



Andrew (Andy) P. Rusczek

Member of the Firm

Boston

125 High Street
Suite 2114
Boston, MA 02110
Tel: 617-603-1083
Fax: 617-249-1573

arusczek@ebglaw.com

Andy Rusczek provides regulatory and compliance advice to a broad range of clients in the health care and life sciences industries, including hospitals, academic medical centers, and related providers as well as pharmaceutical, medical device, and biotechnology companies. His practice encompasses many legal areas within the health care and life sciences space.

Andy has particular experience with respect to the following types of matters, among others:

- Hospital and health plan transactions and affiliations, including negotiations of definitive agreements, revisions to governance documents, regulatory approvals, and diligence matters
- Regulatory and compliance issues for pharmaceutical and device companies
- Formation and operation of accountable care organizations, physician-hospital organizations, independent practice associations, and related multi-provider networks
- Compliance with the federal anti-kickback statute, the Stark law, and other fraud and abuse laws, such as in the context of product discount arrangements, relationships with physicians, and health care transactions
- Development of comprehensive privacy and security policies and related guidance documents in accordance with the European Union General Data Protection Regulation (GDPR) and HIPAA, HITECH, and state privacy laws
- Human subjects research and related issues, both domestically and internationally

Additionally, Andy has gained a strong understanding of the operational aspects and business of pharmaceutical and device companies through prior on-site placements at three different companies. In these positions, he advised clients on various legal issues, including fraud and abuse laws, clinical trials and related issues (such as privacy, subject recruitment, site contracting, informed consent forms, and FDA requirements for INDs), market research, promotional review activities, patient assistance programs, group purchasing organization and customer contracts, discount and

pricing arrangements, sales representative contracts, and state manufacturer conduct and disclosure laws as well as FDA regulations and other legal requirements related to operating a start-up or commercial company.

Before joining Epstein Becker Green, Andy was a partner at a Boston law firm and served as chair of its Health Care & Life Sciences Group. He also served as a community member of the Brigham and Women's Hospital Institutional Review Board (2010-2015).

While attending the University of Pennsylvania Law School, Andy earned a Master of Bioethics from the University of Pennsylvania School of Medicine to better assist future clients with ethical issues involved with human subjects research.

Education

- University of Pennsylvania Law School (J.D., cum laude, 2008)
- University of Pennsylvania School of Medicine (M.B.E., 2008)
- Bowdoin College (A.B., magna cum laude, 2002)
 - Phi Beta Kappa

Bar Admissions

- Massachusetts

Practice Areas

- Compliance Counseling and Defense
- Food and Drug Law
- Fraud and Abuse Counseling and Defense
- Government and Commercial Reimbursement
- Health Regulatory Due Diligence
- Privacy, Cybersecurity, and Data Asset Management
- Stark/Self-Referral

Industries

- Academic Medical Centers
- Health Care and Life Sciences Industry
- Hospitals and Health Systems
- Life Sciences Industry
- Medical Devices and Combination Products

- Pharmaceuticals
- Technology, Media & Telecommunications

Memberships

- American Health Lawyers Association
- Boston Bar Association

Recognition

- *The Best Lawyers in America*, Health Care Law (2017 to 2021)
- *Chambers USA: The World's Leading Lawyers for Business*, Leader in Massachusetts—Healthcare (2019 to 2021)
- *New England Rising Stars*, Health Care (2013 to 2019)