# TRANSITION GUIDE TO HEALTH RECORDS AND THE LAW[[1]](#footnote-1)

**Fifth Edition Updates**

In the years since publication of the 4th edition of *Health Records and the Law* textbook in 2007, there have been tremendous inconsistency in full implementation of HIPAA and the Privacy Rules, their application, and interpretation. This 5th edition addresses the various challenges health records administrators face with the 2013 HIPAA Privacy/Security updates and 2009 HITECH legislation, including:

* The new obligations and liabilities of business associates
* Changes in the covered entity/business associate relationship and business associate agreements
* The new HIPAA obligations of subcontractors
* The definition of a breach and new definition of harm standard
* Revisions to the Notice of Privacy Practices
* Restrictions on the sale of health information
* Changes in authorizations for medical research
* Revisions of patient rights to access and request restrictions on their health records
* New rules for use and disclosure of health information
* Changes to the fundraising opt-out and disclosure provisions for fundraising
* The All of Us Research Program in precision medicine
* Stronger enforcement of HIPAA/HITECH violations and imposition of higher penalties

This 5th edition textbook added one new chapter on blockchain technology but otherwise maintained the same structure and topics as the 4th edition. Each chapter continues to be organized by the same “*Learning Objectives*”, while the “*Key Terms*” have been expanded. Footnotes are now presented as endnotes for ease of reading.

**“NEW” CURRENT ISSUES IN EACH CHAPTER**

New 21st century issues were added in each chapter, including new material on:

Chapter 1. Introduction to the U.S. Legal System

1. Expanded patient control of health records
2. Changes to control the data resources for informational research
3. Data-mining of health records and data derived from bio-specimens
4. Redefined consumer protection for the Internet of Things
5. Emerging risks of de-identified patient data being re-identified
6. Emergence of the world of things that create and communicate health-related data
7. Law enforcement interception of health information from wearable sensors and smart pill bottles

Chapter 2. Health Records and Managed Care

1. Continued non-regulation of electronic health systems (as distinct from health records)
2. New health care fraud guidelines for auditing, detection, and enforcement

Chapter 3. Health Records Requirements

1. Protection of self-critical materials in health records
2. Avoiding health record disclosures in government investigations and lawsuits
3. New CMS interoperability program authorized by HITECH
4. Shielding of health records under attorney-client privilege
5. Emergence of mobile health
6. Changes to compelled authorizations to disclose employee health records
7. Emerging need for health record systems to be designed with contextual access criteria
8. New meaningful use requirements, incentives, and audits
9. New procedural care requirements for opioid and other pain medications use by patients
10. New mandates for encryption of health records before transmission or storage
11. Emerging privacy interests of telemental health patients
12. Dramatic increases in transmitted and stored health information
13. Disclosure of health records by presidential candidates, as well as other elected public officials

Chapter 4. Health Record Entries

1. New legal rights in tort under HIPAA
2. New financial incentives for protecting health records

Chapter 5. Document Consent to Treatment

1. Introduction of citizen science and consumer-driven data commons
2. Changes to documentation of informed consent in bioinformatics and computational genetics
3. New requirements for obtaining informed consent for medical marijuana
4. Changes to health records documentation with the 2018 Final Common Rule

Chapter 6. Access to Health Information

1. Introduction of the Internet of Things, mobile devices, and Big Data
2. New regulatory frameworks for cybersecurity of digital health
3. New restrictions for wirelessly connected medical devices
4. New counterterrorism programs that recruit health providers to monitor patients for radicalization
5. Changes in third-party access to health records
6. New uses of employee wellness information utilizing Big Data analytics
7. Non-regulation of digital health apps that collect lifestyle and health information
8. The new Communicable Disease No-Fly Database containing patient data about passengers
9. Expansion of telemedicine with virtual review of health records
10. Use of genetic information by law enforcement
11. New regulation of direct-to-consumer genetic testing and genetic relative databases

Chapter 7. Reporting and Disclosure Requirements

1. New restrictions on sharing of on student athletes’ health records with the NCAA
2. Changes to state disclosure laws when a patient presents with injuries caused by criminal conduct
3. Demands for a HIPAA private right of action when patient data is subject to a major cyberattack or theft
4. New definition of the “right to be forgotten and erasure”
5. Revisions to mandatory disclosures of longitudinal health records in employment examinations
6. New contextual access criteria and other privacy-enhancing technologies for health records
7. New 21st Century Cures Act
8. New Notice of Proposed Rulemaking to amend the federal research regulations (Common Rule)
9. Enhanced standards for protecting health records from inappropriate access by marketers and fundraisers
10. Restrictions on HIPAA disclosures with regards to treatment, payment, and health care operations
11. Revisions to the public purpose exceptions and HIPAA exclusions
12. New compelled disclosures of health records for gun permits

Chapter 8. Documentation and Disclosure: Special Areas of Concern

1. Changes in documentation of informed consent to preference diagnoses (diagnosing what patients want)
2. Expanded use of certified patient decision aids when physicians are seeking informed consent
3. New requirements that health providers correct health records when medical identity theft occurs

Chapter 9. HIV/AIDS: Mandatory Reporting and Confidentiality

1. Recognition of the informational privacy rights of adolescents
2. Changes to mandatory reporting of HIV-exposing conduct

Chapter 10. Discovery and Admissibility of Health Records

1. New stricter state privacy protections of health records with a “right to be left alone” mindset
2. New definition of practical obscurity with regards to court records containing health records

Chapter 11. Legal Theories in Improper Disclosure Cases

1. Demands for an express remedy to enforce the HIPAA right to privacy and security
2. New causes of action for the improper disclosure of employee health records
3. Changes to the federal privacy and confidentiality research regulations for virtual clinical trials
4. Emerging use of predictive analytics in data mined health records
5. Revisions to the Human Subjects Research Regulations for big data research

Chapter 12. Risk Management and Quality Management

1. Emerging use of medical algorithms for regulatory oversight
2. New prospective payment and care coordination initiatives
3. New health care quality regulations
4. The migration to data-driven medicine
5. New rules for improving outcomes and efficiency

Chapter 13. Electronic Health Records (EHRs)

1. Incorporation of the FDA’s unique device identifier system into EHR systems
2. New Cybersecurity Information Sharing Act of 2016
3. New Internet of Things products that generate data that becomes part of EHRs
4. Stronger enforcement by the Federal Trade Commission of the HIPAA Security Rule
5. EHRs support of health outcomes research using artificial intelligence and data analytics
6. New 21st Century Cures Act of 2016
7. New EHR standards, protocols, and technologies in telemedicine
8. Data mining of EHRs by big-data algorithms for drug repurposing
9. Emergence of black box medicine with big datasets from EHRs
10. Expanded testing of computational algorithms of health information in EHRs
11. Development of second-order EHRs in the era of precision medicine
12. Changes to EHR safeguards for use of opioids and other prescription pain drugs
13. Changing uses of EHRs in clinical use of genomic medicine

Chapter 14. Health Information in Medical Research

1. Expanded use of health information in health records for informational research
2. New consumer-driven data commons arrangements that control the patient data in health records
3. Rise of data cooperatives, citizens science groups, and patient-mediated data sharing systems
4. New patient-centered data aggregation models and patient controlled health records
5. New advanced formal privacy techniques (differential privacy and secure multiparty computations)
6. Emerging organic datasets in large-scale sensor networks for use in medical research

Chapter 15. Looking Ahead to the Future “**NEW**”

1. Migration of electronic health records to blockchain platforms
2. New privacy and security technologies

**“NEW” WEB-BASED RESOURCES FOR INSTRUCTORS AND STUDENTS**

The 5th edition will benefit from new web-based ancillaries with review questions that help readers assess their knowledge. A new section on current health records and law issues has been introduced with suggested discussion points to guide class discussions. Web and video links have been added for further understanding of the health records topics in each chapter. New PowerPoint presentations to enhance lectures are also available for each of the 15 chapters.

**EXPANDED GLOSSARY**

The Glossary has been expanded to over 800 industry-specific and uncommon defined terms. Terms taken from regulatory agencies and the U.S. Code have been edited to clarify Key Terms in the print textbook and the website ancillaries.

1. Blake J. Tobias, Jr., Graduate Student at Saint Joseph’s University, Philadelphia, Pennsylvania. [↑](#footnote-ref-1)