



## Rebecca M. Schaefer

### Partner

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## OVERVIEW

Rebecca Schaefer is a partner in the firm's Health Care practice, focusing her practice on health care and research regulatory and transactional matters. Rebecca has specialized knowledge of issues affecting academic medical centers, including those related to faculty practices, clinical research, mission support, governance and privacy. She provides counseling to universities, health systems, physician practice groups and clinical research institutes and consortia related to strategic affiliations, joint ventures, big data initiatives and compliance matters. Areas of regulatory experience include the Stark Law, Anti-Kickback Statute, Civil Monetary Penalties Law, HIPAA and state privacy statutes, Common Rule and FDA regulations governing human subjects research, NIH grant rules and disclosure requirements, conflict of interest, research misconduct and medical school accreditation, among other areas.

## PROFESSIONAL BACKGROUND

Prior to joining the firm, Rebecca served as an associate university counsel at The University of North Carolina at Chapel Hill, where she was the senior health care attorney for the UNC School of Medicine, UNC Faculty Physicians, and other health affairs schools. In this capacity, Rebecca advised campus and school-based 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 joint ventures and physician practice acquisitions, as well as professional service agreements, academic affiliation, and data use agreements. 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 health care 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, D.C. representing clients from various sectors of the health care 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, health care transactional due diligence, and the research, analysis, and compilation of legal and policy positions to comment on various agencies' rulemaking on behalf of clients.

## 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, “Health Care 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 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 Health Care 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 Health Care 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

- 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
- August 2020, K&L Gates Lawyers Provide Insights on Impact of COVID-19 Across Various Industries
- 15 January 2019, K&L Gates Welcomes Health Care Partner to Research Triangle Park Office

## AREAS OF FOCUS

- Health Care and FDA
- Academic Medical Centers (AMCs)

## REPRESENTATIVE EXPERIENCE

- Conducted health care regulatory due diligence and identified required regulatory consents and approvals in connection with private equity and other investments in health care companies
- Advised on AMC-specific considerations related to mission support and institutional funds flow between the hospital and faculty practice components of an academic medical center
- 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 on the organization of a HIPAA hybrid entity and privacy considerations related to clinical research. Advised on breach analysis and providing notice of unauthorized uses and disclosures of protected health information. Drafted and negotiated business associate agreements and other HIPAA required documents
- Represented faculty practices in the negotiation of joint venture, management services, professional services, space lease, and other agreements
- Advised on faculty physician employment and compensation agreements, including related Stark Law considerations
- Developed positions with relevant University and School of Medicine leadership across a range of integration considerations and drafted components of the Academic Affiliation Agreement in connection with the formerly proposed partnership between UNC Health Care and Atrium Health. Advised on various other academic affiliations
- Counseled academic medical center on privacy and human subjects research regulations pertinent to a precision medicine artificial intelligence start up
- Drafted policies for a physician practice related to compliance with federal and state controlled substances regulations
- Advised health system on Stark compliance related to physician non-monetary compensation
- Counseled an academic medical center on privacy and consent considerations with respect to a biobank repository
- 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
- Prepared draft legislation on behalf of mental and behavioral health services organization to facilitate organizational changes in anticipation of Medicaid reform

- Assisted a newly established health care 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 health care start-ups on entity formation, corporate practice of medicine, licensure, enrollment, reimbursement and contracting considerations.