U.S. Health Law Certificate

The U.S. Health Law Certificate is designed to provide students with comprehensive knowledge of health care law and regulation in the U.S., including public health programs and regulations, health care access and financing, the private insurance market, and Medicaid. Our renowned full-time faculty members teach a variety of courses in U.S. health law and provide advice on the development of the curriculum. Our adjunct faculty, all leading domestic health law and policy practitioners, draw on their wealth of experience to equip our students with the skills to practice in this growing and changing field.

The Certificate in U.S. Health Law is offered in conjunction with the O'Neill Institute for National and Global Health Law (http://www.law.georgetown.edu/oneillinstitute). While this certificate may be completed as a stand-alone program, students who enroll in this certificate program often find it beneficial to pursue their certificate studies along with the Global Health Law LL.M (https://curriculum.law.georgetown.edu/llm/llm-programs/llm-global-health-law). The Certificate in U.S. Health Law is open to students and graduates of Georgetown’s LL.M. programs.

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<th>Requirement</th>
<th>U.S.-Trained Students</th>
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<td>Specialization Credits</td>
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<td>GPA Requirement</td>
<td>A minimum grade point average of B- must be attained in the courses that are counted toward the Certificate’s specialization requirements.</td>
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**Full-time Global Health Law LL.M. students with a scheduling conflict between Global Health Law and Health Law and Policy should consult with Sarah Roache, Director, Global Health Law LLM Programs (contact details below)**

**Note:** This course is open to J.D. students by professor permission. Interested students should contact Ellis Duncan via email at ged5@law.georgetown.edu no later than August 1, 2018 for permission to take this class.

Contact Information
To learn more, please contact:
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Email Address: Sarah Roache (Sarah.Roache@georgetown.edu)
Search LL.M U.S. Health Law Certificate Courses (http://curriculum.law.georgetown.edu/course-search/?program=program_94)
Health law is a vast and expanding field. No single course can survey the area and cover a range of topics including health information privacy, future use of data assets, and conflicts of interest. In doing so, this course will explore the legal and ethical issues at the intersection of health information, including where data comes from, how it is and should be protected, how it can be used, and risks to its integrity and security. In addition to the case book, materials discussed and presented in this course draw from news reports, trade publications, and U.S. government agency materials.

The class requires a paper of approximately 20-25 pages in length.

**Recommended:** Criminal Justice (or Democracy and Coercion) or Criminal Procedure.

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**LAW 2037 v00 Health Information Technology and the Law**

J.D. Seminar (cross-listed) | 2 credit hours

One-fifth of the U.S. economy centers around health care industry sectors. This seminar examines criminal, civil and administrative tools used by federal and state enforcement authorities to police the U.S. healthcare system. We will focus on cases brought under federal and state False Claims Acts (FCA), the Anti-Kickback Statue (AKS), Stark laws, Federal Food Drug and Cosmetic Act (FDCA), and Foreign Corrupt Practices Act (FCPA). The seminar provides a survey of the enforcement activities of the U.S. Department of Justice (DOJ), the Office of Inspector General at Department of Health and Human Services (OIG), and state Medicaid Fraud Control Units (MFCUs) in matters against pharmaceutical and medical device manufacturing companies, physicians, hospitals, clinical practices, nursing homes, laboratories, and others. The seminar materials thoroughly cover the statues, safe-harbors, and regulations that govern the health care industry. We will also discuss risk mitigation strategies and compliance program best practices across industry sectors to provide insight into the impact enforcement has on (1) clinical decision-making, (2) costs to providers, payers, and patients, (3) patient safety, and (4) quality of care. In an effort to maintain a broad perspective with the diverse and frequently changing legal landscape in the area, in addition to the case book, materials discussed and presented in this course are included.

The class requires a paper of approximately 20-25 pages in length.

**Recommended:** Criminal Justice (or Democracy and Coercion) or Criminal Procedure.

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**LAW 206 v03 Health Law and Policy**

J.D. Course (cross-listed) | 4 credit hours

Health law is a vast and expanding field. No single course can survey it all. This course focuses on the organization, financing, and provision of medical care, with an eye toward issues not yet resolved by courts, legislators, regulators, and American society. It also considers some related ethical questions. Topics and themes include the economics of health insurance and managed care, regulatory responses to the market's perceived failures, medical tort law, access to care, consumer choice and patient autonomy, defining and assessing quality, health care providers' conflicts of interest, privacy and confidentiality, and socio-economic and racial disparities in health and medical care.

**LAW 2076 v00 Health Law and Regulation**

LL.M Course (cross-listed) | 3 credit hours

Beyond health insurance and the delivery of health care, goods and services related to individual and public health are highly regulated in the United States, and often serve as a basis for international regulations. These goods and services are a large and growing part of the U.S. and world economy, with some estimates being that more than one-quarter of U.S. food and medical products are regulated by the FDA alone. This regulation is carried out directly by a variety of State and Federal agencies (such as the FDA, the CDC, and the NIH) as well as indirectly through the purchasing power of federally financed programs, such as Medicare.

This course will include an introduction to the basic legal and regulatory frameworks within public health and an overview of the Constitutional limits and policy choices that have led to current law. The course will then move to a review of several major fields of regulation. From a high-level, this includes the regulation of health professionals, health systems, and medical or food products impacting human health. The course will then conclude with an examination of several contemporary problems, such as the safe and effective use of human drug products, infectious-disease prevention and control, ethical research practices, and rationing and allocation of limited resources.

The primary objective of the course is to teach students about the regulation of public health at the intersection of state and federal levels, recognizing that such regulatory frameworks often become the template for international policies. Students will be called on to learn the basics of two fundamental statutes—the Public Health Service Act (PHSA) and the Food, Drug and Cosmetic Act (FDCA). Students will also be called upon to follow examples of administrative change under these statutes, each year analyzing a new set of proposed regulations and sub-regulatory guidance documents. By the end of the course, students will be able to describe the major means by which goods and services used in both personal and public health are controlled, as well as areas in which future changes are likely.

Currently, there is no text or case book on this subject. The primary readings will be assigned by the professor.

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**LAW 199 v03 Law and Regulation of Drugs, Biologics and Devices**

J.D. Course (cross-listed) | 3 credit hours

This course explores the legal, regulatory and policy issues that shape the research, development, and commercialization of drugs and biologics in the United States and Europe, with a particular emphasis on public policy issues. We will consider the role of Federal, State and international regulation; regulatory and ethical issues in the development and testing of new therapies; managing incentives for innovation, including patent, regulatory and data exclusivity; tort liability and its function in the regulation of the pharmaceutical industry; pricing and payment systems and controls; and evolving medical technologies.

**Recommended:** Prior or concurrent enrollment in Administrative Law.

**Note:** This is a required course for the Food and Drug Law Certificate.
LAW 3047 v00 LGBT Health Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203047%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
Despite significant progress in legal protections for—and the visibility of—LGBT people over the past decade, LGBT communities continue to face systemic obstacles to quality health care such as refusals of care, substandard care, and inequitable policies and practices in health care settings. These experiences of discrimination correlate with significant health disparities, including greater exposure to violence, higher rates of tobacco and other substance use, mental health concerns, HIV, and cancer. These disparities are even more pronounced for LGBT people who are also members of other groups that face discrimination because of race, ethnicity, or other aspects of identity—such as people of color and immigrants, among others.

In this seminar, students will learn about LGBT health law and policy issues from a variety of perspectives—including medicine, public health, women's studies, and U.S. foreign policy—and gain a better understanding of the social mistreatment and ostracism of LGBT people at both the individual and community level. Topics covered will include international human rights law, LGBT-inclusive data collection, clinical and cultural competency, and health issues facing LGBT youth and elders. This course will also examine the ways in which LGBT individuals and families are treated under federal, state, and international law and how these policies impact access to health care and contribute to health disparities.

LAW 593 v00 National and Global Health Law: O'Neill Colloquium (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20593%20v00)
J.D. Seminar (cross-listed) | 2-3 credit hours
In this interdisciplinary colloquium, leading national and international scholars in a range of domains will explore fundamental normative and policy problems of contemporary concern in health law. Topics will include health care, public health, global health, science, regulation, politics, ethics, and policy. The colloquium will have participants from across the Georgetown University campus among faculty, senior administration, and students, as well as participants in the Washington health policy and legislative community.

Each seminar session will focus on a presentation by, or structured dialogue with, distinguished guest speakers. Students from the Law Center and other schools within Georgetown University (including Nursing and Health Studies, Medicine, Arts and Sciences, Foreign Service, Business, and other graduate programs) will be expected to prepare for intensive discussions in which experts, faculty and students explore, analyze and deepen their understanding of issues selected for consideration each month. The colloquia will be open to other students and faculty members across Georgetown University as well as interested members of the public, particularly professionals working in health law and policy in Washington.

Note: This seminar requires a paper. J.D. students must register for the 3 credit section of the seminar if they wish to write a paper fulfilling the Upperclass Legal Writing Requirement. The paper requirements of the 2 credit section will not fulfill the J.D. Upperclass Legal Writing Requirement.

LAW 1288 v00 Politics of Litigation and Litigation of Politics (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201288%20v00)
J.D. Seminar (cross-listed) | 2 credit hours
Many of the most important and intense political disputes in American history have come before the federal courts. From the controversy about the Second Bank of the United States reflected in McCulloch v. Maryland, to the conflict about slavery at the core of Dred Scott, to the rise of interest group litigation by civil rights, religious, environmental, and other organizations, those opposed to prevailing laws and policies have taken their grievances to court. In recent years, a new breed of political litigation has proliferated. Increasingly, the losers in legislative battles have leapt immediately into the judicial arena, challenging the constitutionality of the laws enacted over their objection. Increasingly, politicians and the entities they control have deployed litigation as another tool in the partisan arsenal. And increasingly, federal courts have become the arbiters of political disputes between the other two branches of the Federal Government, and between the Federal Government and the States.

This course will use the legal challenges to the Affordable Care Act as an initial case study of how political disputes play out in litigation, from the trial courts to the Supreme Court. We will follow the pattern of political litigation into the Trump Administration, and assess the lessons from the partisan shift in the litigation. We will consider how and why partisan disputes generate litigation and discuss the issues this litigation raises regarding the appropriate role of courts in our democratic system. For the most part, though, the perspective will be practical, as we explore the legal, strategic, and tactical choices advocates make in bringing high profile political cases, in framing the legal issues, in harnessing the rules of procedure, and in managing the political features of the case—both offensively and defensively, and both inside and outside the courtroom. We will discuss the hurdles litigants face in seeking to strike down federal laws, the particular challenges of representing the U.S. Government in defending those laws, and the conflicting pressures that bedevil advocates on both sides of the cases. In some of our sessions, students may be asked to strategize or to argue from the perspective of the plaintiffs or the defendant in the cases.

Prerequisite: Constitutional Law I: The Federal System (or Democracy and Coercion).
Recommended: Prior or concurrent enrollment in Federal Courts and the Federal System.
This course is intended to provoke thought and legal and ethical debate over pressing public policy issues surrounding the major health problems facing America and globally—e.g., infectious diseases, smoking, obesity, violence, injuries, and the environment. First, the course will examine the Constitutional and historical foundations of public health law in the United States. This section will discuss the Constitutional and statutory powers and duties of government to assure the conditions for a healthy and safe population, including the implementation of the Affordable Care Act. Second, the course will examine the conflicts between public health and civil liberties. For example, the course will probe conflicts between: (1) injury and disease surveillance and privacy; (2) labeling and advertising restrictions and freedom of expression; (3) personal control measures (e.g., screening, forced medical treatment and quarantine) and liberty; and (4) commercial public health regulation and property rights. Finally, the course will examine the future of public health law. This “Future” includes a careful analysis of biosecurity—both naturally occurring (e.g., Ebola, pandemic influenza, Zika Virus) and intentional (e.g., bioterrorism such as smallpox and the anthrax attacks after September 11, 2001). This course should be important for all students considering careers in health law as well as those simply interested in exploring and debating the state of public health in America. It is a particularly unique opportunity for students given the expertise of Georgetown Law’s own O’Neill Institute for National and Global Health Law.

LAW 364 v06 Public Health Law and Ethics (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20364%20v06)
J.D. Course (cross-listed) | 3 credit hours
This course explores the interwoven dynamics of legal and ethical aspects of public health issues in the United States and abroad, including infectious diseases, tobacco use, obesity, and the environment, among others. This course will be valuable for students interested in global health law, as well as students looking to broaden and deepen their expertise in preparation for a career in health law more generally.

This course will proceed in three movements. First, it will consider the conceptual foundations of public health law in the United States through the lens of governance, ethics, and human rights, affording particular attention to the statutory and regulatory powers and duties of federal and state governmental entities to protect the health and safety of the population. Second, it will examine the sources of tension between the objectives of public health and civil liberties including, among others: labeling and advertising restrictions and free speech; disease surveillance and privacy; and considerations in personal versus population-based conceptions of health. Lastly, this course will conclude by considering emerging public health issues at the intersection of law and ethics, such as biosecurity, vaccine policy, and the role for public health in broader discussions around health care reform in the United States.
**LAW 3017 v00 Survey of Employee Benefits Law**

LL.M Course (cross-listed) | 2 credit hours
This course provides a general overview of the federal labor and tax law policies and principles that apply to employment-based retirement plans, health care plans, and executive compensation arrangements. Students will examine the principles of the Internal Revenue Code and ERISA that govern the form and operation of employer-sponsored plans, especially tax-qualified pension plans, executive compensation arrangements and welfare plans (with a focus on health care). This class will concentrate on the structure and basic rules that govern such arrangements. In the context of tax-qualified and nonqualified plans and health and welfare programs, this course will explore plan administration, fiduciary duties, claims appeals and litigation.

**Prerequisite:** Federal Income Taxation (formerly Taxation I).


**Note:** Students enrolled in the Employee Benefits Certificate Program may not register for this course.

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**LAW 2080 v00 The Affordable Care Act: Law and Policy Governing Private Health Insurance**

LL.M Seminar (cross-listed) | 3 credit hours
The Patient Protection and Affordable Care Act—President Obama’s signature health reform legislation—has significantly impacted the health care system. Through changes to the regulation of private health insurance, federal subsidies for low-income people, individual and employer mandates, and dramatic expansion of the Medicaid program, millions of Americans have gained health insurance. Yet, implementation of the law’s most significant reforms has been challenging, and the law faces threats of repeal and replacement in coming years.

This course will examine the regulation of private health insurance with an emphasis on the issues that the Affordable Care Act was designed to address. Specifically, the course will explore regulatory changes such as new market reforms and health insurance marketplaces; the impact of federal and state approaches to implementation; legal and regulatory challenges; and areas where changes are anticipated. Guest lectures by speakers including legal experts, health policy experts, state and federal regulators, consumer advocates, and insurers will provide students with an in-depth understanding of how the Affordable Care Act has been implemented and what it means for millions of consumers across the country.

The primary objective of the course is to teach students about the regulation of private health insurance at the federal and state level, with the rare opportunity to witness real-time changes to this complex system. Through this course, students will gain practical experience in identifying and analyzing federal and state laws, regulations, and administrative materials. Students will also gain a broader understanding of regulatory advocacy, its significance in administrative law, and how it has affected Affordable Care Act implementation. By the end of the course, students will be able to describe how private health insurance is regulated at the federal and state level, the major reforms ushered in by the Affordable Care Act, federal and state progress in Affordable Care Act implementation, and likely areas of changes to the law given real-time debates.

**Note:** This is a required course for the U.S. Health Law Certificate.