

Ethical and Legal Issues in Healthcare Informatics

CS584 A1 2026 Spring (Thursdays 6-8:50PM)

Prof. Michael Cannella; michael.evan.cannella@gmail.com

TAs: TBD

Office hours:

Prof. Cannella, Monday 9:0-11:00 AM, or by appointment (remotely)

TAs: TBA

Classroom Location: 685-725 Comm Ave CAS 218

Course Description

Laws, regulations, and ethics guide the practice of health information management (HIM) and health informatics (HI). This course introduces students to the workings of the American legal system and concepts and theories of ethics, examines the legal, ethical, and regulatory issues that impact the protection of confidentiality and integrity of patient information, and, on the other hand, the improvement of accessibility of patient data to enable healthcare providers to make informed decisions based on complete patient data. We will cover laws and regulations that are central to the HIM and HI professions, including the Privacy Act of 1974, the Health Insurance Portability and Accountability Act (HIPAA), the Genetic Information Nondiscrimination Act of 2008 (GINA), the Health Information Technology for Economic and Clinical Health (HITECH) Act, the Food and Drug Administration Safety and Innovation Act (FDASIA), the 21st Century Cures Act, and the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, and more. The goal is to enable HIM and HI practitioners to make effective and informed decisions that prompt patient safety and care quality improvement. Two or three guest speakers who are experts in legal and ethical issues on health information management will be invited to share their experiences and knowledge with students.

Learning Objectives

By completing this course, you will be able to:

- Describe the workings of the American legal system
- Explain concepts and theories of ethics
- Analyze legal and ethical issues central to HIM and HI
- Apply the concepts of risk, quality, and utilization management to HIM and HI related issues
- Discuss healthcare fraud and abuse
- Make informed decisions that prompt patient safety and care quality improvement

Course Outline

This course is presented as a series of modules. The course material is grouped into six modules each spanning a two-week period. The seventh module represents the week of the Final Examination. For modules 1 – 5, each module comprises two lectures, one discussion topic, one quiz, and one assignment. There is also a term project. There is no quiz, discussion, or assignment for module 6.

Discussions – There are weekly discussions on selected topics that were covered in the module. The facilitator(s) and the professor moderate these discussions. You are expected to write an original post, between 300 to 500 words, and make thoughtful responses to at least two different posts of your classmates. You are strongly encouraged to submit your original post as early as possible to leave sufficient time for your classmates to read and comment on your post. Please check the Study Guide for due dates. There are also general discussion boards to ask non-urgent questions and download course materials.

Assignments – There are weekly assignments throughout the course. Please check the Study Guide for due dates.

Assessments – There are weekly quizzes throughout the course. Please check the Study Guide for due dates. Quizzes may be a combination of True/False, single/multiple-choice, matching, and short essay questions.

Term Project – The term project tests your overall understanding and grasp of the course content, and your ability to synthesize that understanding into a research based written paper with an associated presentation.

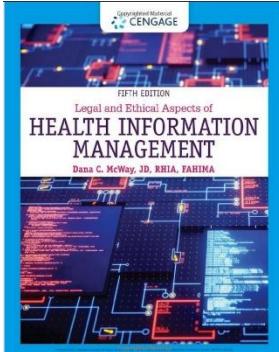
Final Examination – There will be a proctored Final Exam in this course. The exam will either be in person proctored by the Professor or, for online offerings, using a proctoring service called Examity. Detailed instructions regarding your proctored exam will be forthcoming from the Assessment Administrator. You will be responsible for scheduling your appointment. The Final Exam is comprehensive and covers material from the entire course. It is an open-book exam consisting of questions similar to those in the quizzes and assignments.

Prerequisites

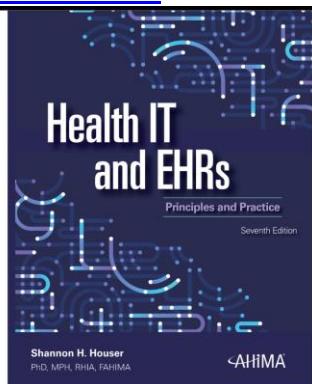
None

Required Books

Legal and Ethical Aspects of Health Information Management, 5th Edition. Dana C. McWay. Cengage. SBN-13: 978-0357361542. ISBN-10: 0357361547.



Houser, S. (2024). Health IT and EHRs: Principles and Practice, 2024, 7th Edition. American Health Information Management Association (AHIMA). <https://reader.yuzu.com/books/978-1-58426-965-6>



All books are made available through the Barnes and Noble First Day program. Details can be found on the Blackboard site by following the link in the topline item on the course page.

Grading Criteria

The final grade for this course will be based on the following:

Quizzes	15%
Assignments	15%
Discussion	15%
Midterm Exam	10%
Project	10%
Class participation	5%
Final Exam	30%

Timeliness

Strict adherence to deadlines is crucial. Late submission of quizzes will not be accepted/graded. In case of an emergency and you are unable to meet any deadline, you must contact your professor **BEFORE** the deadline to discuss your situation.

Discussion Grading Rubric

Online discussion is one of the ways we "participate" in the class. It is important that you post thoughtful messages that move the conversation forward in some way. Please check the Study Guide to find out the due dates for each discussion. Discussions are moderated by your lecturers and are graded. You will be graded on your overall participation in that discussion thread. Late posts are welcome for their intellectual value but will not be considered in your grade. The discussion grading rubric below is our guide to evaluating your discussion contributions.

Your posts should show that you have read the discussion topics and your classmates' posts and have applied all of that to the question at hand. You should engage with the material by analyzing and interpreting it. Your posts should be grammatically clear enough not to present anyone with a problem understanding your point. To earn full points:

- Post your original post early, preferably **within one week into the module**
- Thoughtful and timely responses to **at least two different students**
- The content is complete, on-point, and thoughtful
- Supporting detail is appropriate (such as citations to other sources)
- Content often encourages further discussion on the topic or follows up on others' thoughts
- Postings are characterized by originality, engagement, and relevance to the topic
- Postings demonstrate an understanding of the material assigned and familiarity with the ideas of the course materials

The following chart represents the rubric employed for grading the threaded discussion entries and in-class discussions in the blended course version:

Points	Skills
90–100	Demonstrate excellence in grasping key concepts; Critique the work of others; Stimulate discussions; Include proper citations for support of opinions; Offer new interpretations of discussion material; Express ideas clearly and concisely; Use appropriate vocabulary.
70–80	Show understanding of most course concepts; Offer an occasional divergent viewpoint or challenge; Show some skill in support for opinions; Show signs of disorganization with expression.
50–60	Have a primarily shallow grasp of the material; Rarely take a stand on issues; Offer inadequate levels of support; Poor language use; Garbles much of the message; Only an occasional idea surfaces clearly; Expressions seem disjointed; Overuse of simple sentences and redundancy with words and commentary; Paragraphs often appear unrelated to each other.

10-40	A minimal posting of material. Show no significant understanding of the material. Incoherent writing. Do not respond readily to prompting.
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Credits: GRADING RUBRIC FOR THREADED DISCUSSIONS. From John F. Bauer, "Assessing Student Work from Chat Rooms and Bulletin Boards."

Study Guide

Module 1 (Lectures 1 & 2) – Introduction to American Government and Law

- Basic Foundations of US Government Structure
- Introduction to American Legal System
- American Court systems and Legal Procedures – Examination of Article III Court procedures with an emphasis on ESI

Required reading:

Textbook (McWay) Chapter 1 -2, Goodwin MB, Whelan AM, Gostin LO. *Food and Drug Administration v Alliance for Hippocratic Medicine*—A Cautious Win for Reproductive Health Care and FDA Authority. *JAMA*. 2024;332(6):453–454. doi:10.1001/jama.2024.13161

Recommended reading and other media:

- The [Constitution of the United States of America](#)
- [Methods of Interpreting Statutes](#) (YouTube video)
- [Federal vs State Laws](#) (YouTube video)
- [Federal and State Courts Explained](#) (YouTube video)

Module 2 (Lectures 3 & 4) – Introduction to American Healthcare System and judicial process, and Principles of Liability

- Admissibility of relevant evidence and the hearsay rule as applied to health information
- Explanation of concepts including physician-patient privilege, e-discovery, subpoena, etc.
- Overview of the structure and state of the U.S. Healthcare System
- Principles of liability and Relationships Giving Rise to Specific Forms of Liability/Obligations

Required reading:

Textbook (McWay) Chapter 3 -4, Peter Jacobus, "The E-Discovery Problem of "Modern" Attachments: Case Trends in the Production of Hyperlinked Documents," JDSUPRA, June 13, 2024, available at <https://www.jdsupra.com/legalnews/the-e-discovery-problem-of-modern-3904379/>, & Toyja E. Kelley and Noah J. Mason, "Following the Trail of Lost or Destroyed ESI with Forensic Imaging," For The Defense, May 2024, pp 30-33, available at

<https://www.lockelord.com/newsandevents/publications/2024/05/following-trail-lost-destroyed-esi>

Recommended reading and other media:

- Aaron Carroll (February 2014). [The Healthcare System of the United States](#). [Healthcare Triage](#). (Both links will open to YouTube.)
- [An Overview of Medicare](#)
- [Medicaid website](#)
- Chapter 5. [How Health Care Is Organized—I: Primary, Secondary, and Tertiary Care](#) in the book: Understanding Health Policy: A Clinical Approach. (Requires BU login)
- AHIMA e-Discovery Task Force (2008). [Litigation response planning and policies for E-discovery](#). J AHIMA 79(2): 69-75.
- [Medicaid programs/Brief US Health care coverage history](#) (YouTube video)
- [Mastering Modern Attachments in eDiscovery Webinar](#) (YouTube video)

Module 3 (Lectures 5 & 6) – A overview of ethics

- Understand the difference between ethics, morals, values, etiquette, and law
- Introduce ethical models
- Define codes of ethics and their importance
- Discuss ethical challenges in healthcare with an emphasis on digital technologies
- Discuss bioethical issues with an emphasis on reproductive care and end of life decisions

Required reading:

Textbook (McWay) Chapter 5 - 7, Druedahl, L.C., Kälvemark Sporrong, S. (2024). Patient Perspectives on Data Sharing. In: Corrales Compagnucci, M., Minssen, T., Fenwick, M., Aboy, M., Liddell, K. (eds) The Law and Ethics of Data Sharing in Health Sciences. Perspectives in Law, Business and Innovation. Springer, Singapore. https://doi.org/10.1007/978-981-99-6540-3_4, Hansson, S.O., Fröding, B. Digital Technology in Healthcare—An Ethical Overview. *DISO* 3, 46 (2024). <https://doi.org/10.1007/s44206-024-00121-2>, Howe Iii EG, Elenberg F. Ethical Challenges Posed by Big Data. *Innov Clin Neurosci*. 2020 Oct 1;17(10-12):24-30. PMID: 33898098; PMCID: PMC7819582, <https://pmc.ncbi.nlm.nih.gov/articles/PMC7819582/>. Gosain, J., Keune, J.D., Sinha, M.S. (2024). Dobbs in a Technologized World: Implications for US Data Privacy. In: Corrales Compagnucci, M., Minssen, T., Fenwick, M., Aboy, M., Liddell, K. (eds) The Law and Ethics of Data Sharing in Health Sciences. Perspectives in Law, Business and Innovation. Springer, Singapore. https://doi.org/10.1007/978-981-99-6540-3_6

Recommended reading and other media:

- Code of ethics published by [AHIMA](#), [AMIA](#), and [IMIA](#)
- “The top 10 ethical issues medical students should be taught,” AMA, Dec. 4, 2023, available at <https://www.ama-assn.org/education/changemeded-initiative/top-10-ethical-issues-medical-students-should-be-taught>

- Wexler, A., Largent, E. Ethical considerations for researchers developing and testing minimal-risk devices. *Nat Commun* **14**, 2325 (2023). <https://doi.org/10.1038/s41467-023-38068-6>
- [Ethical dilemma: Whose life is more valuable?](#) (YouTube video)
- [Ethical dilemma: Would you sacrifice one person to save five?](#) (YouTube video)
- [Ethical dilemma: You can only save one— who do you choose?](#) (YouTube video)

Module 4 (Lectures 7 & 8) – Patient record requirements, confidentiality, and informed consent

- Understand the legal requirements for health record content
- Learn health record retention requirements and the issues related to record destruction
- Explain the interrelationship between confidentiality and privacy
- Discuss the various laws on which the right of privacy is based with an added focus on research and deidentified datasets
- Consider the case of GDPR compliance as compared to US privacy rights
- Introduce the concept of informed consent and substituted consent

Required reading:

Textbook (McWay) Chapter 8 -9, Matt Davis, “GDPR Compliance in the U.S.: What to Know,” JD Supra, May 24, 2023, available at <https://www.jdsupra.com/legalnews/gdpr-compliance-in-the-u-s-what-to-know-4133643/>, Steve Alder, “GDPR Requirements for US Companies,” The HIPAA Journal, Oct. 18, 2021, available at <https://www.hipaajournal.com/gdpr-requirements-for-us-companies/>

Recommended reading and other media:

- [Medical Record Maintenance & Access Requirements](#)
<https://www.cms.gov/files/document/mln4840534-medical-record-maintenance-and-access-requirements.pdf>, [GDPR Enforcement Tracker](#)
- Brian Daigle and Mahnaz Khan, “One Year In: GDPR Fines and Investigations against U.S.-Based Firms,” USITC, Sept. 2019, available at https://www.usitc.gov/publications/332/executive_briefings/gdpr_enforcement.pdf
- Haugen, M. B., Tegen, A., Warner, D., & Ahima. (2011). [Fundamentals of the legal health record and designated record set](#). J AHIMA, 82(2), 44-49.
- [Evolution of the Medical Record](#) (YouTube video)
- [Protecting Data Confidentiality](#) (YouTube video)

Module 5 (Lectures 9 & 10) – Access to health information and specialized patient records

- Understand the ownership of health information

- Discuss the access of health information on behalf of the patient and by various parties, such as researchers and business associates with a focus on interoperability, and information blocking rule
- Differentiate specialized patient records and general patient records with a focus on new 42 Part 2 regulations and HIPAA reproductive care information rule
- Discuss the regulations governing patient identification and their practical applications
- Discuss the release of information in the substance abuse setting

Required reading:

Textbook (McWay) Chapter 10 -11 (except only read 42 CFR Part 2 portion in conjunction with Chris Alibrandi O'Connor, "Summary of 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records, Final Rule," Network for Public Health Law, Mar. 15, 2024

<https://www.networkforphl.org/wp-content/uploads/2024/03/Summary-of-42-CFR-Part-2-Confidentiality-of-Substance-Use-Disorder-Patient-Records-Final-Rule.pdf>), Groom Law Group, "Reproductive Health Care: New HIPAA Restrictions & Compliance Checklist," JD Supra, Sept. 10, 2024, available at <https://www.jdsupra.com/legalnews/reproductive-health-care-new-hipaa-2431929/>, "HHS Finalizes Rule Establishing Disincentives for Health Care Providers That Have Committed Information Blocking, <https://www.hhs.gov/about/news/2024/06/24/hhs-finalizes-rule-establishing-disincentives-health-care-providers-that-have-committed-information-blocking.html>, Information Blocking, OIG, <https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/>, CMS Interoperability and Patient Access Final Rule (CMS-9115-F), <https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/policies-and-regulations/cms-interoperability-and-patient-access-final-rule-cms-9115-f>

Recommended reading and other media:

- Health Information Privacy Division. (2020). [Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524](#)
- Federal Trade Commission. (2013). [Fighting Identity Theft with the Red Flags Rule: A How-To Guide for Business](#)
- Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates, OCR Guidance, June 26, 2024, <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html>
- [Information Blocking: What Providers Need to Know](#) (YouTube video)

Module 6 (Lectures 11 & 12) –Information Systems and Engaging in Risk Management Through Compliance Program Development

- Discuss risk management, quality management, and utilization management
- Discuss healthcare fraud and abuse and various related law enforcement agencies

- Discuss strategies for building a successful compliance program to account for legal regimes such as HIPAA Security Rule and fraud, waste and abuse laws
- Discuss challenges surrounding use of new or growing modalities (e.g., telehealth, email, SMS, and AI) in the delivery of care

Required reading:

Textbook (McWay) Chapter 12 -14, Steve Adler, "HIPAA Training Requirements," The HIPAA Journal, May 21, 2023, available at <https://www.hipaajournal.com/hipaa-training-requirements/>, Katie Roemer, "Building an Effective Compliance Program," AAPC, Nov. 1, 2023, available at <https://www.aapc.com/blog/89139-building-an-effective-compliance-program/>, Brian Dunphy, and Samantha Kingsbury, "EnforceMintz — Artificial Intelligence and False Claims Act Enforcement," JD Supra, Feb. 13, 2024, available at <https://www.jdsupra.com/legalnews/enforcemintz-artificial-intelligence-2956151/>

Textbook (Houser) Chapter 15

Recommended reading and other media:

- [HIPAA Compliance Case Examples](#)
- [GDPR compliance checklist for US companies](#)
- [Healthcare Fraud Prevention Partnership](#) (YouTube video)
- [Medicare Fraud and Abuse Training](#) (YouTube video)
- [AI Governance](#) (YouTube video)

Class Meetings, Lectures & Assignments

Lectures, Readings, and Assignments are subject to change and will be announced in class as applicable within a reasonable time frame.

Date	Topic	Readings Due	Assignments Due
Jan. 22	Basic Foundations of US Government Structure Introduction to American Legal System	Textbook (McWay) chapter 1; Sections "About Legal Citations" and "About Legal Research", in Preface	n/a

Jan. 29	American Court systems and Legal Procedures— Examination of Article III Court procedures with an emphasis on ESI	Textbook (McWay) chapter 2; Module 1 online content Goodwin MB, Whelan AM, Gostin LO. Food and Drug Administration v Alliance for Hippocratic Medicine—A Cautious Win for Reproductive Health Care and FDA Authority. <i>JAMA</i> . 2024;332(6):453–454. doi:10.1001/jama.2024.1316	Initial posts for Discussion 1
Feb. 5	Admissibility of relevant evidence and the hearsay rule as applied to health information Overview of the structure and state of the U.S. Healthcare System	Textbook (McWay) chapter 3 Peter Jacobus, “The E-Discovery Problem of “Modern” Attachments: Case Trends in the Production of Hyperlinked Documents,” <i>JDSUPRA</i> , June 13, 2024, available at https://www.jdsupra.com/legalnews/the-e-discovery-problem-of-modern-3904379/ Toyja E. Kelley and Noah J. Mason, “Following the Trail of Lost or Destroyed ESI with Forensic Imaging,” <i>For The Defense</i> , May 2024, pp 30-33, available at https://www.lockelord.com/newsandevents/publications/2024/05/following-trail-lost-destroyed-esi Howe Iii EG, Elenberg F. Ethical Challenges Posed by Big Data. <i>Innov Clin Neurosci</i> . 2020 Oct 1;17(10-12):24-30. PMID: 33898098; PMCID: PMC7819582. Gosain, J., Keune, J.D., Sinha, M.S. (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC7819582/	Assignment 1 Quiz 1 Discussion 1
Feb. 12	Principles of liability and Relationships Giving Rise to Specific Forms of Liability/Obligations	Textbook (McWay) chapter 4; Module 2 online content Dobbs in a Technologized World: Implications for US Data Privacy. In: Corrales Compagnucci, M., Minssen, T., Fenwick, M., Aboy, M., Liddell, K. (eds) <i>The Law and Ethics of Data Sharing in Health Sciences. Perspectives in Law, Business and Innovation</i> . Springer, Singapore. https://doi.org/10.1007/978-981-99-6540-3_6	Initial posts for Discussion 2
Feb. 19	Introduction to ethical standards and decision-making	Textbook (McWay) chapter 5 and 6; Druedahl, L.C., Kälvemark Sporröng, S. (2024). Patient Perspectives on Data Sharing. In: Corrales	Assignment 2 Quiz 2 Discussion 2

	challenges with an emphasis on digital technologies	Compagnucci, M., Minssen, T., Fenwick, M., Aboy, M., Liddell, K. (eds) The Law and Ethics of Data Sharing in Health Sciences. Perspectives in Law, Business and Innovation. Springer, Singapore. https://doi.org/10.1007/978-981-99-6540-3_4 Hansson, S.O., Fröding, B. Digital Technology in Healthcare—An Ethical Overview. DISO 3, 46 (2024). https://doi.org/10.1007/s44206-024-00121-2 ;	
Feb. 26	Introduction to bioethical issues with an emphasis on reproductive care and end of life decisions	Textbook (McWay) chapter 7; Module 3 online content Howe Iii EG, Elenberg F. Ethical Challenges Posed by Big Data. Innov Clin Neurosci. 2020 Oct 1;17(10-12):24-30. PMID: 33898098; PMCID: PMC7819582, https://pmc.ncbi.nlm.nih.gov/articles/PMC7819582/ Dobbs in a Technologized World: Implications for US Data Privacy. In: Corrales Compagnucci, M., Minssen, T., Fenwick, M., Aboy, M., Liddell, K. (eds) The Law and Ethics of Data Sharing in Health Sciences. Perspectives in Law, Business and Innovation. Springer, Singapore. https://doi.org/10.1007/978-981-99-6540-3_6	Initial posts for Discussion 3
Mar. 5	Mid-term exam		
Mar. 19	Introduction to patient record requirements	Textbook (McWay) chapter 8 Textbook (Houser) Chapter 12	Assignment 3 Quiz 3 Discussion 3
Mar. 26	Introduction to confidentiality and informed consent with an added focus on research and deidentified datasets Consider the case of GDPR compliance as	Textbook (McWay) chapter 9; Module 4 online content Matt Davis, “GDPR Compliance in the U.S.: What to Know,” JD Supra, May 24, 2023, available at https://www.jdsupra.com/legalnews/gdpr-compliance-in-the-u-s-what-to-know-4133643/ Steve Alder, “GDPR Requirements for US Companies,” The HIPAA Journal, Oct. 18, 2021, available at https://www.hipaajournal.com/gdpr-requirements-for-us-companies/	Initial posts for Discussion 4

	compared to US privacy rights		
April 2	Access to Health Information	<p>Textbook (McWay) chapter 10</p> <p>“HHS Finalizes Rule Establishing Disincentives for Health Care Providers That Have Committed Information Blocking, https://www.hhs.gov/about/news/2024/06/24/hhs-finalizes-rule-establishing-disincentives-health-care-providers-that-have-committed-information-blocking.html</p> <p>Information Blocking, OIG, https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/</p> <p>CMS Interoperability and Patient Access Final Rule (CMS-9115-F), https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/policies-and-regulations/cms-interoperability-and-patient-access-final-rule-cms-9115-f</p> <p>Textbook (Houser) Chapter 9</p>	Assignment 4 Quiz 4 Discussion 4
April 9	Specialized Patient Records	<p>Textbook (McWay) chapter 11; Module 5 online content</p> <p>Chris Alibrandi O'Connor, “Summary of 42 CFR Part 2, Confidentiality of Substance Use Disorder Patient Records, Final Rule,” Network for Public Health Law, Mar. 15, 2024 https://www.networkforphl.org/wp-content/uploads/2024/03/Summary-of-42-CFR-Part-2-Confidentiality-of-Substance-Use-Disorder-Patient-Records-Final-Rule.pdf</p> <p>Groom Law Group, “Reproductive Health Care: New HIPAA Restrictions & Compliance Checklist,” JD Supra, Sept. 10, 2024, available at https://www.jdsupra.com/legalnews/reproductive-health-care-new-hipaa-2431929/</p>	Initial posts for Discussion 5
April 16	Introduction to risk management, quality	<p>Textbook (McWay) chapter 12 and 13</p> <p>Steve Adler, “HIPAA Training Requirements,” The HIPAA Journal, May 21, 2023, available at</p>	Assignment 5 Quiz 5 Discussion 5

