



Leah D'Aurora Richardson

Partner

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OVERVIEW

Leah D'Aurora Richardson is a partner in the firm's global Health Care and FDA practice group and her practice is exclusively focused on health law, representing academic medical centers, health systems, hospitals, hospices, and ancillary service providers, such as pharmacies, durable medical equipment suppliers, wound care providers, infusion providers, clinical laboratories, IDTFs, specialized management services organizations, and other healthcare clients on transactional and regulatory health law.

Leah advises health care clients on a variety of complex regulatory, compliance and transactional matters related to new business initiatives and existing service lines including compliance with fraud and abuse laws (including anti-kickback statutes and physician self-referral laws); HIPAA and state privacy, security, and breach notification rules; state licensure rules; government and commercial reimbursement issues; enterprise-wide health care and supply chain contract negotiations; and health care regulatory diligence.

Leah has experience in advising hospital and health system-owned and independent retail and specialty pharmacy and infusion providers on all facets of regulatory, reimbursement, operational, compliance and risk management issues including Robinson-Patman requirements, federal DEA and state controlled substances laws, state licensure requirements, limited distribution drug access, manufacturer purchasing arrangements (including fraud and abuse compliance), data sharing arrangements (including HIPAA compliance), payor/PBM negotiations, wholesaler contracts and disputes, and acquisitions/changes of ownership. She is a nationally recognized professional in the 340B Program and serves as primary counsel for dozens of 340B covered entities on all facets of 340B Program compliance, including contract pharmacy arrangements, HRSA audits, manufacturer inquiries, Medicaid billing audits, federal grant compliance, government and private billing compliance related to 340B drug claims, and Program strategy and public policy.

PROFESSIONAL BACKGROUND

Prior to attending law school, Leah was a medicinal chemist for almost ten years at GlaxoSmithKline and Albany Molecular Research.

EDUCATION

- J.D., University of North Carolina at Chapel Hill School of Law, 2012 (*Valedictorian, Highest Honors, Order of the Coif, Honors Writing Scholar, Vol. 90 Managing Editor, North Carolina Law Review*)
- M.S., The Ohio State University, 2000 (*physical organic chemistry*)
- B.A., Wheeling Jesuit College, 1996 (*psychology, magna cum laude, Academic Honors Award*)
- B.S., Wheeling Jesuit College, 1996 (*chemistry, magna cum laude, Academic Honors Award*)

ADMISSIONS

- Bar of North Carolina

THOUGHT LEADERSHIP POWERED BY HUB

- 22 August 2023 , Unpacking CMS's Proposed Rule for Correcting Underpayments for 340B Drug Reimbursement
- 11 May 2023, DEA Temporarily Extends COVID-19 Flexibilities for Controlled Substance Prescriptions via Telemedicine While Evaluating Permanent Rule Changes
- 6 February 2023, Consolidated Appropriations Act of 2023 Extends Telehealth Waivers
- 15 December 2022, Recent Developments to the 340B Drug Pricing Program
- March-October 2022, Transforming Health: Digital Health Legal Insight Series 2022, Parts I, II, and III: D2C Telehealth Services
- 9 August 2022, Genesis Healthcare and the 340B Program Patient Definition
- 21 June 2022, Supreme Court Issues Decision Favorable to Hospitals on 340B Payment Reduction: What to Do Next
- 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
- 19 October 2021, 2021 Hot Topics in the 340B Drug Pricing Program
- 19 August 2021, CMS's Proposal for New Remote Therapeutic Monitoring Codes under the 2022 Medicare Physician Fee Schedule
- 10 August 2021, CMS Proposes to Rescind Most Favored Nation Drug Pricing Rule

- 14 July 2021, HHS Opens Provider Relief Fund Reporting Portal With New Guidance on Reporting Requirements
- 8 July 2021, 340B Update: Supreme Court Accepts Certiorari in 340B Payment Reduction Case
- 23 June 2021, Bipartisan CONNECT for Health Act of 2021 Seeks to Permanently Expand Telehealth Reimbursement
- 15 June 2021, COVID-19: Biden Administration Issues First Major Update to Provider Relief Fund Requirements: Reporting Portal Opens 1 July 2021
- 29 March 2021, 340B Update: Federal Court Halts 340B Administrative Dispute Resolution Rule
- 24 March 2021, Hospitals Ask Supreme Court to Reverse Site-Neutral, 340B Payment Rulings
- 19 January 2021, COVID-19: Provider Relief Funds: What to Expect as Reporting Begins in 2021
- 29 December 2020, Federal Courts Block Implementation of Most Favored Nation Drug Pricing Rule
- 22 December 2020, 340B Update: Recent Supreme Court Ruling May Curtail 340B Program Discriminatory Pricing
- 15 December 2020, HRSA Publishes Long-Awaited (and Long-Overdue) 340B Program Alternative Dispute Resolution Process Final Rule
- 3 December 2020, CMS Issues Most Favored Nation Model Interim Final Rule: What to Expect Next
- 30 November 2020, Trump Administration Issues Flurry of Last Minute Healthcare Regulations: What Will the Incoming Administration Do Next?
- 20 November 2020, COVID-19: CARES Act Provider Relief Fund Compliance and Potential FCA Enforcement
- 3 November 2020, Qui Tam Quarterly - Uncertain Relief: Navigating CARES Act Provider Relief Fund Guidance and False Claims Act Risks
- 16 October 2020, 340B Update: Ryan White Clinics Sue in Response to Contract Pharmacy Actions as Congress Requests Information on Ways to Improve the 340B Program
- 25 September 2020, 340B Update: Congress and the Administration Respond to Drug Manufacturers' 340B Contract Pharmacy Actions
- 10 September 2020, K&L Gates Triage: Rutledge v. Pharmaceutical Care Management Association
- 5 August 2020, 340B Update: Appeals Court Upholds 340B Payment Reduction Under the OPPS as CMS Proposes Further Reductions for CY 2021
- 27 July 2020, President Trump Signs Drug Pricing Executive Orders Reinforcing the Administration's Priorities
- 21 July 2020, 340B Update: HRSA Indicates it Lacks Authority to Enforce 340B Program Guidance

- 8 June 2020, COVID-19: 340B Update: HRSA Updates Guidance Granting New HOPD Flexibility
- 21 May 2020, COVID-19: K&L Gates Triage: Telehealth Expansions During the COVID-19 Emergency - What Providers Need to Know
- 27 April 2020, 340B Update: CMS Opens Acquisition Cost Data Survey for 340B Hospitals
- 24 April 2020, COVID-19: UPDATED HHS Announces Remaining Allocations of CARES Act Provider Relief Funding and Updates Funding Terms and Conditions
- 16 April 2020, COVID-19: UPDATED HHS Delivers Initial \$30 Billion of CARES Act Provider Relief Funding Directly to Medicare
- 16 April 2020, COVID-19: UPDATED HHS Delivers Initial \$30 Billion of CARES Act Provider Relief Funding Directly to Medicare Providers and Suppliers and Quickly Updates Terms and Conditions
- 9 April 2020, COVID-19: Health Care Compliance Considerations and Guidance During COVID-19 Crisis
- 8 April 2020, COVID-19: CMS Expands Accelerated/Advance Payment Program to Assist Providers Impacted by the Pandemic as AHA and Members of Congress Urge Reductions to Interest Rates
- 2 April 2020, COVID-19: K&L Gates Triage: COVID-19 Stark Waivers
- 23 March 2020, COVID-19: 340B Update - HRSA Releases COVID-19 Guidance for 340B Covered Entities
- 18 November 2019, Qui Tam Quarterly - Enforcement Trends in False Claims Act Liability for Patient Assistance Programs
- 25 April 2019, AdvaMed Code of Ethics Revisions Effective January 2020: Implications for Health Care Provider Interactions with Vendors
- March 2019, Qui Tam Quarterly - Health Care's New Wilderness: The Intersection of Telehealth & Ancillary Services
- 16 November 2018, The New Kickback Prohibition for Substance Use Disorder Treatment Facilities, Clinical Laboratories and Recovery Homes
- 9 November 2018, CMS Issues Final Medicare PFS Rule for CY 2019
- 6 August 2018, CMS Issues Proposed Medicare PFS Rule for CY 2019
- 2 July 2018, CMS Requests Public Comments on the Stark Law to Facilitate Care Coordination
- 5 April 2017, K&L Gates Triage: CMS 60-Day Overpayment Rule & OIG Self-Disclosures
- 15 December 2015, CMS Finalizes Two New Exceptions and Other Modifications to the Stark Law
- 3 September 2015, HRSA Issues 340B Program Omnibus Guidance
- 24 July 2015, Potential Stark Changes Ahead
- 9 June 2015, Federal Court Enjoins Texas Medical Board from Enforcing More Stringent Telemedicine Rules

- 11 May 2015, SGR Law Creates Merit-based Incentive Payment System and Incentives for Alternative Payment Model Participation
- 30 April 2015, OIG Issues Compliance Oversight Guidance for Governing Boards of Health Care Organizations

OTHER PUBLICATIONS

- 340B Program Omnibus Guidance: Mega-Changes on the Horizon?, *American Health Lawyers Association Rap Sheet*, November 2015
- Information Exchange in the Formation of an ACO, American Health Lawyers Association, May 2013
- Recent Development, *The "Substantial Uncertainty" of the Viability of Woodson Claims After Valenzuela v. Pallet Express, Inc.*, 90 N.C. L. Rev. 884 (2012).

NEWS & EVENTS

- 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
- 24 February 2020, K&L Gates Names 41 New Partners Across Global Platform

MEDIA MENTIONS

- "Americans Subsidizing Drugs?," Legal Talk Network, 15 January 2021

AREAS OF FOCUS

- Health Care and FDA
- Academic Medical Centers (AMCs)
- Hospitals and Health Systems
- Health Care Fraud and Abuse (U.S.)
- Federal, State, and Local False Claims Act

INDUSTRIES

- Digital Health
- Health Care Sector

- Life Sciences
- Pharmaceuticals, Biologics, and Medical Devices