



Darlene S. Davis

Partner

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OVERVIEW

Darlene Davis is a partner in the Research Triangle Park office. 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; health care 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 & Medicaid Services in its Boston Regional Office.

ACHIEVEMENTS

- Listed by *Chambers USA* for Health Care in North Carolina

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

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- 13 May 2019, CMS Issues Long-Awaited Draft Guidance on Hospital Co-Location and Space Sharing (*Alerts/Updates*)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

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

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

- 23 April 2020, K&L Gates, Lawyers Recognized in 2020 Chambers USA Guide (*Rankings & Recognitions*)

- 26 April 2019, Chambers USA 2019 Guide Ranks K&L Gates, Lawyers Among Leaders (*Press Release*)
- 23 June 2016, K&L Gates, Lawyers Recognized as Leaders in Chambers USA 2016 Guide (*Press Release*)
- 17 February 2016, K&L Gates Names 50 New Partners (*Press Release*)

AREAS OF FOCUS

- Health Care and FDA

INDUSTRIES

- Health Care Sector
- Lab, Pharmacy, and Durable Medical Equipment