



Gina L. Bertolini

Partner

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OVERVIEW

Gina Bertolini advises health care clients on health care privacy and security, fraud and abuse, digital health, and complex commercial health care contracting matters. Gina frequently advises on the complex interplay between privacy, technology, and health care. In the digital health space, she assists health care providers and technology companies in navigating federal and state regulations related to the provision of care via telemedicine, including corporate practice of medicine (CPOM), state licensure, privacy, reimbursement, and state and federal laws for treating and prescribing via remote modalities. In the data privacy and security space, she advises on federal and state privacy laws, structures health care data transactions in the commercial and research spaces, and has managed multiple health system data breaches, from initial mitigation and investigation to interfacing with government regulators and developing notice and response initiatives. Gina develops policies and trainings to address HIPAA, Information Blocking, and Confidentiality of Substance Use Disorder Records compliance, and has advised multiple health systems on the development of their electronic health record systems (including patient portals) and their Information Blocking compliance efforts. Gina also assists health care providers with significant commercial contracting initiatives, including developing comprehensive suites of supply chain contracts and contract playbooks, structuring health system group purchasing organizations (GPOs) and purchasing collaboratives, and negotiating multi-million dollar commercial contract initiatives.

As a former academic medical center in-house attorney, Gina advises on the intersection of complex federal and state policies and the provision of health care, such as EMTALA, 501(r) and state law charity care requirements, the Anti-kickback Statute and Inducements to Beneficiaries laws, and credentialing and peer review. Gina also has experience structuring hospital-third party arrangements, negotiating joint venture and affiliation contracts, and assisting with health care mergers and acquisitions, and advises on physician contracting, including structuring compliant physician compensation arrangements.

Gina has a particular interest in issues related to the facilitation of patient care, including risk management, informed consent, medical ethics, treatment of minors, substance use disorders, and end-of-life decision-making.

Gina is an active author and speaker on critical issues affecting the health care industry.

PROFESSIONAL BACKGROUND

Prior to joining the firm, Gina worked for The University of Michigan as an associate vice president and deputy general counsel for the University of Michigan Health System. She also worked for The University of North Carolina Health Care System as an assistant general counsel. In her role as assistant general counsel, Gina also served as legal director for UNC Physicians Network, LLC, a community-based physician organization owned by UNC Health Care System. Before joining UNC Health Care System, Gina was an associate attorney for six years with the firm's Research Triangle Park office, focusing on health law issues. She also served as a law clerk to the Honorable Elizabeth A. Jenkins, United States District Court for the Middle District of Florida.

ACHIEVEMENTS

- Recognized by *Chambers USA* with a Band 2 ranking for Healthcare in North Carolina, 2022-2023

SPEAKING ENGAGEMENTS

- *The Best Way to Understand Gaps in your IT*, Healthcare IT News, Mobi Health News, Health Finance News, November 8, 2023
- *Treating Behavioral Health Issues and Substance Use Disorders Confidentiality of Substance Use Disorders Records at 42 C.F.R. Part 2: "Areas of Turbulence"*, presentation to the NC Bar Health Law Section Annual Meeting, March 8, 2019
- 340B Mega-Guidance, presentation to the NC Bar Health Law Section Annual Meeting, April 29, 2016
- *Where the Wild Things Are: Health Care Reform & What's In Store for 2016*, K&L Gates "Under the Wire" CLE Seminar, 2016
- *BioEthics and the Lawyer (Exploring the Intersection of Bioethics and the Law and the Impact on the Delivery of Health Care)*, NC Bar Association, Health Law Section Annual Meeting, 2013
- *Appropriate Decisionmakers in Patient Care, Ethics Grand Rounds*, UNC Hospitals; 2012
- *Errors That Grow Into Lawsuits: Minimizing Risk While Providing Quality Patient Care in a Changing Environment*; Legal Issues and Risk Management for Nurses (conference), UNC Center for Leadership Development, 2012
- *The UNC Health Care System and Blue Cross Blue Shield of North Carolina Model Medical Practice: A Blueprint for Success*; AHLA Academic Medical Center conference, 2012 (Washington, D.C.)
- *Making Decisions for Pediatric Patients: Insights from Law and Ethics*, Ethics Grand Rounds, UNC Hospitals, 2011
- *How Informed Does Consent Need to Be? Surgical Ground Rounds*, UNC Hospitals, 2011

- *Informed Consent, Medical Records, and Authorized Representatives, Oh My! Legal and Risk Management Issues in the PACU and Ambulatory Care Centers*; PACU Conference, UNC Center for Leadership Development, 2011
- *Back to the Future: Hospital Acquisition of Physician Practices*, North Carolina Bar Association, 2010

EDUCATION

- J.D., University of California Hastings College of the Law, 2000 (*cum laude*; *Order of the Coif*, *Tony Patino Fellow*; *First Amendment Moot Court Competition*, *Best Oralist*, 1999; *National Moot Court Competition*, 1999-2000; *Womens Law Journal*, *Member*, 1998-2000)
- B.F.A., DePaul University, 1992 (*with honors*)

ADMISSIONS

- Bar of California
- Bar of North Carolina

THOUGHT LEADERSHIP POWERED BY HUB

- 10 April 2024, *Corporate Practice of Medicine: New Relevance in a Changing World*
- 1 April 2024, *Health System Cybersecurity Risks: Part Two*
- 26 March 2024, *Health System Cybersecurity Risks: Part One*
- 19 March 2024, *The Countdown to Complete Your Consumer Health Data Privacy Policy Under the Washington My Health My Data Act*
- 3 October 2023, *Litigation Minute: Pixel Tools in the Health Care Arena*
- 20 September 2023, *Ad Tracking Tech in Health Care: The Current Regulatory and Litigation Landscape for HIPAA-Regulated Entities*
- 29 June 2023, *The Million Dollar Question: Long-Awaited Final Rules Outline Information Blocking Enforcement Priorities and Civil Monetary Penalties Against Certain Information Blockers*
- June 2023, *Generative AI and the Health Care Industry*
- 11 May 2023, *DEA Temporarily Extends COVID-19 Flexibilities for Controlled Substance Prescriptions via Telemedicine While Evaluating Permanent Rule Changes*
- 2 May 2023, *"My Health, My Data" Is First of Its Kind Privacy Law Focused on Protecting Consumer Health Data*

- 27 April 2023, HHS Proposes Heightened Protections for "Highly Sensitive" PHI Related Reproductive Health Care in the Wake of Dobbs
- 23 March 2023, The U.S. Fifth Circuit Court of Appeals Is Poised to Address Emergency Abortions and the Scope of EMTALA's Preemption of State Abortion Laws
- 6 February 2023, Consolidated Appropriations Act of 2023 Extends Telehealth Waivers
- 24 January 2023, Confidentiality of Substance Use Disorder Records: Long-Awaited NPRM Proposes Aligning Part 2 With HIPAA
- 29 November 2022, The Information Blocking Rule's "Glide Path" - Compliance with the Information Blocking Rule After the Limitation on the Scope of EHI is Lifted
- March-October 2022, Transforming Health: Digital Health Legal Insight Series 2022, Parts I, II, and III: D2C Telehealth Services
- 14 July 2022, Privacy of Health Information After Dobbs: OCR Guidance on Disclosures of PHI and the Privacy of Personal Information on Devices
- 10 May 2022, Regulatory, Contractual, and Governance Considerations for Data Transactions
- 17 March 2022, COVID-19: State Law Telehealth Considerations: State Licensure Requirements Persist, Permissible TeleHealth Modalities Generally Expand, and Insurance Parity Laws Ensure Reimbursement (Part 2 of a 3-part Series)
- 21 February 2022 , COVID-19: State Law Telehealth Update: State Licensure Requirements Persist, Permissible Telehealth Modalities Generally Expand, and Insurance Parity Laws Ensure Reimbursement
- February 2022, Tenth Annual "Under the Wire" CLE Webinar
- 20 January 2022, Data Security Breaches in the Health Care Sector
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part I: HIPAA
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part II: HIPAA (Continued) & Additional Important Privacy Considerations
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers - Part III: FDCA
- 18 October 2021, US Regulatory Considerations Applicable to Digital Health Providers and Suppliers – Part IV: Other Potential Applicable Laws
- 7 October 2021, FTC Reminds Vendors of Personal Health Records of Breach Rule Obligations
- 9 August 2021, Cybersecurity Risk in the Health Care Industry
- 23 June 2021, Bipartisan CONNECT for Health Act of 2021 Seeks to Permanently Expand Telehealth Reimbursement

- 17 December 2020, Information Blocking Considerations for Providers Under the CMS Interoperability and Patient Access Final Rule
- 29 October 2020, ONC Interim Final Rule Delays Information Blocking Rule Initial Compliance Deadline
- 2 October 2020, K&L Gates Triage: The Preventing Harm Exception to the ONC Information Blocking Rule
- 1 October 2020, Blocking and Tackling: What Every Health Care Provider's Legal, IT, and Compliance Teams Need to Know About Information Blocking to Make It Through the First Compliance Deadline's Goal Posts
- 11 August 2020, The Practitioner's Guide to SAMHSA's 2020 Final Part 2 Rules - More Changes on the Horizon
- 21 May 2020, COVID-19: K&L Gates Triage: Telehealth Expansions During the COVID-19 Emergency - What Providers Need to Know
- 15 April 2020, What Comes Next for Part 2? The CARES Act's Surprising Overhaul of the Controversial Law Protecting the Confidentiality of Substance Use Disorder Records
- 20 March 2020, COVID-19: Protecting Critical Health Resources to Prevent the Spread of COVID-19: President Trump's Executive Order Gives HHS Secretary Azar Broad Supply Chain Authority
- 5 November 2019, CMS on the Cutting Edge of Innovation: RFI on the Use of Advanced Technology in Program Integrity
- 16 October 2019, K&L Gates Triage: Modernizing Confidentiality Rules for Substance Use Disorder Records (Again): 2019 Proposed Changes to 42 CFR Part 2 - Part 2
- 15 October 2019, SAMHSA's Balancing Act in Its 2019 Proposed Rulemaking: Weighing the Benefits of Enhanced Technology Against the Risks of Breach - Can 42 C.F.R. Part 2 Really Be Modernized?
- 8 October 2019, K&L Gates Triage: The Opioid Epidemic & the Confidentiality of Substance Use Disorder Records: an Update on 42 CFR Part 2 - Part 1 of 2
- 25 April 2019, AdvaMed Code of Ethics Revisions Effective January 2020: Implications for Health Care Provider Interactions with Vendors
- 2 April 2019, CMS Announces Artificial Intelligence Health Outcomes Challenge
- 20 February 2019, North Carolina Attorney General Proposes Stringent Data Breach Legislation
- February 2019, Seventh Annual "Under the Wire" CLE Seminar
- 15 February 2018, K&L Gates Triage: Opioid Epidemic: Recent HIPAA Guidance – What Does It Mean?
- 29 June 2017, K&L Gates Triage: Change is in the Air: Human Subject Research and Revisions to the Common Rule
- 5 April 2016, Disclosure of Substance Use Disorder Records Enters the 21st Century: SAMHSA Proposes Changes to Part 2, But Do They Go Far Enough?

- 3 September 2015, HRSA Issues 340B Program Omnibus Guidance
- 11 August 2015, Cinderella May Not Turn Into a Pumpkin After All: The Proposed Relaxation of the Two-Midnight Rule

OTHER PUBLICATIONS

- “Top Ten Issues in Health Law 2024,” *American Health Law Association*, 1 January 2024
- “Privacy of Health Information After *Dobbs*: OCR Guidance on Disclosures of PHI and The Privacy of Personal Information on Devices,” *Employee Relations Law Journal*, Winter 2022
- “Ransomware Attacks Target Health Care Industry,” *Reuters Westlaw Today*, 31 October 2022
- “5 Steps For Counsel Managing Health Care Data Breaches,” *Law360*, 18 March 2022
- 340B Program Omnibus Guidance: Mega-Changes on the Horizon?, *American Health Lawyers Association Rap Sheet*, November 2015

NEWS & EVENTS

- 12 October 2023, Health Law Boot Camp, Hosted by North Carolina Bar Association
- 1 June 2023, K&L Gates Receives Firm, Individual Rankings in 2023 *Chambers USA* Guide
- 18 August 2022, More Than 350 K&L Gates Lawyers Named Among 2023 Best Lawyers in America, Ones to Watch
- 1 June 2022, K&L Gates Receives Firm, Individual Rankings in 2022 *Chambers USA* Guide
- 22 April 2022, Change Can Happen Fast — Bring an Umbrella (2022 Health Law Section Program), Hosted by North Carolina Bar Association
- 19 August 2021, Nearly 300 K&L Gates Lawyers Named Among 2022 Best Lawyers in America, Ones to Watch
- 8 March 2021, *Report on Medicare Compliance: OFAC Fines Add to Ransomware Peril; 'It's a Between-a-Rock-and-a-Hard-Place Thing'*

MEDIA MENTIONS

- Quoted, “Abortion in Missouri: A look at key claims in the 'decline to sign' effort,” *St. Louis Post-Dispatch*, 17 April 2024
- Quoted, “HHS Offers Plan To Bolster Hospital Defenses In Cyberattacks,” *Law360*, 7 December 2023
- Mentioned, “Health plan payments for OTCs. Expert perspective from K&L Gates,” *Health Business Group and Health Business Blog*, 30 October 2023

- Interviewed and quoted, “OFAC Fines Add to Ransomware Peril; 'It's a Between-a-Rock-and-a-Hard-Place Thing,’” *Report on Medicare Compliance*, Volume 30, Number 9, 8 March 2021

AREAS OF FOCUS

- Health Care and FDA
- Health Care Fraud and Abuse (U.S.)

INDUSTRIES

- Artificial Intelligence
- Digital Health
- Health Care Sector
- Technology