

Darlene S. Davis

Senior Of Counsel

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OVERVIEW

Darlene Davis is a partner at the firm. She focuses her practice exclusively on health law, primarily representing academic medical centers, health systems, hospitals, home health agencies, hospices, nursing homes, and ancillary service providers, such as laboratories, pharmacies, and durable medical equipment suppliers.

In that capacity, she advises clients on a wide range of regulatory and transactional matters, including the HIPAA privacy, security and breach notification rules; Medicare and Medicaid enrollment and certification, coverage and reimbursement; North Carolina licensure rules; the 340B drug pricing program; contracting; healthcare regulatory diligence; and compliance with fraud and abuse laws (including Stark Law and Anti-Kickback Statute).

Prior to attending law school, Darlene worked for the Centers for Medicare and Medicaid Services in its Boston Regional Office.

ACHIEVEMENTS

- Recognized by *Chambers USA* for Healthcare in North Carolina, 2017-2026
- Recognized by *The Best Lawyers in America*® for Health Care Law in Raleigh, NC, 2027

EDUCATION

- J.D., Duke University School of Law, 2007 *(magna cum laude; Order of the Coif; Senior Research Editor, Duke Law Journal; Mordecai Scholar)*
- A.B., Harvard University, 1998 *(cum laude, Phi Beta Kappa)*

ADMISSIONS

- Bar of North Carolina

THOUGHT LEADERSHIP *POWERED BY HUB*

- 9 December 2025, Climbing Back Up the Telehealth Cliff: Congress Extends Medicare Flexibilities Through 30 January 2026
- 10 October 2024, The Wait Is Over: Revised CMS Enrollment Form Puts SNF Ownership and Management Under a Microscope
- 22 August 2023 , Unpacking CMS's Proposed Rule for Correcting Underpayments for 340B Drug Reimbursement
- 21 March 2023 , Rural Emergency Hospitals—Transformative Change or Limited Impact?
- 24 January 2023, Confidentiality of Substance Use Disorder Records: Long-Awaited NPRM Proposes Aligning Part 2 With HIPAA
- 17 November 2022, New Data Available Under the Hospital Price Transparency Rule
- 15 November 2022, Rural Emergency Hospitals: CMS Finalizes Key Policies for New Medicare Provider Type (Part 1 of 2)
- 15 November 2022, Rural Emergency Hospitals: CMS Finalizes Key Policies for New Medicare Provider Type (Part 2 of 2)
- 24 August 2022, Rural Emergency Hospitals: CMS Publishes Proposed Enrollment and Payment Policies for New Medicare Provider Type
- 12 July 2022, New Options for Rural Hospitals: CMS Proposes Conditions of Participation for New "Rural Emergency Hospital" Provider Category
- 5 July 2022, Hospitals, Physician Practices, and Labs – Are You Ready to Report Private Payor Rates for Laboratory Tests?
- April 2022, April 2022 Accolades
- 14 January 2022, SCOTUS Blocks OSHA's ETS and Allows CMS Mandate to Go into Effect
- 23 December 2021, COVID-19: All (Some) or Nothing: Where the Federal Vaccination Mandates Stand as Employers Plan for 2022
- 8 November 2021, 2022 OPPS Final Rule Overview: CMS Finalizes Policies on 340B, Hospital Price Transparency, and Inpatient Only List
- 5 November 2021, Vaccine Mandate: The Rule Is Out and the Details Are Here as CMS Requires COVID-19 Vaccinations for Staff of Most Medicare and Medicaid-Certified Providers and Suppliers
- 21 October 2021, An Update on the CMS Hospital Price Transparency Rule
- 22 July 2021, CMS Proposes to Increase Penalties for Hospital Price Transparency Noncompliance

- 13 August 2020, K&L Gates Triage: 340B Update: Appellate Court Upholds 340B Payment Reduction as CMS Proposes Further Reductions for 2021
- 5 August 2020, 340B Update: Appeals Court Upholds 340B Payment Reduction Under the OPPS as CMS Proposes Further Reductions for CY 2021
- 30 July 2020, Appellate Court's Reversal in AHA v. Azar Poses Existential Threat to Medicare Outpatient Prospective Payment System
- 19 May 2020, COVID-19: Navigating the Path to Recovery - Planning for Life After 1135 Waivers and Other Regulatory Flexibility Ends (Part 1)
- 18 May 2020, CMS Issues IPPS/LTCH Proposed Rule for FY 2021
- 4 May 2020, COVID-19: CMS Releases Additional Blanket Waivers and Flexibilities
- 29 April 2020, COVID-19: Testing and Treatment to Uninsured Patients - Reimbursement Available Under New HHS Payment Program
- 13 March 2020, COVID-19: EMTALA Guidance on COVID-19 While Hospitals Await Potential EMTALA Waivers
- 20 November 2019, CMS Finalizes Hospital Price Transparency Rule and Proposes New Transparency Requirements for Health Plans
- 25 October 2019, K&L Gates Triage: IPPS-Excluded Hospitals May Now Have IPPS-Excluded Units
- 13 May 2019, CMS Issues Long-Awaited Draft Guidance on Hospital Co-Location and Space Sharing
- 8 January 2019, 340B Update: D.C. District Court Overturns OPPS 340B Reimbursement Cut for CY 2018
- 9 November 2018, CMS Issues Final Medicare PFS Rule for CY 2019
- 6 November 2018, CMS Issues CY 2019 OPPS Final Rule
- 6 August 2018, CMS Issues Proposed Medicare PFS Rule for CY 2019
- 3 August 2018, CMS Issues Proposed OPPS Rule for CY 2019
- 7 June 2018, K&L Gates Triage: Proposed Changes to the Federal Satellite Facility Rules
- 14 March 2018, U.S. District Court Upholds CMS’s Application of the Statutory Requirement that Hospitals Be “Primarily Engaged” in Providing Services to Inpatients
- 1 February 2018, Medicare Diabetes Prevention Program Enrollment is Now Open
- 18 December 2017, 340B Update for Hospitals: CMS Publishes FAQs Clarifying Use of Modifiers in Connection with 340B Program Reimbursement Cut on Part B Drugs
- 7 November 2017, CMS Finalizes Changes in CY 2018 OPPS and PFS Final Rules

- 18 September 2017, K&L Gates Triage: Substantial Payment Reductions Proposed in CY 2018 for Hospital Outpatient Departments Subject to the Site-Neutral Payment Rule
- 2 August 2017, CMS Proposes Substantial Payment Reductions in CY 2018 for Off-Campus Hospital Outpatient Departments Subject to the Site-Neutral Rule
- 8 June 2017, K&L Gates Triage: Proposed Changes to the Federal Hospitals-Within-Hospitals Rule
- 18 January 2017, K&L Gates Triage: Section 603 Site-Neutral Payment: Relocation and Expansion of Existing PBDs
- 11 November 2016, CMS Finalizes Rule Establishing New Emergency Preparedness Requirements
- 9 November 2016, CMS Announces Final Rule Implementing Site-Neutral Payment Rule for Certain Off-Campus Hospital Outpatient Provider-Based Departments
- 19 July 2016, CMS Releases Details on Site-Neutral Payment Provision under Bipartisan Budget Act
- 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?
- 8 December 2015, New Law Excludes New Provider-Based Off-Campus Outpatient Hospital Locations from OPPS
- 24 July 2015, Non-Stark Law Proposed Changes to Policies and Payments under the Physician Fee Schedule for CY 2016

OTHER PUBLICATIONS

- Site Neutral Payments - Transaction Concerns, *ABA Business and Transactions Interest Group Business Wire*, Fall 2016
- “Health-Related Quality of Life in Patients Treated for Hypertension: A Review of the Literature from 1990 to 2000,” co-authored article, *Clinical Therapeutics*, 2002
- “How do Precepting Physicians Select Patients for Teaching Medical Students in the Ambulatory Primary Care Setting?” co-authored article, *Journal of General Internal Medicine*, 2003

NEWS & EVENTS

- 4 June 2026, K&L Gates Receives Nearly 235 Firm, Individual Rankings in 2026 *Chambers USA* Guide
- 5 June 2025, K&L Gates Receives More Than 240 Firm, Individual Rankings in 2025 *Chambers USA* Guide
- 6 June 2024, K&L Gates Receives More Than 200 Firm, Individual Rankings in 2024 *Chambers USA* Guide
- 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
- 24 March 2022 , Medicare Changes of Ownership (CHOWs) | Institute on Medicare and Medicaid Payment Issues 2022, Hosted by American Health Law Association
- 21 May 2021, K&L Gates Policy and Regulatory Practice, Lawyers Ranked Among Leaders in 2021 Chambers USA Guide
- 23 April 2020, K&L Gates, Lawyers Recognized in 2020 Chambers USA Guide
- 26 April 2019, Chambers USA 2019 Guide Ranks K&L Gates, Lawyers Among Leaders
- 23 June 2016, K&L Gates, Lawyers Recognized as Leaders in Chambers USA 2016 Guide
- 17 February 2016, K&L Gates Names 50 New Partners

AREAS OF FOCUS

- Healthcare and FDA
- Healthcare Transactions

INDUSTRIES

- Digital Health
- Healthcare
- Lab, Pharmacy, and Durable Medical Equipment
- Life Sciences