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.

This certificate may be completed as a stand-alone program or as part of a Georgetown Law LL.M. program, including the Global Health Law LL.M (https://curriculum.law.georgetown.edu/llm/llm-programs/llm-global-health-law).

### Requirement

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<th>Requirement</th>
<th>U.S.-Trained Students</th>
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<td>Specialization Credits Required</td>
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**GPA Requirement**

A minimum grade point average of B- must be attained in the courses that are counted toward the Certificate’s specialization requirements.

### Contact Information

To learn more, please contact:
Sarah Roache, Director, Global Health Law LL.M. Programs
Phone: (202) 661-6664
Email Address: Sarah Roache (Sarah.Roache@georgetown.edu)

Please address any questions about admissions to the Office of Graduate Admissions (https://www.law.georgetown.edu/admissions-aid/graduate-admissions).

Search LL.M U.S. Health Law Certificate Courses (http://curriculum.law.georgetown.edu/course-search/?program=program_94)

LAW 534 v01 Access to Health Care and Coverage: Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20534%20v01)
J.D. Course (cross-listed) | 3 credit hours
The law governing access to health care has been in flux and in legal dispute in recent years. This course will examine America’s programs for health care access and finance, including employment-based private insurance, Medicare, Medicaid, CHIP, and VA. The course will also examine the enactment, implementation, and litigation of the Affordable Care Act. In addition to these payment systems, the course will also at laws affecting non-comprehensive systems such as emergency rooms, public hospitals, and community health centers. No previous knowledge of health law is required.

**Note:** The course will not focus on biomedical ethics, medical malpractice, or pharmaceutical regulation.

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

LAW 3091 v00 Addiction and Mental Health Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203091%20v00)
LL.M Seminar (cross-listed) | 2 credit hours
Addiction and mental health have increasingly become an integral part of the broader policy landscape. This shift has been accelerated by the impact of social issues such as the opioid epidemic, suicide and homelessness. This seminar will explore the framework of laws and policies promoting human rights, dignity, and recovery for people with substance use disorders and mental health conditions. It will highlight systemic and community responses to addiction, mental health, and related social issues as well as the use of litigation, legislation, advocacy and financial incentives as tools for reform.

**Discussion will include:**

- Evolution of responses to addiction, mental health, and related social issues;
- Human rights, deinstitutionalization and the rights of an individual to receive services in the most integrated setting appropriate to their needs;
- Statutory and regulatory frameworks promoting access to treatment, including the Patient Protection and Affordable Care Act;
- Understanding data, outcome measures, and healthcare finance structures for behavioral health, including Medicaid and commercial insurance;
- The role of litigation to promote accountability and protect civil rights;
- The impact of stigma, the dignity of risk, and harm reduction philosophy;
- Role of the health care and criminal justice systems and trends in reforms;
- The impact of globalization and comparative analysis of international drug policy;
- Cultural competence in legal advocacy and practice.

Guest lectures and discussion will provide real world case studies on laws and policy reforms impacting addiction and mental health.
LAW 065 v02 Alternative, Complementary, and Integrative Medicine, The Legal Issues Seminar (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20065%20v02)
J.D. Seminar (cross-listed) | 3 credit hours
Alternative, Complementary, and Integrative Medicine (“non-traditional medicine”) (“CAM”) is the fastest-growing sector of American Health Care and is one of the fastest growing fields in the United States. Presently, at least 50 percent of Americans are using some form of alternative and complementary therapy such as acupuncture, nutritional supplementation, herbs, massage, yoga, chiropractic and homeopathy. According to the Journal of the American Medical Association in 1997, visits to alternative health care practitioners exceeded total visits to all conventional primary care physicians. The number of clinics and hospitals that integrate some modalities of CAM alongside conventional medicine is growing rapidly. The Institute of Medicine, a part of the National Academy of Sciences, has held recent conferences on the values of both CAM and Integrative Medicine. The NIH is using significant resources to fund research in this area.

This development, of course, is raising legal issues. There is a growing but still unsettled body of law on this subject. Some but not all CAM modalities are now licensed and regulated by at least some states. Federal regulatory bodies, such as the FDA and FTC are trying, within the limits of their statutory authority, to protect what they perceive to be the interests of the public. Yet, they come at the problem through conventional, rather than alternative, eyes. Conventional law is based upon protecting the public from purveyors of the proverbial “snake oil” frauds. And to an extent this law is being used to keep out alternatives to the established health-care modalities. This seminar studies the tensions, legal, economic, and social, of this struggle as it unfolds. This seminar covers several areas of law including administrative law, medical malpractice, informed consent, FDA/FTC law, among others. A paper meeting the upperclass legal writing requirement is required.

LAW 2028 v01 Assisted Reproductive Technologies and the Law (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202028%20v01)
LL.M Seminar (cross-listed) | 2-3 credit hours
This 2 or 3 credit seminar will provide an overview of the underlying and competing laws and policies arising from the assisted reproductive technologies (ARTs) that continually make front page news. Since the 1980 opening of the country’s 1st IVF clinic amidst protests and pickets, courts and legislatures have struggled to create laws and policies in response to continually evolving reproductive advances. Topics will include: the legal status of the IVF embryo in the context of procreative rights; embryo cryopreservation, storage, disposition and mix-ups; legal implications of advances in egg freezing, reproductive genetics and oncofertility; posthumous reproduction; egg and sperm donation; traditional/genetic and gestational surrogacy; unique issues for single and same-sex couples, including the rapidly changing impact of same-sex marriage; and professional standards, economic and regulatory aspects of the ARTs.

New this semester will be the inclusion of two classes that will examine selected legal and policy aspects of comparative ART law perspectives on “third-party ART” and the impact these differences have on cross-border reproductive practices, with a particular focus on surrogacy.

National experts in their respective fields will provide guest lectures on: medical advances in ART (including a field trip to a locally based national IVF clinic); psychosocial aspects of donor egg and 3rd party ART; reproductive genetics; and regulation and public relations for ART providers.

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 for JD students. The paper requirements of the 2 credit section will not fulfill the Upperclass Legal Writing Requirement for JD students.
LAW 3120 v00 Communicating Public and Global Health Law
This course explores how stakeholders understand and communicate the impacts of law on individual and public health outcomes. Many stakeholders, including law-makers, public health experts, regulated industries, health and human rights advocates, and the public, offer unique perspectives and narratives. Through class discussions and participatory exercises, we analyze the tensions that emerge between public health objectives and other legal rights and interests, such as freedom of speech, freedom of movement, and personal choice and responsibility. We imagine how different stakeholders approach health issues, including tobacco control, healthy diets, sexual and reproductive health and infectious disease outbreaks, and how these different approaches inform health law and policy-making and adjudication of contested issues.

The course is designed to teach substantive health law knowledge and practical skills, including legal reasoning, communication, and advocacy. Our analysis and discussions will draw on a wide range of materials, including public comments, advertisements, media, judgments, and legal scholarship. Students will be assessed based on class participation (20%) and presentation of a case study (in pairs or small groups).

Note: Compulsory for National and Global Health Law LLM students and Global Health Law and Governance LLM students (if in residence at Georgetown Law).

LAW 3003 v00 Employee Benefits: Health & Welfare Plans
This course focuses on the tax and ERISA aspects of employer-sponsored health and welfare benefit plans. The tax discussion will concentrate on the conditions for favorable tax treatment of health and welfare benefits (and other statutory fringe benefits), the cafeteria plan rules, the applicable nondiscrimination requirements, and the special rules applicable to funded welfare benefits. The ERISA discussion will focus on plan design, reporting and disclosure, claims procedures, and fiduciary duty rules. The course will integrate the tax and labor aspects of the Affordable Care Act.

Prerequisite: Federal Income Taxation (formerly Taxation I).

Mutually Excluded Courses: Students may not receive credit for this course and Health and Welfare Benefit Plans: Tax & ERISA Aspects.

Note: This course is required for the Employee Benefits Certificate.

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, 2020 for permission to take this class. Students may not withdraw from this class after the add/drop period ends without the permission of the professor.

LAW 1028 v00 Health Care Fraud and Abuse Seminar
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 Statute (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 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.

LAW 2037 v00 Health Information Technology and the Law
Health care decision-making and innovation are increasingly driven and made possible by vast stores of data. The importance of data has created an inevitable push-pull dynamic between concerns for confidentiality and demands for medical progress and cost containment. Data is both a privacy risk and a tremendous asset. This course will explore the legal and ethical issues at the intersection of health information, including where data comes from, how it is used, and risks to its integrity and security. In doing so, this course will cover a range of topics including health information privacy, future use of data assets, and conflicts of interest.
LAW 206 v03 Health Law and Policy (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20206%20v03)

J.D. Course (cross-listed) | 4 credit hours
This course is Georgetown Law’s introduction to the law and policy of health care provision and financing. No single course can serve as a comprehensive introduction, and this class won’t try. Rather, we’ll consider central themes and selected topics, with an eye toward the larger questions that drive legal, political, and ethical conflict in the health sphere. We’ll begin with some context – the non-medical determinants of health, which have much greater influence on population-wide health than does clinical care. We’ll then turn to the idea of a right to health care, then to the roles of markets and government in making care available and containing medical costs. Next up will be an introduction to the Affordable Care Act, with an eye toward its conceptual framework, its critics’ core objections, and the main problems that it has left unresolved. We’ll examine some of the legal conflicts that have arisen over the ACA, then turn to brief introductions to several other areas of health care law, including medical malpractice, antitrust, and the role of for-profit v. non-profit institutions. We’ll finish with consideration of racial disparities in health care and tension between medicine’s clinical and social roles.

COVID-19 has put a spotlight on our medical care system’s shortcomings, as well as the social inequities that shape Americans’ health and well-being. Our nation’s response to COVID will thus play a substantial role in this year’s edition of the course – as both a matter of national urgency and a window onto these shortcomings.

LAW 2076 v00 Health Law and Regulation (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202076%20v00)

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.

Note: This is a required course for the US Health Law Certificate.

LAW 199 v03 Law and Regulation of Drugs, Biologics and Devices (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20199%20v03)

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**

LL.M Seminar (cross-listed) | 2 credit hours
Despite significant progress in legal protections for (and the visibility of) LGBTQ and non-binary people over the past decade, LGBTQ communities continue to face systemic obstacles to quality health care such as refusals of care, substandard care, and inequitable policies and practices in many health care settings. These experiences of discrimination correlate with significant health disparities, including greater exposure to sexual and gendered violence, higher rates of tobacco and other substance use, mental health concerns, HIV acquisition, and cancer. These disparities are even more pronounced for LGBTQ 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, young and older people, people with disabilities, low-income people, and immigrants, among others.

In this seminar, students will learn about LGBTQ 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 LGBTQ people at both the individual and community level. Topics covered will include LGBTQ-inclusive data collection, clinical and cultural competency, reproductive justice, international human rights law, and health issues facing LGBTQ youth and elders. This course will also examine the ways in which LGBTQ 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**

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 fulfilled 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**

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; (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.

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 2080 v00 The Affordable Care Act: Law and Policy Governing Private Health Insurance (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202080%20v00)

LL.M Course (cross-listed) | 3 credit hours
The Patient Protection and Affordable Care Act 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 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 its provisions have been subject to extensive litigation and continued threats of repeal.

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. The course will explore regulatory changes such as new market reforms and health insurance marketplaces; the impact of federal and state approaches to implementation; and legal and regulatory challenges. Guest lectures by speakers—including insurance industry representatives, legal experts, and regulators—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 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 implementation, and likely areas of changes to the law given real-time debates.

LAW 1511 v00 The Battle over “Obamacare”: Lessons for Health Policy & American Governance (http://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201511%20v00)

J.D. Seminar | 3 credit hours
Since the Affordable Care Act became law eight years ago, it has come under unrelenting legal and political attack. It’s been subject to multiple court challenges, and President Trump and congressional Republicans have sought to “repeal and replace” it. Some Democrats, meanwhile, have doubled down, marshalling support for their own, “single-payer” replacement. Meanwhile, some of America’s most bitter cultural conflicts – over sex, gender, and the beginning and end of life – have played out within the framework of the ACA and within the health-care sphere more generally. This seminar will examine the oft-bitter battles over “Obamacare” with an eye toward lessons for health law and policy and for American governance more generally. We’ll examine some of the problems that the ACA and rival Republican and Democratic approaches aim to address, the failings of both markets and regulation in the health sphere, and the politics of health reform.