

**Law 427-001 | Health Law Seminar | Spring 2025 | 2 credits**

**Professor(s):** Jennifer L. Clarke, JD, MPH

**Wed. 4:00 – 6:00 pm EST | Final Exam: N/A**

**Reading(s): [REQUIRED]** 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.

**Communication(s):** [jclark78@gmu.edu](mailto:jclark78@gmu.edu)

**Office Hours: By appointment.**

**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 healthcare 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:*

- Key stakeholders in the healthcare industry
- Regulatory and legislative landscape
- Healthcare financing – a public and private partnership
- Review of key health care laws, including AKS, Stark Law, FCA, and CMP laws and federal initiatives to prevent FWA
- Tools used to enforce compliance with healthcare laws and regulations
- Advocacy and trends in the healthcare industry
- Subspecialties within Healthcare Law including Bioethics, HIPAA/Privacy and IT Security, ADA/non-discrimination

*Course Format:*

The course will be a combination of lectures and individual/group discussions. The lectures will cover the topics above. Individual and 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.

**COURSE OBJECTIVES**

Students will be able to demonstrate knowledge and basic information about health laws and regulations in the US system.

Students will be able to communicate their knowledge about this subject orally and in writing, to a variety of audiences.

Students will be able to apply the course information and skills to real world situations.

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.

## Law 427-001 | Health Law Seminar | Spring 2025 | 2 credits

Professor(s): Jennifer L. Clarke, JD, MPH

Wed. 4:00 – 6:00 pm EST | **Final Exam:** N/A

### GRADING & PARTICIPATION

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 25% of the final grade, a group presentation will account for 25%, and the final paper will account for 50%.

#### *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, as well as presenting the assigned readings on the assigned date.

#### *Group Presentation:*

Students will be paired into groups and assigned to lead a discussion on the assigned date for a portion of the class. Group Presentations should focus on identifying an article or paper relevant to the class topic for that assigned date. Presenters should prepare at least two questions to pose to the class and be prepared to discuss legal issues raised by the article/paper. The article/paper should be sent to the class a week prior to the presentation.

#### *Final Paper:*

The final paper will require students to analyze recent 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 will be presented to the class on April 9, 2025. Final papers will be due by April 23, 2025.** Papers will be graded based on (i) substance including facts, analysis and conclusion, as well as (ii) style including clarity, conciseness, grammar and spelling.

### COURSE SCHEDULE & ASSIGNMENTS

Class Schedule	Class Topic	Detailed Description	Assignments
January 22	Discussion of course objectives, expectations; and requirements; Overview of the healthcare industry.	<ul style="list-style-type: none"><li>• Overview of the structure of the healthcare industry, including key stakeholders in the healthcare industry<ul style="list-style-type: none"><li>– Individuals and their rights</li><li>– Relationships with providers, including hospitals, doctors, advanced practice practitioners, nurses and other allied health care providers</li><li>– Manufacturers, Distributors, and industry players</li><li>– Government authorities and industry oversight</li></ul></li></ul>	<p><u>Readings:</u></p> <ul style="list-style-type: none"><li>• Chapter 1: pgs. 1-23</li></ul> <p><u>Additional Resources:</u></p> <ul style="list-style-type: none"><li>• <a href="#">Patient's Bill of Rights   CMS</a></li><li>• <a href="#">Patient Rights and Responsibilities   MedStar Health</a></li><li>• <a href="#">I. Physician Relationships With Payers   Office of Inspector General   Government Oversight   U.S. Department of Health and Human Services (hhs.gov)</a></li></ul>

**Law 427-001 | Health Law Seminar | Spring 2025 | 2 credits**

**Professor(s):** Jennifer L. Clarke, JD, MPH

**Wed. 4:00 – 6:00 pm EST | Final Exam: N/A**

			<ul style="list-style-type: none"><li>• <a href="#">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)</a></li><li>• <a href="#">III. Physician Relationships With Vendors   Office of Inspector General   Government Oversight   U.S. Department of Health and Human Services (hhs.gov)</a></li></ul>
<b>January 29</b>	Regulatory and legislative landscape – past, present, future	<ul style="list-style-type: none"><li>• Discussion of key laws and regulations and the evolution of the regulatory and legislative landscape<ul style="list-style-type: none"><li>– Public provision of health insurance</li><li>– Regulation of the health industry</li><li>– Certificate of Need</li><li>– Practice of Medicine</li><li>– EMTALA</li></ul></li></ul>	<p><u>Readings:</u></p> <ul style="list-style-type: none"><li>• Chapter 5: pgs. 259-264, 281-288</li><li>• Chapter 8: pgs. 471-473, 492-497, 509-510</li><li>• Chapter 9: pg. 548</li></ul> <p><u>Additional Resources:</u></p> <ul style="list-style-type: none"><li>• <a href="#">Regulations &amp; Guidance   CMS</a></li><li>• <a href="#">Certificate of Need State Laws (ncsl.org)</a></li><li>• <a href="#">Emergency Medical Treatment &amp; Labor Act (EMTALA)   CMS</a></li></ul>
<b>February 5</b>	Healthcare financing	<ul style="list-style-type: none"><li>• Overview of government payors and corresponding laws, regulations, guidelines<ul style="list-style-type: none"><li>– Medicare</li><li>– Medicaid</li><li>– Other government payors, such as Tricare</li><li>– Government contracts and grant funding</li></ul></li></ul>	<p><u>Readings:</u></p> <ul style="list-style-type: none"><li>• Chapter 2: pgs. 51-64, 70-73, 95</li><li>• Chapter 3: pgs. 105-109, 148-158</li></ul> <p><u>Additional Resources:</u></p> <ul style="list-style-type: none"><li>• <a href="#">Home - Centers for Medicare &amp; Medicaid Services   CMS</a></li></ul>

**Law 427-001 | Health Law Seminar | Spring 2025 | 2 credits****Professor(s):** Jennifer L. Clarke, JD, MPH**Wed. 4:00 – 6:00 pm EST | Final Exam:** N/A

			<ul style="list-style-type: none"><li>• <a href="#">Health Resources and Services Administration   HRSA</a></li></ul>
<b>February 12</b>	Healthcare financing (cont.)	<ul style="list-style-type: none"><li>• Overview of government payors (cont.)</li><li>• Brief summary of other payor sources</li></ul>	<u>Additional Resources:</u> <ul style="list-style-type: none"><li>• Chapter 4: pgs. 173-185, 192-200, 201-207, 231-255</li><li>• <a href="#">Consumer Information and Insurance Oversight   CMS</a></li><li>• <a href="#">CMS Innovation Center Homepage   CMS Innovation Center</a></li></ul>
<b>February 19</b>	Review of key health care laws to prevent fraud waste and abuse (FWA)	<ul style="list-style-type: none"><li>• Understanding of federal and state False Claims Acts, Civil Monetary Penalties laws, and Exclusion Statute</li></ul>	<u>Readings:</u> <ul style="list-style-type: none"><li>• Chapter 7: pgs. 375-411</li></ul>
<b>February 26</b>	Review of key health care laws to prevent FWA (cont.)	<ul style="list-style-type: none"><li>• Understanding of federal and state anti-kickback statutes and the Physician Self-Referral (Stark) Law, and other federal and state administrative remedies</li></ul>	<u>Required:</u> <ul style="list-style-type: none"><li>• Chapter 7; pgs. 412-470</li></ul>
<b>March 5</b>	Review of key health care laws to prevent FWA (cont.)	<ul style="list-style-type: none"><li>• Review of FWA laws (cont.)</li></ul>	<u>Additional Resources:</u> <ul style="list-style-type: none"><li>• <a href="#">Fraud &amp; Abuse Laws   Office of Inspector General   Government Oversight   U.S. Department of Health and Human Services (hhs.gov)</a></li><li>• <a href="#">Advisory Opinions   Office of Inspector General   Government Oversight   U.S. Department of Health and Human Services (hhs.gov)</a></li></ul>
<b>March 12</b>	Spring Break – No Class		

**Law 427-001 | Health Law Seminar | Spring 2025 | 2 credits**

**Professor(s):** Jennifer L. Clarke, JD, MPH

**Wed. 4:00 – 6:00 pm EST | Final Exam: N/A**

<b>March 19</b>	Healthcare Compliance	<ul style="list-style-type: none"><li>• Overview of principles of healthcare compliance</li><li>• Review of tools used to enforce compliance with healthcare laws and regulations<ul style="list-style-type: none"><li>– Consent Decrees, Settlement Agreements</li><li>– Corporate Integrity Agreements</li><li>– Mediation and Resolutions</li></ul></li></ul>	<p><u>Readings:</u></p> <ul style="list-style-type: none"><li>• Chapter 7: pg. 466</li><li>• <a href="#">OIG Self Disclosure Protocol</a></li><li>• <a href="#">CMS Self Disclosure Protocol</a></li><li>• <a href="#">Federal Register: Modernization of Compliance Program Guidance Documents</a></li></ul> <p><u>Additional Resources:</u></p> <ul style="list-style-type: none"><li>• <a href="#">DOJ-OIG Report 2023</a></li><li>• <a href="#">Civil Rights Division   DOJ Agreements And Resolutions (justice.gov)</a></li><li>• <a href="#">Corporate Integrity Agreements   Healthcare Compliance   Office of Inspector General   U.S. Department of Health and Human Services (hhs.gov) Resolution Agreements   HHS.gov</a></li></ul>
<b>March 26</b>	HIPAA/Privacy and IT/Security	<ul style="list-style-type: none"><li>• Discussion on protections for healthcare patient data through relevant laws and regulations<ul style="list-style-type: none"><li>– HIPAA/Privacy</li><li>– Information Technology and Security</li></ul></li></ul>	<p><u>Readings:</u></p> <ul style="list-style-type: none"><li>• Chapter 11: pgs. 723-746</li></ul> <p><u>Additional Resources:</u></p> <ul style="list-style-type: none"><li>• <a href="#">HIPAA   HHS.gov</a></li><li>• <a href="#">Health IT Legislation   HealthIT.gov</a></li></ul>
<b>April 2</b>	Non-discrimination laws and ADA in the healthcare industry	<ul style="list-style-type: none"><li>• Overview of non-discrimination laws in healthcare</li><li>• Discussion of American Disabilities Act applied to the healthcare industry</li></ul>	<p><u>Readings:</u></p> <ul style="list-style-type: none"><li>• Chapter 9: pgs. 533-544, 556-566</li></ul> <p><u>Additional Resources:</u></p> <ul style="list-style-type: none"><li>• <a href="#">Laws &amp; Regulations Enforced by OCR   HHS.gov</a></li></ul>

**Law 427-001 | Health Law Seminar | Spring 2025 | 2 credits****Professor(s):** Jennifer L. Clarke, JD, MPH**Wed. 4:00 – 6:00 pm EST | Final Exam: N/A**

<b>April 9</b>	Overview of Bioethics and related subspecialties of healthcare law	<ul style="list-style-type: none"><li>• Discussion of bioethics, including informed consent, health care decision making, and end of life decisions</li></ul>	<p><u>Readings:</u></p> <ul style="list-style-type: none"><li>• Chapter 10: pgs. 609, 682, 702-705</li><li>• Chapter 12; pgs. 781-818</li></ul> <p><u>Additional Resources:</u></p> <ul style="list-style-type: none"><li>• <a href="#">Bioethics Home   Bioethics (nih.gov)</a></li><li>• <a href="#">Home · Five Wishes</a></li><li>• <a href="#">Association of Organ Procurement Organizations - AOPO</a></li></ul>
<b>April 16</b>	Discussion of Final Paper	<ul style="list-style-type: none"><li>• Presentation of proposed paper for preparation of submission</li></ul>	<p><u>Readings:</u></p> <ul style="list-style-type: none"><li>• Chapter 5: pgs. 300-325</li><li>• <a href="#">McKinsey - US Healthcare in 2024 and Beyond</a></li></ul> <p><u>Additional Resources:</u></p> <ul style="list-style-type: none"><li>• <a href="#">The Importance of Lobbying to Advance Health and Science Pol... : Academic Medicine (lww.com)</a></li><li>• <a href="#">The thin line between lobbying and corruption: health advocacy - BMJ Global Health blog</a></li></ul>
	Advocating and Lobbying in the healthcare industry and anticipating trends	<ul style="list-style-type: none"><li>• Intersection of research and analysis with lobbying and advocacy to effectuate change in the healthcare industry</li><li>• Discussion of recent trends</li></ul>	
<b>April 23</b>	Final Paper Due	<ul style="list-style-type: none"><li>• 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. Papers will be graded based on (i) substance including facts, analysis and conclusion, as well as (ii) style including clarity, conciseness, grammar and spelling.</li></ul>	<ul style="list-style-type: none"><li>• Final papers will be due at the end of business day.</li></ul>