Boston University Metropolitan College

Ethical and Legal Issues in Healthcare Informatics
CS584 A1 2024 Summer (Live Classroom Sessions as Indicated from 8-9:30PM)

Prof. Michael Cannella; michael.evan.cannella@gmail.com
Facilitators: Mary Lucas; mmlucas@bu.edu, George Komolafe; geokomo@bu.edu,
 Vijai Diwania; vijaid@bu.edu

Office hours:
Prof. Cannella, Monday 11:30-12:30 PM, or by appointment (remotely)
Facilitators: TBA

Classroom Location: Remote

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.
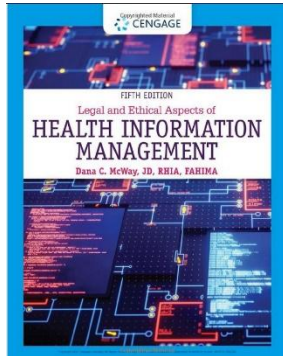
Prerequisites
None

Required Book
Legal and Ethical Aspects of Health Information Management, 5th Edition. Dana C. McWay. Cengage. SBN-13: 978-0357361542. ISBN-10: 0357361547.
Physical copies of the book are available at Mugar Memorial Library, BU.

Boston University Metropolitan College

Grading Criteria

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

Deliverable	Weight
Quizzes	15%
Assignments	15%
Discussion	15%
Final Exam	35%

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.

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 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 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 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 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 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 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/

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)

Boston University Metropolitan College

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
May 6	Basic Foundations of US Government Structure Introduction to American Legal System	Textbook chapter 1; Sections "About Legal Citations" and "About Legal Research", in Preface	n/a
May 9	American Court systems and Legal Procedures– Examination of Article III Court procedures with an emphasis on ESI	Textbook 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. JAMA. 2024;332(6):453–454. doi:10.1001/jama.2024.1316	Initial posts for Discussion 1
May 12	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 chapter 3 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 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. Gosain, J., Keune, J.D., Sinha, M.S. (2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC7819582/	Assignment 1 Quiz 1 Discussion 1

May 15	Principles of liability and Relationships Giving Rise to Specific Forms of Liability/Obligations	Textbook 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) 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 2
May 19	Introduction to ethical standards and decision-making challenges with an emphasis on digital technologies	Textbook chapter 5 and 6; 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;	Assignment 2 Quiz 2 Discussion 2
May 22	Introduction to bioethical issues with an emphasis on reproductive care and end of life decisions	Textbook 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
May 27	Introduction to patient record requirements	Textbook chapter 8	Assignment 3 Quiz 3 Discussion 3

May 29	Introduction to confidentiality and informed consent with an added focus on research and deidentified datasets Consider the case of GDPR compliance as compared to US privacy rights	Textbook 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
June 2	Access to Health Information	Textbook chapter 10 "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	Assignment 4 Quiz 4 Discussion 4
June 5	Specialized Patient Records	Textbook chapter 11; Module 5 online content 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-	Initial posts for Discussion 5

		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/	
June 9	Introduction to risk management, quality management, and utilization management and strategies for building a successful compliance program	Textbook chapter 12 and 13 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/	Assignment 5 Quiz 5 Discussion 5
June 12	Introduction to healthcare fraud and abuse and incorporating those laws into a compliance program	Textbook chapter 14; Module 6 online content Ben Penn, "DOJ's Healthcare Probes of AI Tools Rooted in Purdue Pharma Case," Bloomberg Law, Jan. 29, 2024, available at https://news.bloomberglaw.com/us-law-week/dojs-healthcare-probes-of-ai-tools-rooted-in-purdue-pharma-case	NOTE: Final Project Due June 13
June 16 & 17	Project presentation	Submit Slides at least 2 hours prior to presentation time on assigned date	
June 18 - 21	Final Exam	Signup for time with Examity	