

Julia R. Hesse

Partner

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EDUCATION

University of Pennsylvania Law School
JD, 2001

University of Pennsylvania Center for Bioethics
M Bioethics, 2001

Managing Editor (1999-2000), staff member (2000-2001), *American Journal of Bioethics*

Williams College
cum laude with honors, BA, 1995

Julia Hesse has been recognized by Chambers USA, *Best Lawyers in America*, and named as a *Massachusetts Super Lawyers Rising Star*. She has served as the Vice Chair of the eHealth Privacy & Security Interest Group of the American Bar Association and is past co-chair of the Boston Bar Association Health Law Section.

PRACTICE FOCUS

Health IT

Advises businesses on Health IT issues, including providing advice related to privacy and security issues, patient medical records, electronic prescriptions, health information exchange between and among providers, and the use of data and analytics to measure quality of care for reimbursement purposes. In addition, she advises on the emerging issue of HIT as a measurable quality measurement for Medicare, Medicaid and private plan reimbursement. Ms. Hesse also assists health IT providers in developing privacy and security compliance programs. She assists clients in evaluating potential HIPAA breaches and in securing patient information, evaluating whether notice of the breach is required and developing mitigation strategies when a violation has occurred.

Healthcare Transactions

Advises private equity, venture capital and strategic investors regarding healthcare diligence, regulatory and transactional issues. Ms. Hesse analyzes regulatory issues arising in the context of corporate transactions, working with investors to assess risk related to healthcare regulatory and compliance issues, structuring transactions to comply with regulatory requirements and providing advice in connection with government investigations and compliance remediation.

Regulatory Matters

Counsels a broad range of healthcare clients regarding regulatory matters such as fraud and abuse, self-referral laws, licensing, compliance, insurance, and HIPAA and state law privacy and data security issues, including data breach issues. Ms. Hesse works with many types of healthcare organizations, including licensed healthcare providers, health IT companies, pharmaceutical and medical device companies, and accountable care organizations.

ADMISSIONS

Massachusetts

PRACTICE AREAS

Healthcare

Life Sciences

Privacy & Data Security

Counsels public and private companies and medical institutions on full range of security and privacy issues, including: creating effective privacy policies, including online policies for websites; meeting privacy and security compliance requirements across multiple jurisdictions; ensuring conformity with standards for personal information storage and use; and for reporting of data breaches.

REPRESENTATIVE ENGAGEMENTS***Healthcare Matters***

- Routinely provide strategic advice and regulatory review of proposed ownership and compensation arrangements between providers and physicians to achieve business goals while ensuring compliance with Stark Law and federal and state anti-kickback rules. Counsel university and academic medical centers related to conflict of interest issues, including those relating to conflicts of interest in research, and advise about implementation of programs to monitor compliance with an institution's conflict of interest policies.
- Routinely counsel business organizations and healthcare providers about privacy and data security compliance, including review and revision of policies and conducting audits focused both on HIPAA and state law.
- Extensive experience in data security matters, including acting as lead counsel to institution in addressing data breaches.
- Routinely advise on research compliance matters, including scientific misconduct investigations and advised on the related to development of research program in community physician practices.
- Routinely negotiate managed care contracts on behalf of institutional providers and physician groups.

Private Equity/Corporate Transactional Matters

- Advise private equity and other public and private companies in context of mergers and acquisitions. Routinely work in teams with other subject area experts (such as IP, real estate and tax) and provided oversight for other attorneys to effectuate complex corporate transactions.
- Routinely provide extensive corporate and regulatory review on behalf of private equity firms' and investment banks' acquisition of interests in variety of entities in healthcare sector.
- Routinely advise on corporate formation and governance matters for both for-profit and not-for-profit institutions.

Life Sciences/Human Subjects Protection/FDA Regulatory Matters

- Provide advice related to FDA regulations to institutional providers and pharmaceutical and biotech companies.
- Routinely draft, review and negotiate clinical trial agreements on behalf of institutional providers and pharmaceutical and biotech companies.

- Routinely draft, review and negotiate broad range of agreements on behalf of pharmaceutical and biotech companies, including agreements for and with Contract Research Organizations, clinical laboratory services, and consulting arrangements.
- Review and update human subjects protection program policies and procedures on behalf of hospitals, for-profit IRBs and universities and assisted in AAHRPP accreditation process.

PUBLICATIONS AND PRESENTATIONS

- “Data Security: Stepping Up Your Game and Assessing Threats,” *speaker, HIMSS16, Las Vegas, March 2016.*
- “Best Practices in HIPAA Security Risk Assessment,” *moderator, HIMSS Privacy & Data Security Forum, Boston, December 2015.*
- “Certificates of Confidentiality: When Why and So What,” *speaker, Public Responsibility in Medicine and Research 2015 Social, Behavioral and Educational Research Conference, Boston, November 2015.*
- “Regulatory Developments,” *panel moderator and conference co-organizer, Conference for Dental Service Organizations, New York, October 2015 and October 2016.*
- “Five Years Later- The Next Chapter in Affordable Care Act Implementation,” *speaker, Boston Bar Association, June 2015.*
- "Data Security Hot Topics: Identifying the Enemies Within the Gates—Do You Know Who's In Your System?" *panelist, HIMSS15, Chicago, April 2015.*
- “Certificates of Confidentiality: When, Why, and So What?,” *speaker, Public Responsibility in Medicine and Research’s 2014 Advancing Ethical Research Conference, December 2014.*
- “CMS Meaningful Use Rules Are Off to a Meandering Start,” *author, Health Law360, November 2014.*
- “Here's How Health IT Companies Should Comply With HIPAA," *author, Health Law360, August 2014.*
- “50-State Fraud and Abuse Survey,” *Massachusetts chapter co-author, American Health Lawyers Association, June 2014.*
- “Regulatory Developments,” *panel moderator and conference co-organizer, Conference for Dental Service Organizations, New York, June 2014.*
- “Health IT Market Trends,” *interviewed, The Metropolitan Corporate Counsel, March 2014.*

- "Five Business Risks to Consider When Outsourcing Health IT," *co-author, Technology Law360*, February 2014.
- "Research Free or Die: Legal Protections Against Challenges to Academic Freedom in Research," *speaker, Public Responsibility in Medicine and Research's Advancing Ethical Research Conference*, November 2013.
- "Regulatory Developments," *panel moderator and conference co-organizer, Conference for Dental Service Organizations*, New York, May 2013.
- "The Fiduciary Duty of a Charitable Corporation's Sole Corporate Member: New Law and New Questions," *co-author, Health Law Reporter*, April 2012.
- "BLaw Q&A: Health Law," *featured, Bloomberg Health Law Report*, November 2011.
- "Legal Impediments of Implementing Value-Based Purchasing in Healthcare," *co-author, American Journal of Law Medicine and Ethics*, 2009.
- *National Council of University Research Administrators conference, speaker, 2007.*
- *National Association of College and University Attorneys conference, speaker, 2006.*

PROFESSIONAL AND COMMUNITY INVOLVEMENT

Ms. Hesse is a member of the American Health Lawyers Association, the Boston Bar Association (and is past co-chair of the Health Law Section), the Massachusetts Bar Association and the American Bar Association. She is a member of the HIMSS Legal Task Force. She has served on the Board of Trustees for the Shore Country Day School in Beverly, Massachusetts and a member of the Advisory Board of the Medical-Legal Partnership located in Boston, Massachusetts. Ms. Hesse was co-editor of the Boston Bar Association *Health Law Reporter* from 2009-2012. Ms. Hesse has served as the President of Williams College Class of 1995 and was a community member of the Massachusetts General Hospital IRB from 2003-2008.