liability between brand-name manufacturers and generic manufacturers for the same product? What possible claims might a plaintiff attempt to bring against the prescribing physician of a generic drug? *Use your research skills: see if you can find discussions of this legal principle, the Supreme Court decisions, and what happened when plaintiffs did seek to bring claims using other theories.*

Week 4

Developing Areas of Negligence: Corporate Liability; Wrongful Birth and Wrongful Life; Issues in the Admission and Discharge of Patients Original Date: September 15, 2015

This Class Has Been Rescheduled to September 16, 2015, 3:30 p.m.-6:00 p.m.

Learning Objectives

1. Explore the concept of “corporate liability”: unlike “vicarious liability,” in which one party is held liable due to the negligent conduct of someone else, “corporate liability” imposes a duty directly upon the health care provider to adequately review the qualifications of a third party.
2. Explore two rapidly developing frontiers of health care and the ethical and legal implications they pose to health care decision makers: “wrongful birth” and “wrongful life.”
3. Gain an appreciation for the intersection between constitutionally protected rights and a health care provider’s duty to provide care.

Learning Activities and Assignments

Required Reading:

1. Chapters 7 and 14 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**
2. Text of *Fruiterman v. Granata*--Does the Failure to Recommend CVS Testing, Coupled with the Birth of Twins Suffering Down Syndrome, Prove a Breach of the Standard of Care? Does the Husband Have His Own Claim for Negligence?
3. Text of *Hall v. Dartmouth*--New Hampshire Supreme Court and Wrongful Birth.
4. Text of *Stewart-Graves v. Vaughn*--Washington Supreme Court – Was it Wrong to Resuscitate an Infant?
5. Text of *Morrison v. Health Plan of Nevada*--When and Under What Circumstances May a Managed Care Organization/Health Plan Find Itself Held Liable for the Negligent Selection of a Participating Health Care Provider?
6. Text of *Bradford v. Jai Medical Systems Managed Care Organization, Inc.*--can a preferred provider organization, managed care organization or health benefit plan be held liable for the conduct of an independent physician who is included in the network of participating physicians?
7. “*The Non-Delegable Duty Debate: Holding a Hospital Liable for an Independent Contractor’s Negligence,*” (AHLA Health Care Liability & Litigation Newsletter, May 2015).

8. “*The Bleak New World of Prenatal Genetics: The Emerging Market Of Fetal Testing Could Transform The Idea Of What's Normal*” (Wall Street Journal, June 13, 2013).
9. “*American Way of Birth, Costliest in the World*” ((New York Times, July 1, 2013 Print/June 30, 2013 Web).
10. *Cancer? Not!* [Calling Latent Passive Cells "Cancer" Leads to Unnecessary Treatment with Undesirable Side Effects] (Lundberg, Medscape, 8-29-13)
11. “*Hospital Relationships With Direct-to-Consumer Screening Companies*” (JAMA, August 11, 2014)

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 PM ON THE DAY BEFORE THIS WEEK'S CLASS

Read, “*The Non-Delegable Duty Debate: Holding a Hospital Liable for an Independent Contractor’s Negligence,*” (AHLA Health Care Liability & Litigation Newsletter, May 2015). The article cites *Albain v. Flower Hospital*, 553 N.E. 2d 1038, 1044-48. Your tasks:

1. Find the decision in *Albain v. Flower Hospital*, 553 N.E. 2d 1038, 1044-48 (Ohio Sup. Ct. 1990). Read the decision and answer these questions:
 - a. Did the court conclude that a hospital *is never liable* for the conduct of physicians who are not employed by or under contract to the hospital?
 - b. Explain what the court did hold *with respect to a hospital’s obligations with respect to credentialing*.
2. Find a decision of an Ohio court that *reverses* at least one of the holdings in the Ohio Supreme Court’s 1990 decision in *Albain*. [Hint: the only Ohio -- state, as opposed to the federal or U.S. Supreme Court -- court that could overrule a decision of the Ohio Supreme Court is] Explain which holding the court reversed.

Your written paper must not exceed one page. The page should have 1” left and right margins; a header and footer each at least .5”; and a font at least 12 points in size. You must use full, grammatical, sentences. Remember: Your instructors will stop reading after one page.

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of one of these cases:

1. Text of *Hall v. Dartmouth*-New Hampshire Supreme Court and Wrongful Birth
2. Text of *Stewart-Graves v. Vaughn*-Washington Supreme Court – Was it Wrong to Resuscitate an Infant?
3. Text of *Fruiterman v. Granata*--Does the Failure to Recommend CVS Testing, Coupled with the Birth of Twins Suffering Down Syndrome, Prove a Breach of the Standard of Care? Does the Husband Have His Own Claim for Negligence?

4. Text of *Morrison v. Health Plan of Nevada*--When and Under What Circumstances May a Managed Care Organization/Health Plan Find Itself Held Liable for the Negligent Selection of a Participating Health Care Provider?
5. Text of *Bradford v. Jai Medical Systems Managed Care Organization, Inc.*--can a preferred provider organization, managed care organization or health benefit plan be held liable for the conduct of an independent physician who is included in the network of participating physicians?

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. "The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff's name] appealed.

Part Three: The Court's Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court's decision, and the implications of the court's decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court's final conclusion, and the rationale the court used to justify its conclusion.

3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Each student who has been assigned an article or case to present in class must submit the student's written synopsis to the student's instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Class Discussion Assignment:

Review these four articles that are included in this week's materials:

1. *"The Bleak New World of Prenatal Genetics: The Emerging Market Of Fetal Testing Could Transform The Idea Of What's Normal"* (Wall Street Journal, June 13, 2013).
2. *"American Way of Birth, Costliest in the World"* (New York Times, July 1, 2013 Print/June 30, 2013 Web).
3. *Cancer? Not!" [Calling Latent Passive Cells "Cancer" Leads to Unnecessary Treatment with Undesirable Side Effects]* (Lundberg, Medscape, 8-29-13)
4. *"Hospital Relationships with Direct-to-Consumer Screening Companies"* (Journal of the American Medical Association, August 11, 2014)

Be prepared to discuss these issues:

- How do the evolving standards and recommendations for tests and screenings designed to identify what can be catastrophic conditions potentially affect health care providers' liability for breach of the standard of care?
- How, if at all, should health care decision makers factor the effects that introducing innovative or leading edge tests may have on the cost of health care and potential liability -- not only for failure to perform a test but also for performing a test that is known, for example to have a material incidence of false positives?
- How should health care institutions best manage the evaluation and potential inclusion of screening options and manage the flow of information to patients?

Week 5

Consent for Treatment and Withholding Consent September 22, 2015

Learning Objectives

1. Master the elements and parameters of the two types of consent (express and implied) and the development, elements and status of “informed consent.”
2. Apply the concepts of consent for three different types of patients: the minor patient; the adult competent patient, and the adult incompetent patient.

Learning Activities and Assignments

Required Reading:

1. Chapter 11, and pages 70-89 of Chapter 3, of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**
2. Text of *York v. Mayfield Neurological Institute*.
3. Text of *In re Child of Colleen Hauser and Anthony Hauser*.
4. Text of *Edited Text of Jandre v. Wisconsin Injured Patients and Families Compensation Fund--Court Sustains "Reasonable Patient" Standard for Informed Consent and Need to Communicate All Options, Including Tests for a Diagnosis the Treating Physician Had Ruled Out*
5. Text of *Willis v. Bender--Effect on Patient's Informed Consent Where Physician Lies In Response To Patient Questions About Prior Lawsuits*.
6. Text of *In the Matter of the Detention of D.W. and Franciscan Health Care Systems v. Pierce County Department of Social Services* (WA Sup. Ct. 8-7-14)--State Involuntary Detention Statute Which Requires Detention in Certified Facilities Does Not Authorize Temporary Placement in Hospital Emergency Rooms When Certified Evaluation Facilities are Not Available
7. Snyder, Lois, “*Refusing Medical Treatment: Beyond the Advance Directive*” (ABA Health Law Section e-Source, April 2007, Volume 3 Number 8).
8. Committee on Bioethics, Council on Child and Adolescent Health, American Academy of Pediatrics, “*Informed Consent, Parental Permission and Assent in Pediatric Practice*” (*Pediatrics*, Vol. 95, No. 2, February 1995).
9. Unguru, “*Informed Consent and Assent in Pediatrics*” (Am Acad Pediatrics Bioethics Resident Curriculum, accessible at https://www2.aap.org/sections/bioethics/PDFs/Curriculum_Session4.pdf)

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK'S CLASS.

You are administering the teenage treatment clinic for a large children's hospital medical center. The Teenage Treatment Clinic provides ambulatory medical care to patients between the ages of 13- 19. Teenage patients come for follow-up appointments after orthopaedic and other non-critical surgical care, routine physicals, and treatment of the usual range of ambulatory physical complaints (this clinic does not treat patients who present for psychological or psychiatric conditions -- that is the province of another clinic on the hospital's campus). Your practice managers report that, with increasing frequency, parents of these teenage patients wish to drop off their children and then pick them up after their appointments. **Based on what you have read about consent, prepare a one page consent form for ambulatory treatment of these teenage patients.**

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, for each of these cases:

1. Text of *York v. Mayfield Neurological Institute* (**one student**).
2. Text of *In re Child of Colleen Hauser and Anthony Hauser* (**one student**).
3. Text of *Willis v. Bender*--Effect on Patient's Informed Consent Where Physician Lies In Response To Patient Questions About Prior Lawsuits(**one student**).
4. Edited Text of *Jandre v. Wisconsin Injured Patients and Families Compensation Fund* (*Wis. Sup. Ct. April 17, 2012*) (**Three students**).
 - a. **All of the students assigned to this case:** Prepare a synopsis of the facts and a synopsis of the court's holding (pages 1-9, Parts I and II of the court's decision)
 - b. **One student:** Prepare a synopsis of the court's response to the defendant's arguments that--
 - i. the "plain language" of Wis. Stat. § 448.30 and the *Scaria* decision refer only to treatment, not diagnosis, and even if diagnostic techniques are within the scope of the duty to inform, the duty does not extend to alternative diagnostic tools for conditions unrelated to the condition diagnosed;
 - ii. the jury's verdict on Jandre's informed consent claim was inconsistent with its verdict of non-negligent diagnosis.
 - c. **One student:** Prepare a synopsis of the court's response to the defendant's arguments that--
 - i. under previous decisions in *Martin v. Richards*, and *Bubb v. Brusky*, the physician does not have a duty to inform the patient about conditions unrelated to the condition diagnosed;
 - ii. under the previous decision in *Kuklinski v. Rodriguez*, a physician's duty to inform does not attach until the physician reaches a final diagnosis.

- d. **One student:**
 - i. Prepare a synopsis of the court's response to the defendant's argument that failing to adopt PIC's view of the law of informed consent makes bad law and contravenes sound public policy;
 - ii. Research to see how the Wisconsin Legislature responded to the Wisconsin Supreme Court's decision in *Jandre* and then prepare a synopsis of the Wisconsin Legislature's response.
5. Text of *In the Matter of the Detention of D.W. and Franciscan Health Care Systems v. Pierce County Department of Social Services* (WA Sup. Ct. 8-7-14)--State Involuntary Detention Statute Which Requires Detention in Certified Facilities Does Not Authorize Temporary Placement in Hospital Emergency Rooms When Certified Evaluation Facilities are Not Available (**one student**).

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision. You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. "The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff's name] appealed.

Part Three: The Court's Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court's decision, and the implications of the court's decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court's final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Each student who has been assigned an article or case to present in class must submit the student's written synopsis to the student's instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Week 6

Medical Staff Issues: Money, Self-Interest and Risk Intersect: Granting, Denying, and Terminating Medical Staff Privileges; Exclusive Agreements; Economic Credentialing September 29, 2015

Learning Objectives

1. Learn how courts and legislatures have defined the prerogatives of institutional health care providers -- and hospitals in particular -- to determine whether a particular physician (or type of practitioner) will be awarded privileges and the institution's ability to suspend, revoke, or limit the physician's ability to exercise those privileges
2. Learn how the economics of health care influence institutional credentialing decisions and how the legal systems respond to that phenomenon

Learning Activities and Assignments

Required Reading:

1. Chapter 8 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**
2. Edited text of CMS 5/5/11 Final Regulation--Changes Affecting Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoPs): Credentialing and Privileging of Telemedicine Physicians and Practitioners.
3. Text of *Poliner v. Texas Health System* (5th Cir. July 23, 2008)
4. Synopsis of *Murphy v. Baptist Health*, Ark. Cir. Ct., No. CV 2004-2002, 2/27/09): Arkansas Court Permanently Enjoins Hospital's Use Of Economic Credentialing Policy for Staff.
5. Text of *Badri v Huron Hospital* (DC ND OH 2009)--Suspension and Revocation of Physician's Hospital Privileges Sustained -- HCQIA Grants Immunity to Hospital and Participants
6. Edited Text of Majority Opinion in *Tibbs v. Bunnell* (Ky. Sup. Ct. August 21, 2014): Patient Safety Incident Reports Stored in a Hospital's Patient Safety Evaluation System are Not Entitled to Privilege Against Discovery Under Patient Safety and Quality Improvement Act Since They Were Required Under Another State Law.
7. Text of *Levy v. Clinton Memorial Hospital*.
8. Text of *Paulino v. QHG of Springdale Inc.*-Arkansas Supreme Court Addresses the Existence of a Patient's Remedy Against a Hospital for Injuries by a Surgeon Facilitated by Negligent Credentialing.

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 PM ON THE DAY BEFORE THIS WEEK'S CLASS

Analyze the effect and potential liabilities the CMS final regulation on telemedicine credentialing -- the CMS 5/5/11 Final Regulation on Changes Affecting Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoPs): Credentialing and Privileging of Telemedicine Physicians and Practitioners -- may have on the "originating hospital." Consider what we have learned in the course to date and describe what you think are the risks the originating hospital may face if it grants privileges to the telemedicine physician based solely on the grant of credentials by the "distant site hospital."

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences. Remember: Your instructors will stop reading after one page.

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of one of these cases:

1. Text of *Poliner v. Texas Health System* (5th Cir. July 23, 2008)
2. Text of *Badri v Huron Hospital* (DC ND OH 2009)--Suspension and Revocation of Physician's Hospital Privileges Sustained -- HCQIA Grants Immunity to Hospital and Participants
3. Edited Text of Majority Opinion in *Tibbs v. Bunnell* (Ky. Sup. Ct. August 21, 2014): Patient Safety Incident Reports Stored in a Hospital's Patient Safety Evaluation System are Not Entitled to Privilege Against Discovery Under Patient Safety and Quality Improvement Act Since They Were Required Under Another State Law
4. Text of *Levy v. Clinton Memorial Hospital*
5. Text of *Paulino v. QHG of Springdale Inc.*-Arkansas Supreme Court Addresses the Existence of a Patient's Remedy Against a Hospital for Injuries by a Surgeon Facilitated by Negligent Credentialing

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision. You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. "The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff's name] appealed.

Part Three: The Court's Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court's decision, and the implications of the court's decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court's final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Each student who has been assigned an article or case to present in class must submit the student's written synopsis to the student's instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Class Discussion Topics:

- Having read the synopsis of the court's decision in *Murphy v. Baptist Hospital System*, what economically motivated maneuvering room do you think integrated health care delivery systems continue to possess -- and how should they tailor their desire to deal with competitors who happen to need access to the system's facilities?

- After you prepare your written assignment on the effect of the CMS final regulation on telemedicine credentialing on the “originating hospital,” be prepared to discuss in class, the potential magnitude of the risks the “originating” hospital faces. Do they outweigh the costs the “originating hospital” will incur if it does not adopt the policy in the CMS final regulation? Are there alternatives the originating hospital may deploy to shift the risk?

Week 7

Emergency Care and the Emergency Medical Treatment and Active Labor Act (EMTALA) October 6, 2015

Learning Objectives

1. Understand health care providers' obligations -- or lack thereof -- to provide emergency medical care to patients
2. Begin learning the art of reading and interpreting complex statutory and accompanying regulatory primary material -- the texts of statutes and regulations
3. Master when and how a hospital may be obligated to provide emergency care to patients under the Emergency Medical and Active Labor Act (EMTALA).

Learning Activities and Assignments

Required Reading:

1. Chapter 10 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration.**
2. Text of decision of the Kentucky Court of Appeals in *Thomas v. St. Joseph Healthcare* (No. 2007-CA-001192MR, July 16, 2010): Does A Hospital's Failure to Diagnose and Treat a Patient in Severe Distress Violate the Hospital's EMTALA Stabilization Duty?
3. Text of *Hale v. Northeastern Vermont Regional Hospital Inc.* (D. Vt. 9-30-11): Effect of Hospital's Failure to Use Test Previously Used in Earlier Visits on its "Adequate Screening" EMTALA Obligation.
4. Text of *Moses v. Providence Hosp. and Med. Ctrs.:* (1) May a Third Party Sue under EMTALA? (2) Does Admission to Hospital End EMTALA Obligations?
5. Text of *Pauly v. Stanford Hosp* (ND Cal May 11 2011)--Does a Third Party Really Have Standing to Sue Under EMTALA?
6. Text of *Morales v. Palomar Health (S.D. Cal. Aug. 12, 2014)*--Although Plaintiff Failed to State a Claim Alleging Disparate Screening Treatment Due to Lack of Insurance, Plaintiff Adequately Pled a Claim Based on an Inadequate Screening
7. Edited Text of *Perry v. Owensboro Health, Inc.* (W.D. Ky 7-16-205)--Claim of Failure to Provide an EMTALA Appropriate Screening Dismissed--No Assertion or Facts Showing Disparate Treatment
8. Edited Text of *Adams-Erazo v. Hosp. San Gerado* (D.C. D.P.R., 7-24-15)--Alleged Failure by Hospital Emergency Room Personnel to Follow Written Protocol For Screening Gunshot Wounds Could Violate EMTALA Appropriate Screening Requirement and Results in Denial of Hospital's Motion for Summary Judgment

9. Text of *Baney v. Fick* (D.C. MD PA 2-13-2015)-Patient Who Suffered Adverse Event During Elective Outpatient Surgery Did Not Come to the Emergency Department and EMTALA Therefore Does Not Apply

Reference Materials to Use for This Week's Assignments

1. Text of the EMTALA Final Regulations
2. Text of the EMTALA Statute

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK'S CLASS.

Read the text of the decision of the Kentucky Court of Appeals in *Thomas v. St. Joseph Healthcare* (No. 2007-CA-001192MR, July 16, 2010). The Court of Appeals concluded that, although the defendant hospital did satisfy its EMTALA obligation to provide an "appropriate medical screening" and the hospital thought it failed to detect an emergency condition, the hospital nevertheless failed to discharge its obligation to stabilize the patient's condition. Write your answer to this question (**not more than one page**): why did the court conclude that the hospital had a duty to stabilize an emergency condition even though the hospital argued that its screening failed to reveal an emergency condition?

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of one of these cases:

1. Text of *Hale v. Northeastern Vermont Regional Hospital Inc.* (D. Vt. 9-30-11): Effect of Hospital's Failure to Use Test Previously Used in Earlier Visits on its "Adequate Screening" EMTALA Obligation
2. Text of *Moses v. Providence Hosp. and Med. Ctrs.*: **Two students:**
 - a. May a Third Party Sue under EMTALA?
 - b. Does Admission to Hospital End EMTALA Obligations?
3. Text of *Pauly v. Stanford Hosp* (ND Cal May 11 2011)--Does a Third Party Really Have Standing to Sue Under EMTALA?
4. Text of *Morales v. Palomar Health (S.D. Cal. Aug. 12, 2014)*-Although Plaintiff Failed to State a Claim Alleging Disparate Screening Treatment Due to Lack of Insurance, Plaintiff Adequately Pled a Claim Based on an Inadequate Screening
5. Edited Text of *Perry v. Owensboro Health, Inc.* (W.D. Ky 7-16-205)--Claim of Failure to Provide an EMTALA Appropriate Screening Dismissed-No Assertion or Facts Showing Disparate Treatment
6. Edited Text of *Adams-Erazo v. Hosp. San Gerado* (D.C. D.P.R., 7-24-15)--Alleged Failure by Hospital Emergency Room Personnel to Follow Written Protocol For

- Screening Gunshot Wounds Could Violate EMTALA Appropriate Screening Requirement and Results in Denial of Hospital's Motion for Summary Judgment
7. Text of *Baney v. Fick* (D.C. MD PA 2-13-2015)-Patient Who Suffered Adverse Event During Elective Outpatient Surgery Did Not Come to the Emergency Department and EMTALA Therefore Does Not Apply

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. "The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff's name] appealed.

Part Three: The Court's Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court's decision, and the implications of the court's decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court's final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Each student who has been assigned an article or case to present in class must submit the student's written synopsis to the student's instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Week 8

Conducting a Health Care Business to Minimize Exposure to Liability October 13, 2015

Learning Objectives

1. Understand and learn how to use the concept of “limited liability” that owners of certain types of business organizations -- limited liability companies and corporations in particular -- possess to insulate assets from claims of creditors and minimize risk.
2. Learn the mechanics and legal requirements for organizing and operating various types of business organizations so as to structure relationships among joint venturers to achieve business goals and minimize exposure to liability for the venture’s operations

Learning Activities and Assignments

Required Reading:

1. Pages 169-196 of Chapter 6 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration.**
2. Freedman, William M., “*Practical Aspects Of Choice Of Business Entity.*”

Evaluation: Quiz

This quiz will cover material from the beginning of the course through this week’s class.

Week 9

The Wide World of Taxation: Conducting a Health Care Business to Minimize Exposure to Taxation, Especially When Partnering With Other Players

October 20, 2015

Learning Objectives

1. Master the concepts of federal and state tax-exempt status
2. Learn what organizations must do to acquire and preserve federal tax exempt status for their activities and for the returns on investments they make -- particularly when they form joint ventures with for-profit players.
3. Learn how the standards for state real property and income tax exemption differ from federal income tax exemption and the importance of that distinction

Learning Activities and Assignments

Required Reading:

1. Chapter 12 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**
2. Freedman, William M., “*Supplement to Textbook Chapter 11: Everything You Always Wanted To Know About The Internal Revenue Code’s Grant Of Exempt Status To Certain Organizations.*”
3. Text of *Provena Covenant Medical Center v. Department of Revenue*--Real Property Tax Exemption Denied to Hospital.
4. Text of *AHS Hospital Corp. d/b/a Morristown Memorial Hospital v. Town of Morristown* (New Jersey Tax Court, June 2015): Nonprofit Hospital’s Real Property Tax Exemption Revoked Due to the Hospital’s Involvement in Extensive For Profit Activities-Ownership of Physician Practice and Insurance Company Affiliates; Unreasonable Compensation to Hospital Executives
5. Text of IRS PLR 201433018--Denial of Application for Tax-Exempt Status as a Section 501(e) Cooperative Hospital Service Organization Due to Failure to Allocate Net Profits and Failure to Perform Any of the Specified & Required Cooperative Services on a Centralized Basis
6. Text of Text of PLR 201436050--Healthcare Organization Established to Reduce Hospital Readmissions Denied 501(c)(3) Status--Organization’s Noncharitable Founders Controlled Board and Operations, Allowing for Inurement and Private Benefit; Reducing Readmissions Benefited Noncharitable Founder Thereby Precluding Existence of Charitable Purpose

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK'S CLASS.

Accountable care organizations are the current flavor du jour of managed care delivery system. §3022 of the Affordable Care Act adds a new Section to the Social Security Act and obligates the U.S. Department of Health and Human Services to establish “a shared savings program...that promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.” This program, Congress continued, will enable “groups of providers of services and suppliers meeting criteria specified by the Secretary [to] work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (referred to in this section as an ‘ACO’); and ..ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings...”

You will have read in our textbook and supplementary readings that joint ventures whose owners consist of tax-exempt and taxable entities pose tax challenges to the tax-exempt owners. One very significant challenge: the tax exempt owner’s ownership interest in the joint venture could imperil the tax-exempt owner’s continued eligibility for tax-exempt treatment.

The three agencies with regulatory authority over accountable care organizations have each issued guidance as to how each of them believes these accountable care organization joint ventures must behave in order to avoid running afoul of statutes that each agency enforces. They are: (1) the Centers for Medicare and Medicaid Services on eligibility to participate in the CMS-administered shared savings program; (2) the U.S. Department of Justice and the U.S. Federal Trade Commission with respect to the antitrust aspects of competitors coming together as owners of an accountable care organization, and, (3) last but not least, the Internal Revenue Service/U.S. Treasury Department with respect to the effect on tax-exempt status of the participation by a tax-exempt entity in an accountable care organization.

In October, 2011, CMS issued its final ACO regulation. Simultaneously, the IRS issued updated guidance (because the final CMS regulation differed from the proposed regulation).

Your task:

1. Find the *two pieces of* IRS guidance on the effect on tax-exempt status of the participation by a tax-exempt entity in an accountable care organization.
2. Write a **one page** synopsis of these two issues that are covered in the *two pieces of* guidance you are expected to find:
 - a. What has the IRS said a tax-exempt entity must **make sure happens** in order to guarantee preservation of its exempt status?
 - b. In what scenario has the IRS refused to provide any comfort or solace?

Class Discussion Assignment:

Read IRS PLR 201433018 (denial of application for tax-exempt status as a Section 501(e) cooperative hospital service organization due to failure to allocate net profits and failure to perform any of the specified & required cooperative services on a centralized basis). We'll discuss these issues:

- What business objectives did the hospitals seek to achieve? Were they realistic?
- What lessons can we learn about the IRS's approach to interpretation of the provisions of the Internal Revenue Code governing attempts by health care providers to characterize their operations as tax-free?

Then, read PLR 201436050 (healthcare organization established to reduce hospital readmissions denied 501(c)(3) status--organization's noncharitable founders controlled board and operations, allowing for inurement and private benefit; reducing readmissions benefited noncharitable founder thereby precluding existence of charitable purpose). We'll discuss these issues:

- How seriously does the IRS treat possible inurement?
- What lessons can we learn about the IRS's approach to avoid the bad result the taxpayers suffered in this request for a ruling?

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of one of these cases:

1. Text of *Provena Covenant Medical Center v. Department of Revenue*--Real Property Tax Exemption Denied to Hospital
2. Text of *AHS Hospital Corp. d/b/a Morristown Memorial Hospital v. Town of Morristown* (New Jersey Tax Court, June 2015): Nonprofit Hospital's Real Property Tax Exemption Revoked Due to the Hospital's Involvement in Extensive For Profit Activities-Ownership of Physician Practice and Insurance Company Affiliates; Unreasonable Compensation to Hospital Executives

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but

ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. "The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff's name] appealed.

Part Three: The Court's Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court's decision, and the implications of the court's decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court's final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. *You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.*

Each student who has been assigned an article or case to present in class must submit the student's written synopsis to the student's instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Week 10

Fraud and Abuse Antikickback October 27, 2015

Learning Objectives

1. Pursue the art of reading and interpreting complex statutory and accompanying regulatory primary material -- the texts of statutes and regulations.
2. Learn the statutory proscription against exchanging remuneration for the referral of a federal health care program enrollee: the federal antikickback statute.
3. Understand and learn how to apply the regulations issued by the Office of Inspector General of the U.S. Department of Health & Human Services that provide a “safe harbor” that assures the parties to a relationship or transaction that the parties will not be prosecuted for a violation of the antikickback statute -- and learn the meaning and practical application of a “safe harbor.”
4. Learn how a potential violation of the federal antikickback statute may trigger violations of a number of other federal statutes.
5. Learn that avoiding the violation of the federal antikickback statute for federal health program patients may not be enough: learn about state legislatures’ enactment of similar statutes that apply to commercially insured patients.

Learning Activities and Assignments

Required Reading:

1. Pages 521-527, 532-538, and 546-553 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**.
2. PowerPoint Presentation Handout: *Introduction to Antikickback*.
3. Freedman, William M., “*An Introduction to Antikickback--The Statute and a Synopsis of the Cases.*”
4. “*Health Alliance of Greater Cincinnati and The Christ Hospital to Pay \$108 Million for Violating Anti-Kickback Statute*” (DOJ Release, May 21, 2010).
5. Text of Department of Justice 6-2-2015 Announcement-Two New York Doctors Sentenced to Prison for Accepting Remuneration--More Than \$100,000--in Exchange for Referrals of \$1.8 Million in Clinical Laboratory Tests to Biodagnostic Laboratory Services
6. Text of Complaint in U.S. v. Berkeley Heartlab-Heart Diagnostic Lab and BlueWave HealthCare Consulting Paid \$80 Million in "Referral Fees" to Physicians In Exchange for Referrals for Cardiovascular Biomarker Blood Tests
7. Text of OIG Advisory Opinion 2015-04-- Laboratory's Proposal To Enter Into Agreements With Physician Practices To Provide All Laboratory Services For The Practices' Patients And Waive All Fees For Those Practices' Patients Who Are Enrollees

Of Insurance Plans That Require The Patients To Use A Different Laboratory Could Violate The Federal Antikickback Statute-Free Services In Exchange For Referral Of All Federal Health Care Program Patients

8. Description of Ducati Medical Center’s proposed cardiac emergency telemedicine arrangement with area community hospitals (for use in preparing written assignment).
9. A series of scenarios described in “An Exercise in Hospital-Physician Joint Ventures” (for use in preparing for class discussion).

Reference Materials to Use In Solving This Week’s Assignments

1. The text of the Antikickback Safe Harbor Regulations.
2. Federal Register text of 10-3-14 OIG Proposed Regulations--New Antikickback Safe Harbors, Including Free Or Discounted Local Transportation Services; Civil Monetary Penalty Exceptions Including Copayment Reductions For Certain Hospital Outpatient Services; Remuneration That Poses A Low Risk Of Harm, And Coupons, Rebates, Or Other Retailer Reward Programs
3. The text of the Ohio Anti-Kickback Statute (ORC §3999.22).

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK’S CLASS.

An Exercise to Learn How to Analyze A Transaction for Compliance with the Federal Antikickback Statute

Review the PowerPoint presentation, “*Introduction to Antikickback*,” the assigned material from J. Stuart Showalter, **The Law of Healthcare Administration**, and “*An Introduction to Antikickback--The Statute and a Synopsis of the Cases.*”

Then, read the description of Ducati Medical Center’s proposed cardiac emergency telemedicine arrangement with area community hospitals. With your copy of the Antikickback Safe Harbor Regulations at your side, use your internet or library-based research tools to determine whether the Office of Inspector General of the U.S. Department of Health & Human Services, has issued any antikickback guidance on a transaction similar to the arrangement Ducati Medical Center has proposed and, if so, determine what the OIG concluded, whether the transaction the OIG reviewed differs from the transaction Ducati Medical Center has proposed, and whether that difference might lead the OIG to reach a different conclusion if it investigates the transaction proposed by Ducati Medical Center. Write your analysis using this format:

1. The OIG has issued this guidance on a similar transaction [identify the guidance and give a two sentence description of the guidance].Ducati Medical Center’s proposed arrangement [choose one of these two options]:
 - a. May violate the federal antikickback statute because [insert your reason]

- b. Either does not violate the federal antikickback statute or qualifies for one of the “safe harbors” in the federal antikickback regulations because [insert your reason]
2. The transaction the OIG described differs/does not differ from Ducati Medical Center’s proposal in this respect: [insert a short description of any difference]. This difference/the lack of any difference means the OIG [choose one of these options]:
 - a. will reach a **different and less favorable** conclusion if it investigates Ducati Medical Center or the community hospitals because [insert your conclusion and your reason]
 - b. will reach a **different and more favorable conclusion** if it investigates Ducati Medical Center or the community hospitals because [insert your conclusion and your reason]
 - c. will reach a **the same conclusion** if it investigates Ducati Medical Center or the community hospitals because [insert the likely conclusion and your reason]
3. Describe the changes you recommend Ducati Medical Center should make to its proposed arrangement to reduce the antikickback risks you identified.

Class Discussion Assignment:

Using the resources for this week and your exploration of OIG advisory opinions and articles that you can retrieve using your student Lexis subscription, Google Scholar, and internet resources, review the scenarios described in “An Exercise in Hospital-Physician Joint Ventures” and answer the questions that are posed at the end. We will review the scenarios and collaborate to reach answers to the questions.

Week 11

Stark II Physician Self-Referral November 3, 2015

Learning Objectives

1. Master the art of reading and interpreting complex statutory and accompanying regulatory primary material -- the texts of statutes and regulations.
2. Learn the statutory prohibition of a physician's referral of a Medicare or Medicaid patient to an entity for "designated health services" when the physician possesses a financial relationship with the entity: the federal Stark II physician self-referral statute.
3. Understand and learn how to apply the regulations issued by the U.S. Centers for Medicare and Medicaid Services that provide exceptions for certain relationships or transactions that might otherwise violate the federal Stark II physician self-referral statute.
4. Learn how a potential violation of the federal Stark II physician self-referral statute may trigger violations of a number of other federal statutes
5. Learn that avoiding the violation of the Stark II physician self-referral statute for federal health program patients may not be enough: learn about state legislatures' enactment of similar statutes that apply to commercially insured patients.

Learning Activities and Assignments

Required Reading:

1. Pages 538-545 of Chapter 15 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration.**
2. PowerPoint Presentation: *Stark II Physician Self-Referral.*
3. Edited text of *Singh v. Bradford Regional Medical Center* (W.D. PA November 2010): Equipment Sublease From Physician Group to Hospital Fails to Qualify for either Stark II Indirect Compensation Arrangement or the Equipment Lease Exception.
4. Text of *Pasieka v. Chaves* (Mich. Ct. App., No. 304190, unpublished 10/23/12): Can A Stark II-compliant hospital-physician recruitment agreement allow a hospital to escape the frying pan, only to end up in the fire?
5. Text of *U.S. ex. rel. Drakeford v. Tuomey* (4th Cir. 7-2-2015) sustaining \$237,454,195 False Claims Act award against hospital for stark physician compensation agreement violations-productivity bonus based on personally performed services collections varied with volume or value of referrals for corresponding hospital-billed ancillary service technical fees
6. Synopsis of September 28, 2012 GAO Imaging Self-Referral Study: "*Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions.*"
7. CMS-OIG November 2, 2011 Interim Final Rule--*Waiver of Stark-Antikickback for Certain ACOs--Be Sure to Read "Part IV" -- which contains the waiver.*

8. Description and diagram for a proposed joint venture between Home Health Services Company and Parent Physician Company (for use in preparing the written assignment).

Reference Materials to Use In Solving This Week's Assignments

1. The text of the Stark II statute.
2. The text of the Stark II Phase III Physician Self-Referral Regulations.
3. Excerpts From Preamble Discussion and Text of Proposed Regulations on Changes to Existing and New Stark II Exceptions in the CMS July 15, 2015 Proposed Regulation on Modifications to 2015 Medicare Physician Fee Schedule
4. The text of the Ohio physician self-referral statute.
5. Excerpts from the text of the Federal Civil Monetary Penalty Regulations-- 42 C.F.R. §§1003.101 and 1003.102.
6. Federal Register Text of OIG May 12, 2014 Proposed Regulation-Amendment of Civil Monetary Penalty Regulations to Reflect Expanded Authority in Affordable Care Act
7. Stark II Supplemental Material and Hints for Solving the Written Assignment.

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK'S CLASS.

Review the description and diagram for a proposed joint venture between Home Health Services Company and Parent Physician Company in the Course Materials for Module 5 (the "Proposed Joint Venture"). Then, answer -- in a written paper -- your analysis of the application of the Stark II physician self-referral statute and regulations to the Proposed Joint Venture **by answering these questions:**

Make sure you read ALL of the questions in this assignment before you begin preparing your answers, for there is a valuable hint that awaits you. Then, review two of the Toolbox materials: the text of the Stark II Phase III Regulations and the Stark II Supplemental Material and Hints for Solving the Written Assignment

1. Is a "physician" involved? (Review the definition of "physician in the Stark II Phase III Regulations.)
2. Has a referral taken place? (Review definition of "referral" in the Stark II Phase III Regulations.)
3. Will the patients be patients the referral of whom trigger the application of the Stark II statute? (Review the "general rule" that describes the elements of the Stark II prohibition in the Stark II Phase III Regulations.)
4. Is the service to be provided to patients a "designated health service"? Review the definition of "designated health services" in the Stark II Phase III Regulations.
5. Does a "financial relationship" exist between a "physician" and an entity that will provide designated health services to patients referred by the physician? **Warning: there may be more than one financial relationship.**

6. If one or more financial relationships exists, trace the chain(s) of unbroken relationships from a physician to the entity providing the designated health services. Go to that portion of the regulations that defines “financial relationships.” Remember that there are four of them: direct ownership interests; indirect ownership interests; direct compensation arrangements; indirect compensation arrangements. (Why “unbroken”? Because the portion of the regulations defining financial relationships says so.)
7. Once you have identified a chain, determine whether an exception in the regulations applies and whether all of its elements are satisfied. ***Hint: One of the chains contains a relationship for which there is no exception -- and which therefore violates the Stark II statute (assuming that “designated health services” are involved). Which relationship causes the problem? Identify it.***
8. How would you change the transaction so as to fix the problematic link? In describing a solution, be practical. You are hereby warned: do **not** suggest creating a publicly traded mutual fund. What is the simplest solution you can propose? For example, if you have identified an indirect compensation arrangement, there are two ways to avoid trouble. First, determine whether you can modify the relationship so that it does not rise to the level of an indirect compensation arrangement, as that term is defined in Reg. §411.354 and its definition of an indirect compensation interest. (Remember, if the relationship does not fall within the definition of “indirect compensation arrangement,” then there is NO compensation arrangement and we do not trigger Stark and we go home and sleep peacefully (at least as to Stark)). Second, even if the relationship does satisfy the definition, is there an exception? What does it require? How would you structure the relationship so as to guarantee you satisfy the exception?
- 9.

Class Presentation Assignments:

1. A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of *Pasioka v. Chaves* (Mich. Ct. App., No. 304190, unpublished 10/23/12): Can A Stark II-compliant hospital-physician recruitment agreement allow a hospital to escape the frying pan, only to end up in the fire?
2. Two class members will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, on the two issues discussed by the court in the edited text of *Singh v. Bradford Regional Medical Center* (W.D. PA November 2010).
 - a) One student will review the facts pertinent to the issue of, and the conclusion and rationale of the court as to, whether the equipment sublease from the physician group to the hospital rose to the level of an indirect compensation arrangement and, if so, whether the equipment lease arrangement qualified for the indirect compensation exception in the Stark II regulations.
 - b) One student will review the facts pertinent to the issue of, and the conclusion and rationale of the court as to, whether the equipment sublease satisfied the Stark II regulations' exception for equipment leases.
3. A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of *U.S. ex. rel. Drakeford v. Tuomey* (4th Cir. 7-2-2015) sustaining \$237,454,195 False Claims Act award against hospital for stark physician compensation agreement violations-productivity bonus based on personally performed services collections varied with volume or value of referrals for corresponding hospital-billed ancillary service technical fees

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. “The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff’s name] appealed.

Part Three: The Court’s Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1” left and right margins; a header and footer each at least .5”; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court’s decision, and the implications of the court’s decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court’s final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Each student who has been assigned an article or case to present in class must submit the student’s written synopsis to the student’s instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Class Discussion Assignment:

Review the synopsis of the September 28, 2012 GAO Imaging Self-Referral Study (“Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions”) and the CMS-OIG November 2, 2011 Interim Final Rule--Waiver of Stark-Antikickback for Certain ACOs (be Sure to Read “Part IV” -- which contains the waiver).

We will discuss these topics:

1. We will review the key concepts embedded in the Stark II statute and the Stark II Phase III regulations’ exceptions that health care decision makers must understand in order to evaluate relationships with physicians to insure they do not violate the Stark II physician self-referral statute and regulations’ general rule that prohibits referrals of certain patients for, and billing for, designated health services.

2. We will review the literature to see why Stark II's general rule reflects the reality that physicians who derive profit from the performance of ancillary health services do react to that stimulus.
3. We will review the written assignment's scenario and collectively formulate the "correct" answer.
4. We will see how the Affordable Care Act's endorsement and creation of "accountable care organizations" intersects with Stark II requirements

Week 12

False Claims Act; ERISA, Health Plans, and Health Care Providers November 10, 2015

Learning Objectives

1. Learn the basics of the False Claims Act and how enterprising “relators” are using imaginative theories to assert claims against health care providers
2. Employer-sponsored and Affordable Care Act health care exchange offered health benefit plans are coping with increasing costs by, among other tactics, shrinking the size of their networks. Learn how the Employee Retirement Income Security Act of 1974 -- which regulates rights and privileges of participants and beneficiaries in “welfare plans,” provides a club for plans to use against providers -- and may also hand providers with a weapon.
3. Learn how courts evaluate, and under what circumstances courts will enforce, noncompetition undertakings in written agreements.

Learning Activities and Assignments

Required Reading:

1. Pages 527-532 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**.
2. Text of *Central Indiana Podiatry v. Krueger*.
3. Text of *Busch v. Premier Integrated Medical*.
4. "The False Claims Act: A Primer," U.S. Department of Justice, Accessed 8-6-2015)
5. Corcoran and Poindexter, "False Claims Act Primer," AHLA Fraud and Compliance Forum, October 6-7, 2014
6. Youtt and Thomas "False Claims Act Actions--The Developing Case Law Regarding If and When Opinions of Medical Necessity Can Be Fraudulent," American Bar Association *The Health Lawyer*, April 2015
7. Lord, Danzig & Gregory, "Corporate Integrity Agreements After 20 Years: The Burgeoning Costs of Settling FCA Cases and Fending Off Medicare Exclusion," AHLA Fraud & Abuse Newsletter, American Health Lawyers Association Fraud and Abuse Practice Group, June 2015, p. 7-10
8. Excerpt from *Kane ex rel. United States et al. v. Healthfirst* (S.D.N.Y. Aug. 3, 2015): "Reverse False Claims" Under the False Claims Act: Background; the Fraud Enforcement and Recovery Act's Changes; and the Affordable Care Act's Amendment of the False Claims Act Requiring Repayment of Overpayments Within 60 Days of "Identification"
9. "After Surgery, Surprise \$117,000 Medical Bill From Doctor He Didn't Know [--Perils of Unknown Out of Network Providers]"(New York Times, 9-20-14)

10. Edited Text of *Pennsylvania Chiropractic Ass'n v. Independence Blue Cross* (N.D. IL 3-28-14)-An In-Network Provider Entitled to Exercise ERISA Remedies to Appeal Plan Determinations of Allowable Charges and Medical Necessity
11. Text of Miller & Chevalier March 10, 2015 Letter Soliciting American Benefits Council Amicus Participation in *Pennsylvania Chiropractic Ass'n v. Independence Blue Cross* (Pending Before the 7th Cir.)-Is an In-Network Provider Entitled to Exercise ERISA Remedies to Appeal Plan Determinations of Allowable Charges and Medical Necessity?
12. Text of *Advanced Orthopedics & Sports Medicine v. Blue Cross Blue Shield of Mass.*(D.N.J. 7-20-2015)-Health Plan's Anti-Assignment Clause Deprived Out-of-Network Provider Standing to Sue the Plan Under ERISA for Failure to Make Adequate Payment

Reference Materials to Use In Solving This Week's Assignments

1. ERISA Remedies And ERISA Preemption: Text of ERISA §502 [29 U.S.C. §1132]— Civil Enforcement, and ERISA §514 [29 U.S.C. §1144]--Preemption
2. Health Care Insurer's Physician Group Participation Agreement
3. Sample Accountable Care Organization Agreement with Participating Practitioners
4. HESA 581 Session 12-Scenario For Use in Preparing Written Assignment

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK'S CLASS.

Read the text of *Advanced Orthopedics & Sports Medicine v. Blue Cross Blue Shield of Mass.*(D.N.J. 7-20-2015)-Health Plan's Anti-Assignment Clause Deprived Out-of-Network Provider Standing to Sue the Plan Under ERISA for Failure to Make Adequate Payment

Write a synopsis of the decision. Your synopsis should follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. “The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff’s name] appealed.

Part Three: The Court’s Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1” left and right margins; a header and footer each at least .5”; and a font at least 12 points in size. You must use full, grammatical, sentences.

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of one of these cases:

1. Text of *Central Indiana Podiatry v. Krueger*.
2. Text of *Busch v. Premier Integrated Medical*.

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court’s decision: “The court held that.... because....” Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don’t copy and paste the court’s recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge’s decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. “The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff’s name] appealed.

Part Three: The Court’s Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1” left and right margins; a header and footer each at least .5”; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court’s decision, and the implications of the court’s decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court’s final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Each student who has been assigned an article or case to present in class must submit the student’s written synopsis to the student’s instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Classroom Discussion:

False Claims Act: We will review the scenario students used to prepare their written assignment, and the articles that are part of this session’s required reading, to understand the basics of the operation (and dire financial penalties imposed by) the False Claims Act. We will explore:

- The types of conduct that can trigger a False Claims Act claim. We want to explore the types of administrative and operational systems we believe may prevent or ameliorate these claims
 - Conditions of participation v. conditions of payment
 - When can care prove so deficient that it amounts to a “false claim”
 - “Reverse false claims”
 - The requirement to repay overpayments within 60 days of “identification”

ERISA, ERISA Preemption, ERISA Remedies, and the In- and Out-of-Network Provider: We will explore:

- the cases, articles, and reference materials that illustrate a trend in health benefit plans to constrain the number of providers,
- the resulting possibility that patients will unknowingly receive services from out-of-network providers,
- the strategies plans use to suppress the plan’s obligations to pay for services (especially those provided by out-of-network providers)

- actions providers could take under ERISA to recoup money -- even though, for those who are network providers, their provider agreements may limit their ability to do so.

Students should read these materials and use their digital research resources to explore these issues and to see how the U.S. Department of Labor, which enforces ERISA rights, and legislatures are responding to these problems.

Week 13

Rights and Responsibilities of Health Care Providers to Secure the Privacy of Patients' Health Information; Regulation of Health Care Facts-A Case Study November 17, 2015

Learning Objectives

1. Understand the federal statutory scheme that governs health care providers' obligations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as it has been amended by The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009.
2. Learn about the tension among competing goals: assure that only those health care treatments (and drugs in particular) that are safe and effective are marketed to physicians and consumers; assure the communication of accurate information about health care treatments (and drugs in particular); and the Constitutional protection of the right to free speech

Learning Activities and Assignments

Required Reading:

1. Pages 291-320 of Chapter 9 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration**.
2. PowerPoint Slide Presentation on "*An Introduction to HIPAA for Health Plan Lawyers*" (Tolley, AHLA, 1-10-2013)(Part 1 of 2).
3. Transcript Accompanying PowerPoint Presentation on "*An Introduction to HIPAA for Health Plan Lawyers*" (Tolley, AHLA, 1-10-2013)(Part 1 of 2).
4. PowerPoint Slide Presentation on "*Understanding the Impact of the 1-25-13 HIPAA Omnibus Rule*" (Tolley and Gersh, AHLA, 2-20-2013)(Part 2 of 2).
5. Transcript Accompanying PowerPoint Slide Presentation on "*Understanding the Impact of the 1-25-13 HIPAA Omnibus Rule*" (Tolley and Gersh, AHLA, 2-20-2013)(Part 2 of 2).
6. Text of *U.S. ex. rel. Sheldon v. Kettering Health Network* (S.D. OH 1-6-2015)--Victim of a HIPAA Privacy Breach Does Not Possess a False Claims Act Remedy Against the Hospital at Which the Breach Occurred
7. Text of *Turk v. Oiler*--Cleveland Clinic Sued by Patient Over Medical Records Release in Response to Grand Jury Subpoena--Application of State Statute More Stringent than HIPAA is Upheld.
8. Text of *Howard v. Ark. Children's Hosp* (E.D. Ark. 7-1-15)--District Court Denies Hospital's Motion for Summary Judgment-Former Employees Who Disclosed Protected Health Information to Their Attorney in a False Claims Act Claim Did Not Violate HIPAA Because They Satisfied the Conditions for Protection as Whistleblowers in HIPAA Privacy Rule §164.502(j)(1)

9. Text of *Amarin Pharma, Inc. v. U.S. Food and Drug Admin.* (S.D.N.Y. Aug. 7, 2015): First Amendment Overrides FDA Regulations-Drug Manufacturer May Distribute Truthful and Non-Misleading Statements About Off-Label Uses of a Prescription Drug
10. “*Kardashian Promotes a Pill, and the F.D.A. Strikes-- F.D.A. Warns Company Over Kardashian Instagram Marketing*” (New York Times, 8-12-13-2015)

Reference Materials for This Week’s Topic

1. U.S. Department of Health & Human Services, “Summary Of The HIPAA Privacy Rule,” <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf> (published prior to the enactment of HITECH)(A Section by Section Summary).
2. Text of the federal HIPAA Privacy & Security Standard Regulations as of March, 2013 and current as of August 2015.
3. *HIPAA Privacy and Security Scenarios*.

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK’S CLASS.

Using the materials for this week’s session, your student Lexis-Nexis subscription, and the internet resources supplied to you, answer the questions about the security requirements and restrictions that affect a health care provider’s ability to use or disclose “protected health information” under HIPAA that appear in the document titled, *HIPAA Privacy and Security Scenarios*.

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of one of these cases:

1. Text of *U.S. ex. rel. Sheldon v. Kettering Health Network* (S.D. OH 1-6-2015)--Victim of a HIPAA Privacy Breach Does Not Possess a False Claims Act Remedy Against the Hospital at Which the Breach Occurred
2. Text of *Turk v. Oiler*--Cleveland Clinic Sued by Patient Over Medical Records Release in Response to Grand Jury Subpoena--Application of State Statute More Stringent than HIPAA is Upheld
3. Text of *Gard v. Harris*--Did Physician's Disclosure of Patient Information to Other Health Care Providers Violate HIPAA Privacy Rule? How do the HIPAA “exceptions” permitting disclosure of “protected health information” work in the health care environment’s real world?

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision. You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. "The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff's name] appealed.

Part Three: The Court's Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1" left and right margins; a header and footer each at least .5"; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court's decision, and the implications of the court's decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court's final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Each student who has been assigned an article or case to present in class must submit the student's written synopsis to the student's instructor and classmates by 6:00 p.m. on the day before the class for which the student was initially assigned to present.

Classroom Discussion:

1. We will discuss the questions about the security requirements and restrictions that affect a health care provider's ability to use or disclose "protected health information" under HIPAA that appear in the document titled, *HIPAA Privacy and Security Scenarios*.
2. Read the text of
 - a. *Amarin Pharma, Inc. v. U.S. Food and Drug Admin.* (S.D.N.Y. Aug. 7, 2015): First Amendment Overrides FDA Regulations-Drug Manufacturer May Distribute Truthful and Non-Misleading Statements About Off-Label Uses of a Prescription Drug; and
 - b. "Kardashian Promotes a Pill, and the F.D.A. Strikes-- F.D.A. Warns Company Over Kardashian Instagram Marketing" (New York Times, 8-12-13-2015)

We will discuss another aspect of "privacy": when and under what circumstances may the [federal] government regulate speech in the pursuit of health care safety and efficacy?

Week 14

**No Class-Thanksgiving Holiday
November 24, 2015**

Week 15

Antitrust December 1, 2015

Learning Objectives

1. Understand the basic principles of antitrust laws and the manner in which the enforcement agencies and private plaintiffs are likely to assert a violation of the antitrust laws.
2. Learn how the antitrust laws apply when health care delivery systems seek to award the use of their facilities to selected providers on an exclusive basis.
3. Learn how to factor antitrust considerations when evaluating health care delivery opportunities that involve collaboration with others

Learning Activities and Assignments

Required Reading:

1. Chapter 13 of 7th edition of J. Stuart Showalter, **The Law of Healthcare Administration.**
2. “How Should Decision Makers Analyze the Potential Antitrust Risks Associated with a Transaction? (Instructor’s PowerPoint Handout).
3. Freedman, William M., “Recent Antitrust Developments Of Particular Interest To The Health Care Industry.”
4. “New Laws and Rising Costs Create a Surge of Supersizing Hospitals” (New York Times, August 13, 2013).
5. Text of Federal Trade Commission November, 2011 Administrative Complaint Challenging Hospital Merger: *In Re OSF Healthcare and Rockford Health System.*
6. Text of *ProMedica Health System v. Federal Trade Commission* (6th Cir. 4-22-14)--6th Circuit Sustains FTC Determination That ProMedica Merger with St. Luke Hospital Violated Clayton Act §7
7. Text of *Signature MD, Inc. v. MDVIP, Inc.* (C.D. Cal. 4-21-15): District Court Denies Motion to Dismiss Signature MD Allegation that MDVIP Concierge Physician Agreement's Post-Termination Noncompetition Ban on Practicing Concierge Medicine Liquidated Damages, and Non-Disclosure Provisions Violate Sherman Act §1 and §2
8. Text of *Methodist Health Services Corporation v. OSF Healthcare System b/d/a Saint Francis Medical Center* (D.C. C.D. Ill 3-25-15)- Smaller Hospital Prevails in Antitrust Complaint Against Dominant System’s Demand for Health Plan Exclusivity in Exchange for Discounts-District Court Denies Defendant's Motion to Dismiss by Defining Market Narrowly-Health Care Services Sold to Commercial Health Insurers are in a Different Market than Health Care Services Sold to Government Payers
9. Edited Text of *Omni Healthcare, Inc. v. Health First, Inc.* (M.D. Fla. 1-22-15)-- Community-Based Physician Practices Stated an Antitrust Claim Against Hospital System's PHO Provider Contract Terms

10. Text of *St. Alphonsus Med. Ctr-Nampa v. St. Luke's Health System* (9th.Cir. 2-10-15)- Hospital Purchase of Dominant Physician Practice is Anticompetitive and Requires Divestiture
11. Text of Complaint in *U.S. and Michigan v. Hillsdale Community Health Center et. al.* (D.C. E.D. MI 6-25-15)- Four Michigan Area Hospitals' Agreement Not to Advertise in the Oher's Market Area Constitutes Prohibited Market Allocation Under Sherman Act §1

Written Assignment:

YOUR WRITTEN ASSIGNMENT IS DUE BY 6:00 P.M. ON THE DAY BEFORE THIS WEEK'S CLASS.

Use your research tools (Lexis, the legal research tools described in your course materials) to locate, and then read the text (or articles describing) the October 20, 2011 Final Policy Statement issued jointly by the U.S Department of Justice and the U.S. Federal Trade Commission entitled, "Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program." Write a short (i.e., less than one page) answer to this question: *how do the final guidelines affect a health care system that wishes to form an accountable care organization all of whose physician participants will consist of physicians employed by the system?*

Class Presentation Assignments:

A class member will be assigned the responsibility for (1) preparing a written synopsis and then (2) making an in-class oral presentation, of:

1. Text of *ProMedica Health System v. Federal Trade Commission* (6th Cir. 4-22-14)--6th Circuit Sustains FTC Determination That ProMedica Merger with St. Luke Hospital Violated Clayton Act §7

Here are your instructions for your class presentation:

Your written synopsis. Your written paper must follow this pattern:

Part One: Executive Summary: Prepare a one to two sentence summary of the court's decision: "The court held that.... because...." Remember: your audience consists of health care decision makers -- not attorneys. You are trying to convey, in one to two sentences, the outcome of the decision and the crucial, fundamental reason(s) why the court decided the way it did.

Part Two: Facts. Provide a description of the facts of the case. Remember: don't copy and paste the court's recitation of the facts. That portion of the decision is filled with interesting - but ultimately extraneous facts -- facts which the judge did not actually rely upon in reaching the judge's decision You should end your factual recital by telling the reader the posture of the case: where are we in the judicial proceedings? Is this the opinion of an appellate court or the trial court? In either case, where did the case stand when the judge wrote the opinion? Is this an

opinion written following a jury verdict? Or is this an opinion written in response to a decision on a motion to dismiss or motion for summary judgment?

Example: [Recite what you think are the relevant facts]. “The defendant, [insert the name], moved for summary judgment, asserting that [insert]. The trial court granted the motion for summary judgment and [insert plaintiff’s name] appealed.

Part Three: The Court’s Decision. Tell the reader what the court decided and why. Remember: if the decision is an opinion of an appeals court, tell the reader what standard the judge used to evaluate the correctness of the decision that is being appealed.

Your written paper must not exceed one page. The page should have 1” left and right margins; a header and footer each at least .5”; and a font at least 12 points in size. You must use full, grammatical, sentences.

Your oral presentation. Present your synopsis just as you would at a management meeting. Your objective is to alert your audience to the key facts, the court’s decision, and the implications of the court’s decision. Therefore:

1. Your oral presentation should begin with your brief executive summary.
2. Outline -- in complete and understandable sentences --, the key facts the court’s final conclusion, and the rationale the court used to justify its conclusion.
3. Tell your audience -- health care decision makers -- how you think this decision affects the delivery of health care and how health care providers should react to the decision.

You must present your assigned case in *EIGHT MINUTES* or less. Use your time wisely. You should practice your presentation before an audience (one classmate or friend will do nicely) before you make your presentation in class.

Students who have been assigned an article or case to present in class must submit their written synopses BY 6:00 P.M. ON THE DAY BEFORE THE CLASS FOR WHICH THE STUDENT WAS INITIALLY ASSIGNED TO PRESENT.

Classroom Discussion:

We will discuss the issues raised in *Signature MD, Inc. v. MDVIP, Inc.* (District Court Denies Motion to Dismiss Signature MD Allegation that MDVIP Concierge Physician Agreement's Post-Termination Noncompetition Ban on Practicing Concierge Medicine Liquidated Damages, and Non-Disclosure Provisions Violate Sherman Act §1 and §2), *Methodist Health Services Corporation v. OSF Healthcare System b/d/a Saint Francis Medical Center* (Smaller Hospital Prevails in Antitrust Complaint Against Dominant System’s Demand for Health Plan Exclusivity in Exchange for Discounts), *Omni Healthcare, Inc. v. Health First, Inc.* (Community-Based Physician Practices Stated an Antitrust Claim Against Hospital System's PHO Provider Contract Terms), *St. Alphonsus Med. Ctr-Nampa v. St. Luke's Health System* (Hospital Purchase of Dominant Physician Practice is Anticompetitive and Requires Divestiture), and the complaint in

U.S. and Michigan v. Hillsdale Community Health Center et. al. (Four Michigan Area Hospitals' Agreement Not to Advertise in the Oher's Market Area Constitutes Prohibited Market Allocation Under Sherman Act §1).

To facilitate our discussion, you should prepare a short synopsis of the reasoning of the court in each decision and the key facts that produced the result. One paragraph should do nicely for each case.

Week 16

Health Care Reform: Emerging Issues in the Delivery and Consumption of Health Care December 8, 2015

Learning Objectives

1. Understand the mechanics and salient features of the federal Affordable Care Act.
2. Understand the options that federal and state lawmakers have -- and the challenges they face -- in assuring citizens access to affordable health care.

Learning Activities and Assignments

Required Reading:

1. "Patient Protection and Affordable Care Act: Medicare and Medicaid Program Integrity Provision Implementation Highlights" (Congressional Research Service, May 29, 2014)
2. "Summary of Administrative Simplification Provisions in the Patient Protection and Affordable Care Act," (U.S. Department of Health & Human Services, April 2014)
3. Text of US Supreme Court Decision in *King v Burwell* (6-25-15)-- IRC Section 36B Tax Credits Are Available To Individuals in States with Federally Facilitated Exchanges
4. Gilden, Madrigal, & Moroney, "Rubber, Meet Road: Final IRC Section 501(r) Regulations Mean the Time for Compliance Is Now" (AHLA 2015 Annual Meeting, June 29 – July 1, 2015)
5. Sobel and Salganicoff, "Round 2 on the Legal Challenges to Contraceptive Coverage: Are Nonprofits 'Substantially Burdened' by the Accommodation?" (Kaiser Family Foundation Issue Brief, May 2015)
6. CMS CCIIO 7-10-15 Fact Sheet Synopsis of Tri-Agency 7-14-15 Final Regulations on Coverage of Preventive Services Under PHS Act §2713 (Added by the Affordable Care Act), Finalizing 7-19-10 Interim Final Regulations, 8-27-14 2014 Interim Final Regulations on Process Eligible Organization Uses To Provide Notice Of Its Religious Objection To The Coverage Of Contraceptive Services, And 8-27-14 Proposed Regulations on Definition Of Eligible Organization
7. Baim, et. al., "Transparency Requirements, Healthcare Fraud And Abuse Law Changes, And Program Integrity Provisions Enacted As Part Of Health Reform Legislation," (AHLA Health Lawyers Weekly, April 2, 2010).
8. Elmendorf, Douglas, "Four Observations About the Federal Budget" [Fiscal Health Requires Tax Hikes, Cuts to Popular Programs, or Both] (Congressional Budget Office March 7, 2011 Presentation to National Association for Business Economics).
9. Kaiser Family Foundation, "A Guide to the Supreme Court's Affordable Care Act Decision" (July 6, 2012).
10. Government Accountability Office, "The Federal Government's Long-Term Fiscal Outlook-Fall 2012 Update" (December 2012).

11. Kaiser Family Foundation, "*Comparison of Medicare Premium Support Proposals*" (March 29, 2012).
12. Taylor, Lisa D., "*The What and the Why of the Sunshine Act*" [Disclosure by Manufacturers of Payments to Physicians and Group Purchasing Organization Disclosure of Physician Ownership Interests (§6002 of the Affordable Care Act)] (ABA Health Law Section Physician Issues Interest Group, May 30, 2013).
13. Freedman, William, "*How the Affordable Care Act is Driving Change Across the Health Care Landscape*"
14. Freedman, William, "*Group Health Plans: Factors Affecting Health Care Providers and the Costs They Generate for Employers and Participants*"
15. Text of IRS Notice 2015-16--Potential Approaches to IRC §4980I "Cadillac Tax"-Excise Tax on High Cost Employer-Sponsored Health Coverage
16. CMS Fact Sheet Synopsis of 7-15-15 Proposed Regulation- Proposed Policy, Payment, And Quality Provisions Changes To The Medicare Physician Fee Schedule For Calendar Year 2016, Including Introduction of the Merit-Based Incentive Payment System (MIPS) Resulting From The Repeal Of The Sustainable Growth Rate (SGR) Formula by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

Reference Materials for This Week's Topic

1. Consolidated Text of Patient Protection and Affordable Care Act (P.L. 111-148) as Amended Through January 2, 2013
2. Kaiser Family Foundation June 18, 2010 Summary of Patient Protection and Affordable Care Act (P.L. 111-148), as Modified by the Health Care and Education Reconciliation Act (P.L. 111-152).
3. Text of IRS 12-31-14 Final Regulations (T.D. 9708)--Code §501(r) Requirements -- Community Health Needs Assessment and Implementation Strategy to Meet Needs; Written Financial Assistance Policies; Limits on Emergency Charges and Collection Activities

Written Assignment Classroom Presentations

Class members will be divided into groups. Each group will be assigned one of the following five topics. Using the reference materials for this week's topic and the required readings, research your topic, prepare handout materials for your classmates and then make a group in-class presentation on your topic.

1. How should integrated hospital health care delivery systems plan for, and what elements should they include in, the community needs assessment requirements and restrictions on certain types of payments and collection practices instituted by the Affordable Care Act?
2. How has the Affordable Care Act spurred changes in the methodology that will be used to compensate health care providers? Consider federal health care programs -- Medicare - - and commercial non-governmental programs. What challenges do health care providers face?
3. Long Term Care Systems is a nonprofit system that operates skilled nursing and rehabilitation facilities in a three-state area. It employs 1,500 employees. Of that number,

1,200 are semi-skilled employees who earn less than 200% of the federal poverty level. Approximately 1,000 of these 1,200 employees currently work more than 30, but fewer than 37.5 hours per week. Long Term Care Systems sponsors a fully insured group health benefit plan. The plan currently only covers the System headquarters full time employees and its full time licensed practical and registered nurses and physicians (approximately 250 employees). For this purpose, the plan defines full time as regularly scheduled to work 37.5 hours per week or more. Long Term Care Systems pays the single premium (currently \$3,500 per year); eligible employees who wish family coverage must pay the difference between the single premium and the family premium (the family premium currently is \$12,500, so employees who wish family coverage must pay \$9,000 per year). In 2015:

- a. What changes must Long Term Care Systems make to its group health plan in order to satisfy the requirements of the Affordable Care Act and avoid the Act's employer "pay or play" penalties?
 - b. Will the cost of those changes exceed the penalties? What would you recommend?
4. How will the "Sunshine Act" provisions of the Affordable Care Act affect medical device and pharmaceutical manufacturers' relationships with physicians?
 5. How will the "Cadillac" tax on high cost employer-provided coverage (IRC §4980I, added by the Affordable Care Act) affect employer-sponsored plans? Which plans are affected? How are they responding (e.g., what are their lobbyists suggesting)? What steps could these employers take to reduce their exposure to the excise tax?