

U.S. HEALTH LAW CERTIFICATE

The Certificate in U.S. Health Law is designed to provide students with comprehensive knowledge of health care law and regulation in the United States, 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.

Certificate Program Requirements

Requirement	U.S.-Trained Students	Foreign-Trained Students
Specialization Credits Required	10	10
Program Course Requirements	1) Regulating Private Health Insurance and Health Care Prices: Legal and Policy Disputes; 2) Health Law and Regulation	1) Regulating Private Health Insurance and Health Care Prices: Legal and Policy Disputes; 2) Health Law and Regulation
GPA Requirement	A minimum grade point average of B- must be attained in the courses that are counted toward the Certificate's specialization requirements.	A minimum grade point average of B- must be attained in the courses that are counted toward the Certificate's specialization requirements.

Eligibility Requirements

- The Certificate in U.S. Health Law can be pursued in conjunction with an LL.M. degree.
- J.D. students are not eligible to pursue the Certificate in U.S. Health Law as part of their J.D. degree studies.
- Students cannot be admitted into the U.S. Health Law program on a standalone basis.
- Students who wish to apply for the Certificate should do so by notifying their LL.M. Program Director no later than the last day of add/drop activity in the last semester before their graduation.

Contact Information

To learn more, please contact:

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

Below is a list of courses that are currently offered or have previously been offered to students to satisfy coursework for Georgetown's Certificate in U.S. Health Law program.

Please refer to the Georgetown Law Curriculum Guide (<https://curriculum.law.georgetown.edu/course-search/>) for a current list of curricular offerings related to health law which may be sorted using the *U.S. Health Law Certificate* tab under the drop-down menu for *Courses in a Graduate Program*.

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

LAW 534 v01 Access to Health Care and Coverage: Law and Policy (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 534 v01>)

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 3166 v00 Access to Reproductive Healthcare Under the Law (How We Got to Dobbs and What's Next?) (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3166 v00>)

LL.M. Seminar (cross-listed) | 2 credit hours

The course will look at the legal treatment of reproductive rights in early America through the mid-1800's and to the legalization of abortion. We will examine how we got from *Roe v. Wade* to *Dobbs v. Jackson Women's Health Care* and discuss the legal and practical impact of the Supreme Court's reversal of *Roe*, as well as state attempts to ban or restrict abortion. The course will directly address Institutional Learning Objective 8 by requiring students to think critically about the law's claim to neutrality and its differential effects on subordinated groups, including those identified by race, gender, indigeneity, and class and consider whether one person's moral or ethical position should prevail when that position has disparate negative impacts on marginalized communities. We will look at how the law is intersecting with issues of race, sex, class, religion, sexual orientation, and politics to shape the culture of the country and our individual lives. The course will conclude with a review of the current legal battles relating to abortion, emergency contraception, assisted reproduction and gender affirming care, and discuss the legal theories at play, which are being used by both sides of the debate in competing iterations.

Prerequisite: Constitutional Law.

Note: This course meets the upper-level graduation requirement for JD students matriculating in Fall 2022 and later under the following Institutional Learning Outcome, which provides that the course will provide students with an "[a]bility to think critically about the law's claim to neutrality and its differential effects on subordinated groups, including those identified by race, gender, indigeneity, and class."

LAW 3091 v01 Addiction and Mental Health Law ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3091 v01](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203091v01))

LL.M. Seminar (cross-listed) | 2 credit hours

According to a U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) 2021 survey, nearly 1 in 3 adults had either a substance use disorder or a mental illness in the prior year, and 46 percent of young adults 18-25 had either a substance use disorder or a mental illness. Due to the increased prevalence of these chronic disorders, and their nexus to the public health crisis of suicide, opioid addiction, and homelessness, it is critically important for lawyers and advocates to have a strong understanding of behavioral health law from the constitutional to local regulatory level.

This course is a practice-based seminar that is designed to improve the students' practical legal skills – writing, analysis, oral communication, issue spotting, and attention to detail – while examining key laws, legal decisions, and policies in Addiction and Mental Health Law. 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, grants and financial incentives as tools for prevention and reform.

Discussions will include:

- Institution-based issues such as the involuntary detention and civil commitments of individuals with a serious mental illness, restraint and seclusion, the right to appropriate treatment under *Youngberg v. Romeo*, institutional reform under 42 U.S.C. § 1983 and *Monell v. Department of Social Services of the City of New York*, and the Department of Justice's authority under the Civil Rights for Institutionalized Persons Act;
- Forensic issues such as pretrial competency, Not Guilty By Reason of Insanity, and forced medication for competency purposes under *Sell v. United States*;
- Community-based issues such as deinstitutionalization, rights of an individual to receive services in the most integrated setting appropriate to their needs, housing discrimination, Medicaid, rulemaking and administrative adjudications under the Administrative Procedure Act, behavioral health provider licensure and regulation, and the False Claims Act;
- Federal and state/local initiatives such as 911 diversion programs and co-responder law enforcement teams, mental health courts and diversion, harm reduction strategies, e.g. decriminalization of fentanyl testing paraphernalia, federal State Opioid Response grants, rapid rehousing initiatives, and liberalization of 42 CFR Part 2 to facilitate increased information sharing for Substance Use Disorder treatment records;
- Understanding the Triple Aim in healthcare, data, outcome measures, and healthcare finance structures for behavioral health, including Medicaid and commercial insurance;
- Role of the health care and criminal justice systems and trends in reforms; and
- 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.

Mutually Excluded Courses: Students may not receive credit for this course and Addiction and Mental Health Law and Policy.

LAW 3091 v00 Addiction and Mental Health Law and Policy ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3091 v00](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203091v00))

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 overdose 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 (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 065 v02>)

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 or 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, licensure, among others. This seminar discusses the balancing of paternalism vs. individual rights. A paper meeting the upperclass legal writing requirement is required.

LAW 2028 v01 Assisted Reproductive Technologies and the Law (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 2028 v01>)

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 (highlighted by the currently changing and challenging legal context); 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 impact of legally recognized same-sex marriage; and professional and regulatory aspects of the ARTs.

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; psychosocial aspects of donor egg and 3rd party ART; reproductive genetics; and potentially other emerging developments.

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 1789 v00 Biotechnology and the Law Seminar ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1789 v00](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%201789%20v00))

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

This is a survey class, examining issues ranging from drug regulation, clinical trials, assisted reproductive technology, telemedicine, and stem cell development/regulation to the commercialization of the human body. For this class we will use the *Biotechnology, Bioethics, & The Law Casebook* (Goodwin, et. al., eds). This course requires substantial reading, preparation, organization, and the ability to analyze subtle nuances between various judicial decisions, legislative enactments, ethics, and legal rules, which sometimes may seem in conflict.

In this class, we will examine whether emerging biotechnological conflicts are best resolved by regulation, judicial intervention, or private negotiation. Professor Goodwin encourages robust dialogue. As such, students should come to class prepared with their ideas, intuitions, and opinions. Their analysis should demonstrate a grasp of the materials. Students are expected to discuss the materials, act responsibly toward their peers, as well as conduct themselves in a professional manner. There are no prerequisites for this course. However, students must be prepared for rigorous discussions and substantial reading assignments. This course is a building block for the other courses in ethics, health law, and a law and science curriculum, including Patents, Food & Drug Law, Health Regulations, and Bioethics. The core competencies expected in this class are critical thinking and the application of social, legal, moral, and economic reasoning.

Much of the reading assigned for class will be covered during discussion.

However, some assigned readings may not be covered given limited class time. Nonetheless, students are responsible for all reading materials. The readings include excerpts from medical journals, regulations, cases, newspapers, and social science periodicals.

Course Goals

The goals of this course are to:

- *Introduce students to the study of biotechnological developments, health policy, and ethics;*
- *Familiarize students with the medical and legal literature on the topic;*
- *Engage students with practical as well as theoretical ideas in biotechnology law;*
- *Stimulate intellectual curiosity about the subject matter;*
- *And inspire critical thinking and thoughtful analysis.*

Note: This course will meet in the 500 First Street Building in Room 700 (7th Floor Conference Room).

LAW 3120 v00 Communicating Public and Global Health Law ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3120 v00](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203120%20v00))

LL.M. Seminar | 1 credit hour

This interdisciplinary course applies communications theories and approaches to the fields of public and global health law. Many stakeholders, including law-makers, public health experts, regulated industries, health and human rights advocates, and the public, offer unique perspectives and narratives on health-related legal and policy interventions. 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 individual autonomy. We explore 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 the 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 information campaigns, advertisements, media, communications theories, and legal scholarship. Students will be assessed based on class participation (20%) and presentation of a case study in small groups (80%)

LAW 3003 v00 Employee Benefits: Health & Welfare Plans ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3003 v00](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203003%20v00))

LL.M. Seminar (cross-listed) | 2 credit hours

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, labor and public policy aspects of the Affordable Care Act and other health care reforms.

Prerequisite: Federal Income Taxation.

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

Note: This course is part of the following graduate programs: Health Law LL.M. Taxation LL.M.

This course is required for the Employee Benefits Certificate. Students may not withdraw from this class after the add/drop period ends without the permission of the professor.

LAW 1844 v00 Federal Regulation of Biopharma: Commercial Considerations, Risk Identification and Mitigation (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1844 v00>)

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

This seminar provides an overview of the principal legal issues impacting the commercialization, sale and marketing of biopharmaceutical products. It:

- Provides an overview of the structure and operation of the biopharmaceutical industry, including manufacturers of innovator and generic products;
- Explores the principal laws governing the sale and marketing of biopharmaceuticals, including relevant portions of the Federal Food, Drug, and Cosmetics Act, the False Claims Act, and the Federal Anti-Kickback Statute;
- Explores how these laws create liability for both biopharmaceutical companies and their executives for the manner in which such companies price, report prices on, communicate about, and interact with regulators and health care providers about their products;
- Addresses industry-specific government investigations, risk assessment, and compliance efforts; and
- Concludes with a table-top exercise in which students role play a government investigation.

LAW 1834 v00 Follow the Science? Medicine in the Law's Crossfire (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1834 v00>)

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

More than ever, parties to bitterly-contested legal and political questions invoke medicine to support their side. Abortion, LGBTQ rights, criminal responsibility, racial equity, and vaccines and other measures against COVID-19 are among the areas of conflict that have drawn medical science and judgment into the mix. Often, physicians have been eager participants, sometimes going beyond what science shows. Such participation has a long, oft-troubling history: biomedical expertise has been invoked to identify witches, "prove" the inferiority of racial and ethnic groups, and block women's access to educational and professional opportunity. This seminar will explore advocates' use and abuse of medical science and judgment from America's founding to the present, with an eye toward distinguishing between what courts, political leaders, and parties to conflict should and shouldn't call upon medicine to do.

LAW 1836 v00 Global Health Security and the Law (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1836 v00>)

LL.M. Seminar (cross-listed) | 1 credit hour

This course analyzes the subject matter of global health security as it is shaped by international agreements and national implementation and preparedness laws. As societies and economies are increasingly interwoven and interdependent, new forms of health security threats have arisen, and nations are now contending with such implications through established agreements like the International Health Regulations (2005), a draft new pandemic agreement, and various forms of "soft power" diplomacy to mitigate infectious disease risks. In recent years, the realm of health security has expanded greatly with more governments, companies, and NGOs working to solve problems and pursue opportunities. Most prominently, the COVID-19 pandemic has shattered existing paradigms of stability and security, with ramifications from the global perspective down to that of nearly every world citizen. Over an immersive weekend of overview and interaction, this course highlights prominent threat categories, namely the "3-D threats" of Disaster, Disease, and Disorder. This seminar will be devoted as an active legal laboratory in which student ideas are solicited and shaped with the participation of the class.

The objective of the course is to crystallize student understanding at the international, national, and local legal level, the perspective viewed by national and organizational leaderships, and to frame student thinking by developing a broad, contextual understanding of the situation of health security. The course will draw connections between direct experience with purposeful intent through class exercises. Practical frameworks will be employed to simplify the dynamics within complex situations, and to organize student thinking about actions and options. An overnight simulation activity assessing a humanitarian crisis between the first and second day invites analysis about cause-effect, goals-intentions, and interventions-consequences. Two special guest speakers will share experiences on the policy frontlines, further enriching classroom dialogue. The course relies on active participation that feeds a mutual learning environment and that catalyzes and reveals students' ideas as they occur, thereby fostering an at-the-ready style of nimble thinking and conversing.

LAW 1028 v00 Health Care Fraud and Abuse Seminar (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1028 v00>)

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 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 statutes, 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 206 v03 Health Care Law and Policy (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 206 v03>)

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.

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

LAW 3165 v00 Health Care Privacy and Security (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3165 v00>)

LL.M. Seminar (cross-listed) | 1 credit hour

This course will explore the primary legal and policy principles surrounding the use and disclosure of personal data across the healthcare industry – the key privacy and security laws, regulations and principles that govern how the healthcare industry operates. We also will focus on the concepts surrounding the privacy of health information, and evaluate why this information should be treated differently than other personal information (if at all). We will learn through understanding the relevant legislative and regulatory provisions, and by applying a series of case/situation examples for class discussion. The overall goal of the course is to provide both an understanding of the relevant legal principles for health care privacy in general and to develop an ability to address how these issues arise in legal practice.

This course will emphasize the primary privacy and information security principles set out in the Health Insurance Portability and Accountability Act ("HIPAA") as a baseline framework for compliance, and will explore how these rules apply in theory and in practice. We will discuss the best approaches for overall HIPAA compliance. We also will explore emerging areas for privacy and information security, including new enforcement principles, issues related to security breaches and breach notification, and the emergence of "non-HIPAA" data as a new challenge to the privacy and data security regulatory structure (including important developments connected to the Dobbs decision and the COVID-19 pandemic). We will spend some time on issues related to privacy and medical research. We also will assess how these issues affect the business of healthcare, including a broad range of strategic and compliance issues affecting healthcare companies and others that use personal data. We will conclude with an analysis of these issues going forward – how the law and the health care system are changing and how the regulation of the privacy of personal health data can impact these developments.

Recommended: Information Privacy Law (recommended but not required)

Note: WEEK ONE COURSE. This course will meet for one week only on the following days: Monday, January 6, 2025, through Thursday, January 9, 2025, 1:30 p.m. - 5:30 p.m. The course will have a take-home exam that must be completed during the week of January 18 and January 25, 2025.

This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course.

LAW 2037 v00 Health Information Technology and the Law ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 2037 v00](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%202037%20v00))

LL.M. Seminar (cross-listed) | 2 credit hours

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 and should be protected, how it can be 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.

Note: This course is part of the following graduate programs: Master of Law and Technology Technology Law & Policy LL.M.

LAW 2076 v00 Health Law and Regulation ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 2076 v00](https://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 3145 v00 Indigenous Health Law and Access to Health Care ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3145 v00](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%203145%20v00))

LL.M. Seminar (cross-listed) | 1 credit hour

This course will examine US treaties, court cases, and Congressional acts to explore what it means for the Right to Health to exist, the ways that right is recognized among indigenous peoples, and major shortfalls in achieving equity through these paths. American Indians and Alaska Natives (AIAN) experience serious health disparities in key morbidity/mortality indicators. AIANs are also a bell-weather subgroup in the US for unusual disease such as bubonic plague or the rapid dissemination of novel infectious disease such as happened among tribes in the covid-19 pandemic. In addition to risk and vulnerability that contribute to health disparities, sovereign nation status of the 574 federally recognized tribes in the US and the Indian Health Service that serves them are particular structures shown to mitigate despair and promote future well-being in remarkably difficult circumstances. There are unique laws, operations, and tensions that undergird these structures. Recent actions to strengthen treaty obligations and extend equity movements to indigenous peoples are gathering energy to address health and justice disparities.

This course focuses on the laws and systems foundational to access to care and health services for Indigenous peoples in the US. The course will include discussions on self-determination, sovereignty, funding, social determinants of health, inter-generational trauma and additional elements of Indigenous health law in the US and compare these to other Indigenous health systems particularly those in Canada, Australia and New Zealand.

The course is designed to provide practical skills for students interested in health equity and justice, Indigenous access to care, Indigenous health law, and policy implementation. The course illuminates, in particular, outcomes of shared American history and distinctive obligations, systems, and opportunities to address ethnic disparities.

Recommended: Administrative Law; Federal Indian Law.

LAW 199 v03 Law and Regulation of Drugs, Biologics and Devices ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 199 v03](https://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, biologics, and medical devices in the United States. We will consider the history and role of federal regulation of medical technologies; legal 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 life sciences industry; and other issues. We will explore these issues using real-world examples, including the government and industry response to the COVID-19 pandemic.

Recommended: Prior or concurrent enrollment in Administrative Law.

Note: This is a required course for the U.S. Health Law Certificate Food and Drug Law Certificate.

LAW 3047 v00 LGBTQ Health Law and Policy (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3047 v00>)

LL.M. Seminar (cross-listed) | 2 credit hours

Course Description

Despite progress in legal protections for LGBTQ+ and non-binary people, and in the face of recent setbacks, LGBTQ+ communities continue to face systemic obstacles to quality health care such as coverage, refusals of care, substandard care, lack of access to culturally competent care, discrimination, and inequitable policies and practices in health care settings. These experiences correlate with significant health disparities, including greater exposure to sexual, institutional, and state violence, higher rates of tobacco and other substance use, mental health concerns, HIV and other infectious diseases, 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 Black, Indigenous, and other People of Color, young and older people, people with disabilities, people with low incomes, 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, public benefits, health insurance, social determinants of health, and U.S. foreign policy—and gain a better understanding of the legal and social mistreatment of LGBTQ people at both the individual and community level and its impact on health. Topics covered will include health care access, LGBTQ-inclusive data collection, clinical and cultural competency, disability rights, reproductive justice, and health issues facing LGBTQ + youth and older adults. This course will also examine how 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.

Course Goals & Student Learning Outcomes

The primary objective of the course is to teach students about health disparities faced by LGBTQ+ communities, to identify the laws and policies that contribute to these health disparities, identify legal and policy measures to reduce those disparities, and to discuss emerging issues and topics that affect LGBTQ+ peoples' health. Through this course, students will learn about the impact that federal, state, and international laws and policies have on LGBTQ+ health, including speakers who are actively working in the LGBTQ+ community at nonprofits, Capitol Hill, and government agencies. Past speakers include attorneys from the NAACP Legal Defense and Education Fund, Lambda Legal, National Center for Transgender Equality, the National Immigration Law Center, and the Presidential Advisory Council on HIV/AIDS.

This seminar will help students develop critical thinking skills and will provide a clearer understanding of how federal, state, and international laws and policies impact LGBTQ+ health. The course will also highlight how lawyers can use the tools of law (e.g., litigation, legislation, regulatory action) to advance health justice and equity amid a rapidly changing legal and political environment.

LAW 1426 v00 Medical Malpractice Seminar (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 1426 v00>)

J.D. Seminar (cross-listed) | 2-3 credit hours

This seminar focuses on the empirical literature on medical malpractice, medical malpractice litigation, and tort reform. We will cover physician and institutional liability, health care quality and medical error, the economics of litigating medical malpractice cases, the market for representation, the causes of malpractice crises, and the effect of the reforms that have resulted (and been proposed).

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 593 v00 National and Global Health Law: O'Neill Colloquium (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 593 v00>)

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.

Mutually Excluded Courses: Students may not receive credit for this course and Pandemics, Global Health, and the Law Seminar.

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 364 v07 Public Health Law and Ethics ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 364 v07](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20364%20v07))
J.D. Course (cross-listed) | 3 credit hours

This course explores the interwoven dynamics of law, ethics, and science in public health through examination of core legal theory and practice-based examples. With COVID-19 ushering law, policy, and decision-making around public health into broad public awareness, this class will draw upon current issues in society, enabling students to apply legal and ethical concepts to real-world scenarios. By spotlighting recent and historical examples of public health law in action, including COVID-19, opioids, obesity, tobacco, and the environment, this course will be valuable for students interested in health law and equity, as well as students seeking to deepen their expertise in public policy.

Students will learn the conceptual foundations of public health law in the United States, with 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 and the judicial decisions that shape them. Sources of tension between public health goals and objectives and civil liberties will be interactively contemplated, including, among others: disease surveillance and privacy; labeling and advertising restrictions and free speech; and considerations around individual versus population-based conceptions of health. Discussions of recent major legislative developments and court decisions impacting jurisprudence, public health authority, and individual rights will be incorporated alongside primary themes. Throughout the course, students will engage with public health law through applied learning—case studies and class exercises—focused on analyzing emerging issues, comparing national and global responses, understanding ethical implications, and developing legal and policy strategies that integrate health equity and address social determinants of health.

LAW 364 v08 Public Health Law and Ethics ([https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 364 v08](https://curriculum.law.georgetown.edu/course-search/?keyword=LAW%20364%20v08))
J.D. Course (cross-listed) | 3 credit hours

This course explores the interwoven dynamics of law, ethics, and science in public health through examination of core legal theory and practice-based examples. With the COVID-19 pandemic and multi-country mpox outbreak ushering law, policy, and decision-making around public health into broad public awareness, this class will draw upon current issues in society, enabling students to apply legal and ethical concepts to real-world scenarios. By spotlighting recent and historical examples of public health law in action, including health emergencies (e.g., COVID-19, Ebola, Zika, and mpox), non-communicable diseases (e.g., diabetes and cardiovascular disease, including the role of nutrition and physical activity, tobacco, and the environment, this course will be valuable for students interested in health law and equity, as well as students seeking to deepen their expertise in public policy. We will also discuss the deeper social, economic, and commercial determinates of health.

Students will learn the conceptual foundations of public health law in the United States, with 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 and the judicial decisions that shape them. Sources of tension between public health goals and objectives and civil liberties will be interactively contemplated, including, among others: disease surveillance and privacy; labeling and advertising restrictions and free speech; and considerations around individual versus population-based conceptions of health. Discussions of recent major legislative developments and court decisions impacting jurisprudence, public health authority, and individual rights will be incorporated alongside primary themes.

Throughout the course, students will engage with public health law through applied learning—case studies and class exercises—focused on analyzing emerging issues, comparing national and global responses, understanding ethical implications, and developing legal and policy strategies that integrate health equity and address social determinants of health.

Note: This course meets on a condensed schedule. It will meet twice a week for the 1st eight weeks, then the course will meet once a week for the next five weeks. The last class meeting is on Wednesday, 11/20.

LAW 2080 v01 Regulating Private Health Insurance and Health Care Prices: Legal and Policy Disputes (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 2080 v01>)

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

Access to affordable and quality health care eludes millions of Americans. Through changes ushered in by the Patient Protection and Affordable Care Act (ACA), millions of Americans have gained health insurance. At the same time, implementation of the law's reforms have been challenging, and its provisions have been subject to extensive litigation and continued threats of repeal. Health care costs also continue to climb for privately-insured Americans more broadly – leading to calls for further action to regulate health care prices – the main driver of rising costs.

The legal and policy clashes over the ACA's implementation have also foreshadowed future obstacles facing subsequent major health care reform initiatives - such as the No Surprises Act and Medicare Drug Price Negotiation Program.

This course will examine the regulation of private health insurance and health care prices in commercial insurance and public programs. The course will explore federal regulatory changes under the ACA; subsequent reforms to private insurance under the No Surprises Act and other measures under consideration to address health care pricing; the new authority for Medicare to negotiate the price of prescription drugs; and legal challenges burdening the regulation of private health insurance and efforts to regulate health care prices. This course will also situate health care in the broader context of measures to address public health and population health, interrogate the persistent disparities in health care access and quality and the challenges to addressing those disparities, including what became more visible during the COVID-19 pandemic. Guest lectures will provide students with a greater, contextualized understanding of former and current legal and policy disputes related to private health insurance regulation and measures to address rising health care prices. The course will also explore what these legal and policy efforts mean for consumers, public health, and broad work to address inequities in health care access and outcomes—as well as where Congress and the White House may push forward with health reform in the future.

LAW 3090 v00 Reproductive Rights (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3090 v00>)

LL.M. Course (cross-listed) | 2 credit hours

This course will explore the history and law of reproductive rights in the United States. The majority of the semester will be spent analyzing the constitutional framework, jurisprudence and federal and state regulations governing forced sterilization, contraception and abortion from the 1920s until today. We will consider the historical, social and religious context of the regulation of reproduction; gender, race and socioeconomic class issues; and the practical impact of the regulations in effect today. This course is primarily focused on reproductive rights in the United States, but we may consider comparative international perspectives.

Please note that this course will not cover regulation of parenting, adoption, foster care, assisted reproductive technologies or related reproductive health topics, or reproductive justice in any meaningful detail.

All students are expected to read the assignments, attend class, and prepare for active discussion every week. Depending on course enrollment, I may assign small groups of students to assist me in leading each week's discussion of the assigned materials. Short oral presentations on current events or topics of particular interest will likely be assigned during the second half of the semester.

Grading: Class participation, including oral presentations, and/or short reaction papers will represent at least 35% of the final grade. A take-home exam will account for the remaining 65%.

Recommended: Constitutional Law I

Note: The course incorporates some international perspectives, and US reproductive jurisprudence is influential globally—but happy to discuss further since the focus is US law.

LAW 837 v00 Research with Human Subjects: Law, Policy & Ethics
(<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 837 v00>)

LL.M. Seminar (cross-listed) | 1 credit hour

This course provides an opportunity to explore issues related to the use of humans as research subjects. The course will begin by examining the history of human subject research, including the abuses that led to the creation of our modern legal protections. Following a discussion of the ethical principles of research involving humans, we will carefully explore the legal treatment of human subjects, focusing on US regulations and international instruments. Core sources will include: the Common Rule (45 CFR 46), Belmont Report, Declaration of Helsinki, Nuremberg Code, and CIOMS. After exploring a series of foundational themes and issues through the first half of the week, the remainder of the class will focus on in-depth case studies. Topics may include: international research, research involving vulnerable populations (children, prisoners, and pregnant women), informed consent, research on subjects with impaired decision-making abilities, genetic/genomic research, risk-benefit analysis, coercion/undue inducement, use of placebos, and IRB governance.

Note: WEEK ONE COURSE. This course will meet for one week only on the following days: Monday, January 9, 2023 through Thursday, January 12, 2023, 9:00 a.m. - 12:20 p.m. The course will have a take-home exam that must be completed between January 20 and January 27, 2023.

This course is mandatory pass/fail and will not count toward the 7 credit pass/fail limit for J.D. students. ATTENDANCE IS MANDATORY AT ALL CLASS SESSIONS. Enrolled students must be in attendance at the start of the first class session in order to remain enrolled. Waitlisted students must be in attendance at the start of the first class session in order to remain eligible to be admitted off the waitlist. All enrolled students must attend each class session in its entirety. Failure to attend the first class session in its entirety will result in a drop; failure to attend any subsequent class session in its entirety may result in a withdrawal. Enrolled students will have until the beginning of the second class session to request a drop by contacting the Office of the Registrar; a student who no longer wishes to remain enrolled after the second class session begins will not be permitted to drop the class but may request a withdrawal from an academic advisor in the Office of Academic Affairs. Withdrawals are permitted up until the last class for this specific course. **NOTE: Mandatory attendance rules will be enforced for this class for the Spring 2023 semester. Graduating students are encouraged to ensure they have enough credits should they be prevented from attending due to COVID-19 symptoms, isolation, quarantine, or other disruptions.**

LAW 3017 v00 Survey of Employee Benefits Law (<https://curriculum.law.georgetown.edu/course-search/?keyword=LAW 3017 v00>)

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.

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

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

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 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 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 levels, 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.