



Rebecca M. Schaefer

Partner

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OVERVIEW

Rebecca Schaefer is a partner in the firm's Healthcare and FDA practice group, focusing her practice on healthcare and research regulatory and transactional matters. Rebecca has specific knowledge of issues affecting academic medical centers, including those related to health system growth and realignment initiatives, faculty practices, clinical research, mission support, governance and privacy. She provides counseling to health systems, universities, physician practice groups and clinical research institutes and consortia related to strategic affiliations, mergers and acquisitions, joint ventures, service line development and entity formation, genomic data transactions, data governance, and compliance matters.

Areas of regulatory experience include the Stark Law, Anti-Kickback Statute, Civil Monetary Penalties Law, 501(r) and state charity care laws, HIPAA and state data protection statutes, DOJ bulk sensitive data cross-border transfer rule, Common Rule and FDA regulations governing IRBs and human subjects research, NIH grant rules and disclosure requirements, conflict of interest, research misconduct, and ACGME and medical school accreditation, among other areas. As a dedicated legal professional, Rebecca is focused on delivering strategic, business-minded, and mission-focused counsel across complex and multi-faceted matters, with a commitment to client advocacy and a collaborative approach. Rebecca works closely with health systems, AMCs and others to navigate evolving regulatory landscapes, manage risk, and achieve their institutional goals, through a practice grounded in precision, responsiveness, pragmatism, and a deep understanding of both the legal and business drivers shaping the healthcare industry.

PROFESSIONAL BACKGROUND

Prior to joining the firm, Rebecca served as Associate University Counsel at The University of North Carolina at Chapel Hill, where she was the senior healthcare lawyer for the UNC School of Medicine, UNC Faculty Physicians, and other health affairs schools. In this capacity, Rebecca advised leadership on myriad regulatory, transactional, institutional policy, and governance matters. Rebecca has counseled clients in the areas of fraud and abuse, privacy, human subjects research, and life sciences regulation. Her transactional experience includes hospital and health system mergers and acquisitions, joint ventures and physician practice acquisitions, as well as professional service agreements, academic affiliations, and data consortium transactions. Rebecca has drafted and counseled on faculty physician employment matters, including physician compensation plans, employment

agreements, and restrictive covenants. Overall, her work for the university applied healthcare regulatory and transactional experience to structure and facilitate various opportunities that furthered the patient care, clinical research, and medical education missions of the institution. Prior to UNC-Chapel Hill, Rebecca was in private practice with a large firm in Washington, DC representing clients from various sectors of the healthcare industry—including hospitals, medical management companies, physician groups, pharmaceutical and medical device companies, patient advocacy groups, and trade associations—on matters such as clinical trial agreements, regulatory compliance counseling, healthcare transactional due diligence, and the research, analysis, and compilation of legal and policy positions to comment on various agencies' rulemaking on behalf of clients.

ACHIEVEMENTS

- Recognized by *The Best Lawyers in America*® for Health Care Law in Morrisville, NC, 2025-2026

PROFESSIONAL / CIVIC ACTIVITIES

- American Health Lawyers Association

SPEAKING ENGAGEMENTS

- Presenter, Health Law Institute, “A Look Back at 2023: Research Year-in-Review,” *Pennsylvania Bar Institute*, 12 March 2024
- Presenter, “Healthcare Transactions: Structuring Considerations and Key Regulatory Issues,” *K&L Gates Under the Wire*, 1 February 2024
- Presenter, AHLA Annual Meeting, “Health Care Data Transactions: Navigating the Regulatory and Valuation Challenges,” *American Health Law Association*, 27 June 2023
- Presenter, AHLA Annual Meeting, “Where Quality Meets Research: Emerging Strategies, Opportunities, and Risks of Integrated Clinical Records,” *American Health Law Association*, 28 June 2021
- Presenter, “Case Studies in Faculty Consulting-Legal Issues and Policy Choices,” *AHLA Academic Medical Centers and Teaching Hospitals Institute*, January 2020

EDUCATION

- J.D., University of Virginia School of Law, 2008 (*Order of the Coif*)
- MPH, University of Virginia, 2008 (*with honors*)
- B.A., Davidson College, 2001 (*with high honors, magna cum laude, Phi Beta Kappa*)

ADMISSIONS

- Bar of North Carolina

THOUGHT LEADERSHIP POWERED BY HUB

- 5 March 2026, A Closer Look at HHS's RFI on Accelerating the Adoption of AI in Clinical Care
- 14 August 2025, NIH Committed Unlawful Impoundment—GAO Decision Finds NIH's Withholding of Grant Funds Violated Impoundment Control Act—Implications for Federal Grantees
- 26 September 2024, Long-Awaited Changes to Research Misconduct Rules Have Arrived
- 5 March 2024, Highlights From FDA Regulatory Developments in Clinical Trials: 2023 Recap and 2024 Forecast
- 1 February 2024, Twelfth Annual "Under the Wire" CLE Webinar
- 14 September 2023, Ensuring Continuity of Care Following a Cyberattack: ARPA-H Launches Project to Enhance Cybersecurity Tools for HealthCare Organizations
- 1 June 2023, Highlights for Research Institutions and Sponsors in FDA's Recent Draft Guidance on Decentralized Clinical Trials
- 26 September 2022, Issue-Spotting Hospital Activities that May Trigger FDA Regulatory Oversight
- 31 August 2022, All Federal Research Agencies to Update Public Access Policies
- 29 August 2022, Cybersecurity & HIPAA: NIST's Practical Guidance Updates for Covered Entities and Business Associates
- 10 May 2022, Regulatory, Contractual, and Governance Considerations for Data Transactions
- 7 October 2021, FTC Reminds Vendors of Personal Health Records of Breach Rule Obligations
- 14 September 2021, Congressional and Enforcement Priorities Related to Higher Education Issues
- 15 July 2021, When Regulatory Review is Necessary: Clinical Research vs. Quality Initiatives
- 1 July 2021, More Than Innovation and Competition: The Latest Proposed Monitoring and Enforcement Mechanisms Targeting Foreign Influence in U.S. Research
- 15 April 2021, Biden Administration Seeks to Establish New US\$6.5 Billion Health Research Agency to Target Key Disease Areas
- 16 March 2021, Emerging National Security Considerations for AMCs and Research Universities: Foreign Influence Oversight and Enforcement Trends
- 18 February 2021, What AMCs May Expect in Healthcare Policy Priorities from the New Congress and the Biden Administration
- 22 December 2020, The Tortoise and the Hare? HIPAA Joins the Regulatory Sprint to Coordinated Care
- 23 November 2020, COVID-19: Frontline University Perspective on the Pandemic's Disruption to Ongoing Research, and Public Policy Projections for a Federal Response

- 19 November 2020, Research Community Alert – NIH Finalizes Updated Data Sharing Policy
- 17 November 2020, Health Care Cybersecurity Attacks - Practical Steps and Legal Considerations to Prepare for, Respond to, and Minimize Risk
- 29 October 2020, K&L Gates Triage: Eye on Election 2020: California v. Texas and the Future of the Affordable Care Act
- 20 August 2020, K&L Gates Triage: HIPAA: Do Hospitals Need a Business Associate Agreement with their Health System Parent Corporation?
- 16 June 2020, Motivations & Models for Health Systems Forming Captive Venture Capital Funds
- 19 May 2020, COVID-19: Navigating the Path to Recovery - Planning for Life After 1135 Waivers and Other Regulatory Flexibility Ends (Part 1)
- 22 April 2020, COVID-19: FCC Telehealth Program Funding for Health Care Providers
- 15 April 2020, COVID-19: Regulatory Guidance and Flexibilities for the Clinical Research Community
- 20 March 2020, COVID-19: HIPAA - Updates
- 5 February 2020, Antitrust Agencies Release Draft Vertical Merger Guidelines: A Healthcare Perspective
- 17 September 2019, CMS Proposes Rules to Implement SUPPORT Act Coverage and Reimbursement of Opioid Treatment
- 8 July 2019, Qui Tam Quarterly - The Department of Justice False Claims Act Policy Issue
- 9 May 2019, K&L Gates Triage: HIPAA Enforcement Discretion, Disputes, and Data

OTHER PUBLICATIONS

- [“Legal trends health care investors should know: Q&A with K&L Gates partners Christopher Nasson, Wells Beckett and Rebecca Schaefer,”](#) *Boston Business Journal*, 1 October 2024
- [Top Ten 2023: Research Related Developments to Watch,](#) *AHLA's Speaking of Health Law podcast*, 10 March 2023
- ["Top Ten Issues in Health Law 2023,"](#) *American Health Law Association*, 1 January 2023
- ["Antitrust Enforcement of No-Poach Agreements in Health Care and Unique Considerations for AMCs,"](#) *American Health Law Association*, 18 August 2022
- [“Navigating the Regulatory and Valuation Challenges in Health Care Data Transactions,”](#) *American Health Law Association*, 1 April 2022
- ["Clinical Research in a Post-Pandemic World,"](#) *American Health Law Association*, 22 November 2021
- ["STRATEGIC PERSPECTIVES: Case study in models for academic health systems structuring venture capital investments: Henry Ford Health System,"](#) *Health Law Daily*, 10 September 2021

- [“CMS Issues Final Rule to Implement SUPPORT Act Coverage and Reimbursement of Opioid Treatment,”](#) *AHLA Weekly*, 14 February 2020
- [“Lurking Legal Issues for AMCs in Faculty-Led Consulting for Industry via Institutional Contracts,”](#) *American Health Lawyers Association*, May 2019
- [“Hospitals' Role in Combatting the Opioid Crisis,”](#) *Healthcare Business Today*, 2 April 2019

NEWS & EVENTS

- 26 June 2023, AHLA Annual Meeting, Hosted by AHLA
- 15 January 2019, K&L Gates Welcomes Health Care Partner to Research Triangle Park Office

AREAS OF FOCUS

- Healthcare and FDA
- Academic Medical Centers (AMCs)
- Healthcare Transactions

INDUSTRIES

- Digital Health
- Healthcare
- Life Sciences

REPRESENTATIVE EXPERIENCE

- Represented BJC HealthCare in its affiliation by member substitution with Saint Luke's Health System, resulting in a combined system with US\$10 billion in revenues
- Represented an Indiana-based health system in multiple community hospital acquisitions
- Served as lead counsel to a major AMC in structuring and negotiating the formation of a genomic data consortium with eight Fortune Global 500 pharmaceutical companies. The transaction involved a collaboration with a sequencing company to whole genome sequence the AMC's biobank and pairing the genomic data with de-identified medical record data to enable life science research and development. Support included structuring a unique consortium model; regulatory counseling on HIPAA, GDPR, Common Rule, NIH Certificates of Confidentiality, Anti-Kickback Statute, export control, and other legal considerations; negotiating intellectual property, data access, and licensing terms; and advising on IT security requirements, valuation, tax, and complex commercial contracting issues

- Represented a community-based nonprofit health system in the establishment and accreditation of a de novo school of medicine in partnership with a university, including navigating licensure and governance considerations
- Served as lead regulatory counsel for the diligence team advising a multistate investor-owned hospital system in its acquisition of a national post-acute care provider valued at over US\$1 billion
- Represented an academic health system in the design and renegotiation of its affiliation agreement with its primary university school of medicine affiliate, including advising on AMC-specific considerations related to mission support and redesign of funds flow
- Represented a university in negotiating a settlement related to its affiliation agreement with a health system and the ongoing support of the faculty practice and school of medicine
- Represented an academic health system in the transition of its air ambulance life flight program from an external provider to internal operations, and coordinated review and negotiation of aircraft purchases and related financing, aviation services provider operating agreement, and licensure and enrollment work streams
- Advised a children's hospital on the establishment of a biorepository and use of resources from existing biobanks in industry collaborations. Additionally, counseled on regulatory and legal considerations with proposals to leverage residual biospecimens leftover from routine clinical care in commercial research partnerships with life science companies
- Represented an academic health system in a precision medicine initiative that involved an arrangement with a spin-off of their GPO—a precision medicine AI startup—creating a federated model data lake with other participating systems in which digital health technology companies could iteratively train their algorithms. Issues considered and navigated included HIPAA, human research subject protections, intellectual property, commercial terms, and fraud and abuse considerations
- Advised an academic health system on the Stark Law and Anti-Kickback-related considerations associated with, and assisted in structuring, a novel model for expanding the system's community physician practice and physician network
- Drafted, revised, and negotiated a variety of agreements between clinical trial sponsors, clinical research organizations (CROs), principal investigators, and other third parties to govern the conduct of numerous clinical trials
- Drafted a suite of inter-related agreements in furtherance of establishing a clinical trials research network within a health system
- Advised an institution on the organization of a HIPAA hybrid entity and privacy considerations related to clinical research, as well as the intersection of the hybrid entity with the HIPAA-affiliated covered entity of the institution's health system partner
- Selected as legal counsel for an ARPA-H funded grant to assist a healthcare technology company in establishing a national data exchange by which hospitals will license de-identified digital images and surgical videos to approved requestors in furtherance of developing medical technologies, including AI technologies

- Represented a hospital system in a data licensing transaction with a digital health company facilitating broadscale, algorithm-based de-identification of EHR data for subsequent use in life science research applications, including drug target discovery and clinical trial matching. Project also involved advising on consent and privacy issues related to large-scale digitization of existing pathology slides and a collaborative master research agreement among the academic health system partners participating with the digital health company
- Represented faculty practices in the negotiation of joint venture, management services, professional services, space lease, and other agreements
- Provided research security training to the leadership team of an academic health system's research institutes to address requirements related to foreign influence, NSPM-33, CHIPS and Science Act, and NDAA-233
- Assisted NIH-funded cooperative groups in updating their conflict of interest (COI) policies and disclosure forms to address research security-related requirements
- Assisted an academic health system in conducting a clinical trial billing audit, including supporting the development of billing coverage analyses (BCAs) to understand whether protocol-related charges were appropriately billed to study sponsor or payor
- Supported a number of high-profile research misconduct investigations, guiding internal investigatory processes, representing institutions in related disclosures and refunds to grant-making agencies, and through disciplinary proceedings of faculty under the relevant tenure code
- Advised a multistate nonprofit health system on the revision of its financial assistance policies and charity care practices in compliance with 501(r) and state charity care laws in the various jurisdictions in which the system operates, including representing the system in responding to 501(r)-related IRS audits
- Assisted a health system in reviewing Stark compliance related to physician compensation arrangements, including investigation, preparation, and filing of several Self-Referral Disclosure Protocols (SRDPs) with CMS
- Represented multiple health systems in the acquisition of community hospitals, including conducting due diligence, crafting definitive transaction agreements, and advising on integration and operational considerations
- Assisted a newly established healthcare facility in the development of an active clinical research program, including developing policies necessary for receipt of federal grants and proper administration of clinical trial billing, and negotiated multiple clinical trial agreements
- Counseled healthcare startups on entity formation, corporate practice of medicine, licensure, enrollment, reimbursement, and contracting considerations