George Mason University Antonin Scalia Law School
Law 427-001
Health Law Seminar
Fall 2023 Syllabus
Wednesdays 4 – 6 PM
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Office hours available upon request

Course Description:

This seminar will provide students with a broad overview of the U.S. healthcare system and the laws and regulations affecting such complex industry in the provision of healthcare services and supplies to its direct and indirect consumers. Students will learn the fundamentals of health laws, regulatory compliance, and the legislative and policy landscape of the healthcare industry. Students will also gain a basic understanding of the ethical considerations governing health law and public health policy.

Course Topics:

1. Key stakeholders in the healthcare industry
2. Regulatory and legislative landscape
3. Healthcare financing – a public and private partnership
4. Review of key health care laws, including AKS, Stark Law, FCA, and CMP laws and federal initiatives to prevent FWA
5. Tools used to enforce compliance with healthcare laws and regulations including Consent Decrees, Settlement Agreements, Corporate Integrity Agreements and Resolutions
6. Intersection of research and analysis with lobbying and advocacy to effectuate change in the healthcare industry
7. Subspecialties within Health Law – FDA Regulation, Bioethics, HIPAA/Privacy and IT Security, ADA/non-discrimination

Course Format:

The course will be a combination of lectures and group discussions. The lectures will cover the topics above. Group discussions will allow students to apply these concepts to current real-world scenarios and engage in critical thinking and analysis. Where appropriate and when available, guest lecturers will be invited to provide a unique perspective on the specific topic for that scheduled class.

Student Assessment:

The seminar will be assessed through a combination of (1) individual class participation, (2) group presentation, and (3) final paper. Individual class participation will account for 30% of the final grade, a group presentation will account for 30%, and the final paper will account for 40%.

1. Individual Class Participation: Students will be responsible for completing assigned readings prior to class. Class participation will be graded based on attendance and participation in class discussion.
2. Group Presentation: Students will be paired into groups and assigned to lead a group discussion at each scheduled class. Group Presentations will focus on identifying an article or paper within the past year and leading a discussion during a portion of the class. Students should be prepared to discuss legal issues raised by the article/paper and prepare one-two questions to discuss. The article/paper should be sent to me by Monday before the assigned class with questions to be posed.
3. Final Paper: The final paper will require students to analyze recent high-profile legislation, regulation or court case and the impacts to access to health care. Final papers should be at least 20 pages, double-spaced in the format of a white paper, journal article or law review. ***Concepts for papers must be submitted by September 6th for prior approval. Final papers will be due by November 22, 2023.*** Papers will be graded based on (i) substance including facts, analysis and conclusion, as well as (ii) style including clarity, conciseness, grammar and spelling.

Required Textbook:

The seminar text is the *Law of the American Health Care, Third Edition* authored by Nicole Huberfeld, Elizabeth Weeks, Kevin Outterson, and Matthew Lawrence. Additional readings may be assigned throughout the semester and supplied to each student.

Learning Outcome Statements:

1. Students will be able to demonstrate knowledge and basic information about health laws and regulations in the US system
2. Students will be able to communicate their knowledge about this subject orally and in writing, to a variety of audiences.
3. Students will be able to apply the course information and skills to real world situations.
4. Students will be able to reflect on how they learn about health care laws and regulations and create plans to incorporate that approach into their own work.

Course Schedule and Outline:

Class Schedule	Class Topic	Detailed Description	Assignments
August 23	Discussion of course objectives, expectations; and requirements; Overview of the healthcare industry.	• Overview of the structure of the healthcare industry, including key stakeholders in the healthcare industry – Individuals and their rights – Relationships with providers, including hospitals, doctors, advanced practice practitioners, nurses and other allied health care providers – Manufacturers, Distributers, and industry players – Government authorities and industry oversight	Required: • Chapter 1: pgs. 1-16 (16 pages) Additional Resources: • Patient's Bill of Rights | CMS • Patient Rights and Responsibilities | MedStar Health • I. Physician Relationships With Payers | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (hhs.gov) • II. Physician Relationships With Fellow Providers: Physicians, Hospitals, Nursing Homes, Etc. | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (hhs.gov) • III. Physician Relationships With Vendors | Office of Inspector General | Government Oversight | U.S. Department of

			Health and Human Services (hhs.gov)
August 30	Regulatory and legislative landscape – past, present, future	• Discussion of key laws and regulations and the evolution of the regulatory and legislative landscape – Public provision of health insurance – Regulation of the health industry – Certificate of Need – Practice of Medicine – EMTALA	Required: • Chapter 5: pgs. 259-264, 281-288 • Chapter 8: pgs. 471-473,492-497, 509-510 • Chapter 9: pg. 548 (25 pages) Additional Resources: • Regulations & Guidance | CMS • Certificate of Need State Laws (ncsl.org) • Issue brief: Corporate practice of medicine (ama-assn.org) • Emergency Medical Treatment & Labor Act (EMTALA) | CMS
September 6	Healthcare financing through government contracts and grants	• Overview of government payors and corresponding laws, regulations, guidelines – Medicare – Medicaid – Other government payors, such as Tricare – Government contracts and grant funding	Required: • ***Submit concept for Final Paper for prior approval*** • Chapter 2: pgs. 51-64, 70-73, 95 • Chapter 3: pgs. 105-109, 148-158 (35 pages) Additional Resources: • Home - Centers for Medicare &

			Medicaid Services | CMS • Health Resources and Services Administration | HRSA
September 13	Healthcare financing with private payors and alternative payment models	• Overview of private payors, including employment sponsored health insurance – Commercial payors – Managed care – Insurance exchange – ERISA	Required: • Chapter 4: pgs. 173-185, 192-200, 201-207, 231-255 (54 pages) Additional Resources: • Consumer Information and Insurance Oversight | CMS • CMS Innovation Center Homepage | CMS Innovation Center
September 20	Review of key health care laws to prevent fraud waste and abuse (FWA)	• Understanding of federal and state False Claims Acts, Civil Monetary Penalties laws, and Exclusion Statute	Required: • Chapter 7: pgs. 375-411 (37 pages) Additional Resources: • Fraud & Abuse Laws | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (hhs.gov)

September 27	Review of key health care laws to prevent FWA (cont.)	• Understanding of federal and state anti-kickback statutes and the Physician Self-Referral (Stark) Law, and other federal and state administrative remedies	Required: • Chapter 7; pgs. 412-470 (59 pages) Additional Resources: • Advisory Opinions | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services (hhs.gov)
October 4	Healthcare Compliance	• Review of FWA concepts • Overview of principles of healthcare compliance • Review of tools used to enforce compliance with healthcare laws and regulations – Consent Decrees, Settlement Agreements – Corporate Integrity Agreements – Mediation and Resolutions	Required: • Chapter 7: pg. 466 • Self-Disclosure Protocol 2021 (hhs.gov) • Federal Register: Modernization of Compliance Program Guidance Documents (16 pages) Additional Resources: • FY2020 Health Care Fruad and Abuse Control Program Annual Report (justice.gov) • Civil Rights Division | DOJ Agreements And Resolutions (justice.gov) • Corporate Integrity Agreements |

			Healthcare Compliance | Office of Inspector General | U.S. Department of Health and Human Services (hhs.gov) • Resolution Agreements | HHS.gov • PhRMA-Code---Final.pdf
October 11	Subspecialties within Health Law – FDA Regulation	• Overview of FDA regulations relating to drug and device manufacturing and distribution • Discussion of intersection between advancing healthcare through clinical trials	Required: • Chapter 12; pgs. 781-818 (37 pages) Additional Resources: • CFR - Code of Federal Regulations Title 21 (fda.gov) • 45 CFR 46 | HHS.gov • Clinical Trials: What Patients Need to Know | FDA
October 18	Subspecialties within Health Law – HIPAA/Privacy and IT/Security	• Discussion on protections for healthcare patient data through relevant laws and regulations – HIPAA/Privacy – Information Technology and Security	Required: • Chapter 11: pgs. 723-746 (24 pages) Additional Resources: • HIPAA | HHS.gov • Health IT Legislation | HealthIT.gov

October 25	Subspecialties within Health Law – Non-discrimination laws and ADA	• Overview of non-discrimination laws in healthcare • Discussion of American Disabilities Act applied to the healthcare industry	Required: • Chapter 9: pgs. 533-544, 556-566 (22 pages) Additional Resources: • Laws & Regulations Enforced by OCR | HHS.gov
November 1	Subspecialties within Health Law – Bioethics and Medical Malpractice	• Discussion of informed consent and health care decision making, including end of life decisions • Overview of medical malpractice	Required: • Chapter 10: pgs. 609, 682, 702-705 (6 pages) Additional Resources: • Bioethics Home | Bioethics (nih.gov) • Home · Five Wishes • Association of Organ Procurement Organizations - AOPO
November 8	Advocating and lobbying for change	• Intersection of research and analysis with lobbying and advocacy to effectuate change in the healthcare industry • Industry organizations • Conflicts of interest	Required: • Chapter 5: pgs. 300-325 (26 pages) Additional Resources: • The Importance of Lobbying to Advance Health and Science

			Pol... : Academic Medicine (lww.com) • The thin line between lobbying and corruption: health advocacy - BMJ Global Health blog • Identifying and Determining Involvement of Stakeholders (cdc.gov)
November 15	Trends in the healthcare industry	• Discussion of recent trends – COVID response – Telehealth – Artificial Intelligence	Required: • US healthcare developments in 2023 and beyond | McKinsey (10 pages)
November 22	Final Paper Due	• The final paper will require students to analyze recent high-profile legislation, regulation or court case and the impacts to access to health care. Final papers should be at least 20 pages, double-spaced in the format of a white paper, journal article or law review. ***Concepts for papers must be submitted by September 6th for prior approval.*** Papers will be graded based on (i) substance including facts, analysis and conclusion, as well as (ii) style including	Required: • Final papers will be due at the end of business day.

		clarity, conciseness, grammar and spelling.	