

# HEALTH LAW MJ CORE CURRICULUM AT LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

In the Health Law MJ program, designed for working health law professionals, students typically complete the program on a part-time basis over six consecutive 13-week terms. Students begin the program with a series of required foundational courses, then select from several elective options, and complete the program with a thesis or capstone project. See below for a general curriculum overview of the Health Law MJ program.\*

TERM 1

LAW 900: Introduction to Legal Study and Legal Writing (4 credits)

This foundational course introduces students to the sources and functions of law in our society. The course begins with an explanation of the structure of the American court system. Students then learn to read and brief cases, synthesize cases, and develop basic legal writing and analysis skills. Through multiple short writing assignments, students learn to construct a legal office memorandum, the final course requirement. The course utilizes legal cases and problems and provides students with background for future studies.

TERM 2

**LAW 901: Introduction to Legal Research** (1 credits)

This course provides an overview of the legal research process. Students will learn basic legal research skills with a focus on online legal sources. Students will learn methods to find health law cases, statutes, regulations and law journal articles. Finally, we will emphasize the importance of proper attribution and citation in legal writing.

**LAW 902: Introduction to Health Law and Policy** (3 credits)

This course is designed to expose students to the legal and policy issues that arise from and govern the relationship between and among patients and health care providers. Areas of focus include: conflicts between cost effective and high quality health care, access to care, individual and institutional liability, public and private regulation, accreditation and licensure, hospital/medical staff relationships, informed consent and other patient rights, consumer protections and corporate responsibility, fraud and abuse, and other legal and policy issues in the acute care setting.

\*Note that curricular offerings and requirements are subject to change.



#### **LAW 903: Introduction to Health Care Financing** (3 credits)

This course is designed to establish a basic foundation of key business and financial characteristics of the healthcare industry—especially the provider and payment sectors— for law students who may have little financial background/education. The course opens with an overview of the health care industry, followed by a primer on some essential, basic accounting and financial concepts keeping in mind that this is not an "accounting" course; only basic accounting terms and concepts are presented. The course will then explore the key business and financial aspects of a number of sectors and sub-sectors of the health care industry. At several points during the course, the intersection of finance and law will be discussed. Throughout the course, in both the handouts and the lectures, the professor attempts wherever possible to use "real-world" examples in order to provide students with maximum relevance in today's health care business and regulatory environments.

#### LAW 904: Health Care Regulation and Policy (3 credits)

The role of government in health care is explored through a review of major government health programs and policies. Students will learn how health policy gets formulated, evaluated, and assessed and will explore the process of new policy implementation. Issues to be explored will be drawn from the wide array of health matters in which governments are involved.



Choose 6 credits of elective options (see sample list)



#### LAW 951: Thesis or Capstone I (2 credits)

The purpose of this course and the course that follows, Law 952, is to guide you through the process of producing a master's thesis of publishable quality or a culminating program project. To achieve this goal, your professor will provide feedback on your submissions throughout the course and the resulting paper or project will demonstrate your expertise on a topic of your choosing.

#### **Choose 3 credits of elective options**

(see sample list)



#### LAW 952: Thesis or Capstone II (2 credits)

The purpose of this course and the course that precedes it, Law 951, is to guide you through the process of producing a master's thesis of publishable quality or a culminating program project. To achieve this goal, your professor will provide feedback on your submissions throughout the course and the resulting paper or project will demonstrate your expertise on a topic of your choosing.

#### **Choose 3 credits of elective options**

(see sample list)

# SAMPLE ELECTIVE OFFERINGS

#### 816: RACIAL JUSTICE SEMINAR SERIES (1 CREDIT)

This course exposes students to unique and emerging racial justice issues in health care or compliance. Each emerging issue is selected based on its likely impact on the industry and its timeliness given current political, business or health care challenges. This course is structuredover 13-weeks, in which we will alternate between reading weeks (where students are given reading material to introduce them to each issue) and synchronous classroom lectures by national experts on each subject.

# 829: GLOBAL COMPLIANCE (3 CREDITS)

This course will offer students the opportunity to learn how to build a compliance and ethics program. Students will study significant areas of law from both the U.S. and foreign jurisdictions that impact doing business abroad or foreign companies doing business in the U.S. A selection of areas of law that will be covered include the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and privacy regulations in the European Union. Students will learn how to perform a risk assessment, write policies, develop a training plan, and will brief a European privacy case.

# 832: CONTRACT DRAFTING (3 CREDITS)

The purpose of this course is to provide exposure to the fundamentals of contract drafting. During the course we will examine the purpose and process of drafting documents. We will use multiple client scenarios to highlight the ways contracts vary among different types of transactions. We will draft contracts, in whole and in part. In some instances, we will start with form documents borrowed from prior transactions and we will revise these documents to reflect the particular facts and circumstances surrounding our transaction. In other instances we will work through drafting a document from scratch. Finally, we will discuss how to draft in language that is clear and unambiguous. By the end of the semester, students should have a basic understanding of how and why contracts are drafted and negotiated. In addition, each student should be able to draft a precise and practical document for a basic business transaction.

#### 835: COMPLIANCE TRAINING METHODS (3 CREDITS)

This 2-credit course is designed to provide students with practical experience in developing training and education material. An emphasis will be placed on explaining complex regulations and laws to a workforce. The course will also explore varying pedagogical methods for delivering compliance education.

# 836: COMPLIANCE SEMINAR SERIES (1 CREDIT)

This course exposes students to the seven elements of an effective compliance program and emerging compliance law issues impacting business and industry. Each element/issue has the potential to effect businesses, non-profit organizations, attorneys, and consumers. Each emerging issue is selected based on its likely impact on the industry and its timeliness, given current political and legal challenges.

# 837: BREACH INCIDENT MANAGEMENT AND REPORTING (3 CREDITS)

A breach of privacy is considered inappropriate use or disclosure of personal data. Numerous laws regulate what constitutes a breach and the legal obligations if there is a breach. This course will examine: (a) what constitutes a "breach" or "incident" under a variety of scenarios and industries, (b) what legal obligations regulated entities have to act on a breach or incident, (c) what liabilities in tort or contract may exist as the result of breaches, (d) corrective actions to manage breaches and minimize recurrence, (e) electronic security measures to minimize breaches and incidents, (f) a survey of the most common cyberattacks for students to gain familiarity with trends in electronic breaches, and (g) practice in drafting notices, incident reports, and corrective actions.

#### 838: EUROPEAN UNION PRIVACY LAW (3 CREDITS)

European Union Regulation 2016/679 was adopted by the European Parliament and European Council in 2016 and has world-wide privacy law implications, not merely for activities inside the European Union. The law seeks to protect natural persons when their personal data is used by any regulated entity doing business in the EU. The law also requires regulated entities to have organized compliance efforts on a global scale. The course will examine: (a) the history of privacy law in the EU, (b) the response of the EU member states to past EU privacy directives and the current law, (c) the current EU privacy law's impact on business and data storage around the world, (d) the compliance organizational structures needed to respond to the law, and (e) liability associated with non-compliance. No background on EU law is needed; the course will begin with teaching the basic legal and constitutional structure of the European Union in order to situate the course privacy law material.

#### 845: FOREIGN CORRUPT PRACTICES ACT (3 CREDITS)

This course will focus on laws that prohibit the bribing of foreign officials for business purposes, principally the US Foreign Corrupt Practices Act but also including other national and international laws. After an in-depth study of the substantive law, we will discuss how and why companies aim to comply.

#### 857: LEADERSHIP AND STRATEGY (3 CREDITS)

As a leader or manager in your organization, it is your job to find the right people, engage and motivate them, and structure and operate the organization in a way that enables and inspires people to perform at their best. And, you have to do this in a way that preserves the organization's financial health and protects it from legal risks. Your professional success depends directly on your ability to make the right strategic decisions, and effectively lead and inspire individuals, teams and projects. This course is designed to enhance your ability to do this. This course also will enable students to examine varied approaches to leadership that are based on personal and organizational mission, vision and values. Students will have an opportunity to explore their own values and approach to leadership and accountability.

By the end of this class students will be able to:

- Model the characteristics and skills of visionary leaders
- Critically define and analyze business problems and formulate data- and information-driven business decisions
- Articulate the responsibility leaders have to all stakeholders and the application of ethical principles to business practices
- Successfully participate in and lead multi-functional team projects
- Demonstrate proficiency in the various forms of communication

#### 858: CYBERSECURITY MANAGEMENT (3 CREDITS)

This course will introduce students to the key legal, business and ethical issues related to cybersecurity. Students will gain familiarity with a framework for approaching cybersecurity through evaluating threats, risks and vulnerabilities and developing appropriate and proportional policies, processes and countermeasures to maintain the integrity of computers, systems and data.

# 859: ENVIRONMENTAL ENFORCEMENT AND REGULATION (3 CREDITS)

This class will provide an overview of corporate compliance principles applied in the environmental context, as well as to provide a general overview of federal environmental law compliance. This course will examine the principles of an effective corporate environmental compliance program and will provide a framework for students to identify, prevent, detect, respond, and correct any environmental non-compliance.

## 907: BIOETHICS AND SOCIAL JUSTICE (3 CREDITS)

This course will be an introduction to biomedical ethics (bioethics), the law and social justice. Law and bioethics have become inextricably intertwined, with law initially guiding bioethics but more recently, bioethics having a great deal of influence on the law and policy development.

This is a survey course covering a range of topics including: ethical theory, end of life care issues, informed consent, assisted reproduction, research ethics, social justice, and health care reform and related impacts on public health issues. Due to the breadth of the subject, a thorough consideration of each topic listed cannot be achieved and certain important topics, such as genetics issues, will not be addressed here. Broad health care policy issues are also covered in other LOYOLA courses, so that content will not be duplicated in this course.

The purpose of the course will be to increase your understanding of the interrelationship between law and bioethics and the role of bioethics in the development of current laws, policies and practices in the United States.

# 909: RISK MANAGEMENT, PATIENT SAFETY AND QUALITY (3 CREDITS)

This course is designed as a general survey course to provide you with an introduction to the concepts associated with managing risk, promoting quality and enhancing safety in the health care industry. The course begins with a general description of traditional risk management and then proceeds to discussion the various aspects of risk management, patient safety and quality that influence the delivery of health care.

## 910: HEALTH CARE COMPLIANCE (3 CREDITS)

This course will progress from the basics of a compliance program, including the compliance operations and the Code of Conduct, to specific issues facing the healthcare industry such as anti-kickback, Stark, False Claims Act, and civil monetary penalties; conflicts of interest and governance; tax; coding and billing; privacy, technology, data, and security; and the link between regulatory issues and quality of care. Students will be assigned projects to show them how to implement in a practical setting the various laws, regulations, and standards as well as understand the enforcement environment.

## 912: LIABILITY & DISPUTE RESOLUTION IN HEALTH CARE (3 CREDITS)

In this course students will take an in-depth look at both the substantive and procedural law of medical negligence litigation and alternative dispute resolution. Students will also review and discuss the motivations behind medical malpractice litigation and the importance of communication in the mitigation of risk following patient harm. Students will discover, during the course, the impact of medical harm and litigation on patients, families, caregivers and society, in general. The primary methodologies used in ADR, arbitration, and mediation are reviewed through a series of case examples.

### 917: PUBLIC HEALTH AND THE LAW (3 CREDITS)

Public Health Law will cover core legal issues in the regulation of population health matters. The course will provide students with an overview of an array of legal topics that concern regulatory theory, administrative law, and individual rights' concerns. The role of law will be considered at all levels of agency operation, local, state, federal and international.

#### 918: HEALTH CARE PRIVACY AND SECURITY (3 CREDITS)

This course will cover health information law and policy as it pertains to data security and privacy of electronic health records in the United States. Students will examine how individual health information is collected, maintained, and transferred in this electronic information age, and the ramifications when such information is improperly protected, stolen, and misused.

#### 920: HEALTH LAW SEMINAR SERIES (1 CREDIT)

This course exposes students to emerging issues impacting the health care industry. Each issue has the potential to impact providers, health care organizations, health care attorneys, and consumers. This course is structured over 13 weeks, in which we alternate between reading weeks, where students are given reading material to introduce them to each issue, and synchronous classroom lectures by national experts on each subject.

#### 922: ADVANCED HEALTH CARE COMPLIANCE (3 CREDITS)

This course explores advanced concepts in health care compliance. This course will present a complex health care compliance scenario each module which the student must analyze and comment upon. The scenarios will cover a broad array of regulatory subject matters which must be analyzed in the context of compliance program principles.

## 923: ADVANCED PRIVACY PROGRAM MANAGEMENT (3 CREDITS)

This course builds on Law 918, Introduction to Healthcare Privacy and Security. It also incorporates concepts from non-healthcare settings as well as various regulatory law principles which address privacy and security standards. A basic understanding of the seven (7) elements of an effective compliance program as issued in the Federal Sentencing Guidelines is necessary since the course is taught using three complex scenarios with readings and assignments designed to take the student through the analysis and development of the major elements of an effective privacy compliance program.

# 924: CONDUCTING INTERNAL INVESTIGATIONS (3 CREDITS)

This seminar will cover practical techniques in responding to suspected non-compliance as well as liability exposure in how investigations are handled. The seminar will also discuss resolution of identified non-compliance and methods for discharging an organization's legal obligations to correct non-compliance, including self-disclosures and refunds. Additionally, the seminar will cover responding to government inquiries and audits. The seminar will focus on applying these techniques across industries. LAW 910 (Health Care Compliance) or LAW 839 (MJ Corporate Compliance) are preferred prerequisites but are not required.

#### 925: DRAFTING POLICIES AND PROCEDURES (3 CREDITS)

Written standards are the infrastructure for every organization. This course will explore the various types of written standards for organizations to deploy, including policies, codes of conduct, and procedures. The course will explore the actions necessary to develop, launch, and audit effective written standards. Students will examine and critique publicly available standards. Students also will draft standards.

# 926: HUMAN SUBJECTS PROTECTION (3 CREDITS)

This course is designed to provide a comprehensive overview of the regulatory controls and the ethical framework governing research that involves human participants.

# 927: FOOD AND DRUG LAW (3 CREDITS)

Review of the Federal Food Drug and Cosmetic Act (FDCA), implementing regulations and judicial interpretations as they relate to the drug and device regulatory process in the U.S. The course will cover: history, jurisdiction and structure of the FDA; overview of drug regulation and pathways for drug approval; overview of device regulation and pathways for new device approval; drug patent and market exclusivity; regulation of clinical investigations involving drugs/devices; drug promotion/marketing and intersection with False Claims Act and First Amendment; regulation of controlled substances; and FDA inspections and recalls. Emphasis will be placed on the intersection of FDA legal concepts with compliance practice.

## 929: ENTERPRISE RISK MANAGEMENT (3 CREDITS)

Enterprise Risk Management (ERM) provides a comprehensive framework for making strategic decisions, taking into consideration concepts of both value creation and value protection. The approach looks at strategies for managing risk, uncertainty and growth and their relationship to total value. This course will cover the specific skills and techniques necessary to manage risk across increasingly complex organizations and to align business strategies with goals and culture.

# 930: LEADERSHIP AND MANAGEMENT SEMINAR SERIES (1 CREDIT)

This course is comprised of a series of lectures on topics in leadership and management by different experts in the field. Every other week students attend a live synchronous class on a leadership or management topic. Topics vary each term and are intended to cover hot topics and essential skills in leadership and management. The course is open to students in online business and health law programs.

# 958: CLINICAL RESEARCH COMPLIANCE (3 CREDITS)

This course serves as an introduction to the growing area of health law known as "life sciences." The theme for this course centers on the research and development of pharmaceutical drugs and devices and the role of the FDA in regulating this process. Topics covered will include genomics, personalized medicine, the FCPA, basic patent and intellectual property issues, and financing. Students will learn to analyze the FDA approval process.