

Andrew D. Ruskin

Partner

Washington, DC
+1.202.778.9415

Andrew.ruskin@klgates.com

OVERVIEW

Andrew Ruskin is a partner at the firm. He is a member of the Healthcare and FDA practice group. Andy's practice concentrates on the myriad ways that Medicare and Medicaid reimbursement and compliance shape the US healthcare ecosystem. Medicare and Medicaid regulations impact how healthcare providers and suppliers, and the entities that sell to them, such as drug and device manufacturers, structure themselves and their arrangements with each other. Healthcare and life sciences clients regularly seek Andy's counsel on developing strategies that simultaneously address regulatory challenges while achieving organizational objectives. With almost a quarter century of practice representing clients in this area, Andy has examined, and solved for, a vast array of healthcare regulatory issues. His deep market knowledge allows Andy to simultaneously provide macro and micro perspectives on a healthcare client's most challenging concerns.

For healthcare providers, Andy provides practical guidance on compliance with a wide range of regulatory requirements, including the Provider Based Rule, rules governing graduate medical education, 340B compliance, and clinical trial reimbursement rules. Andy also provides experienced counsel on elections made for wage index purposes, including navigating rules pertaining to submissions to the Medicare Geographic Classification Review Board and to the CMS Regional Office for wage index and rural redesignations. Andy works with clients to closely examine billing rules to determine whether they have repayment obligations under the 60 Day Repayment Rule and assists in developing Compliance Program safeguards. Where clients disagree with the government's assessment of their entitlement to payment, Andy represents them before regulatory tribunals, including the Provider Reimbursement Review Board, and defends them in Federal court proceedings and government investigations against claims involving False Claims Act liability. The complex regulatory requirements also serve as a backdrop to the advice he gives to clients when they seek his counsel developing provider affiliation agreements, joint venture agreements, and provider acquisitions.

For drug and device manufacturers, Andy serves as a Market Access professional. His understanding of the drivers of Medicare and Medicaid payment, including Price Reporting concerns, and the program integrity risks associated with these payments, such as Anti-Kickback Statute and False Claims Act risk, allows him to be highly effective at negotiating agreements with distributors, group purchasing organizations, payors, 3PLs, and customers, as well as in presenting matters to the Centers for Medicare & Medicaid Services, where reimbursement for a product may not yet be optimal, in light of its value. Andy has appeared before the HCPCS Committee to assist with obtaining a new code. He also advises these entities on their Price Reporting policies,

and Market Access policies, including their business rules pertaining to patient assistance programs, copay cards, and payments to foundations. Andy also assists with healthcare regulatory due diligence and strategizing for manufacturers seeking to acquire a product. Additionally, he defends manufacturers from False Claims Act liability where sales or marketing practices have been challenged.

A recognized thought leader and an active member of industry organizations, Andy serves as the current Chair of the American Health Law Association's Institute on Medicare and Medicaid Payment Issues, is a member of the Health Law Advisory Committee to Wolters Kluwer CCH, and is on the Editorial Advisory Board to HCCA's Report on Medicare Compliance. He is a sought-after speaker on current developments in Drug Pricing for such industry organizations as the American Conference Institute.

PROFESSIONAL BACKGROUND

Prior to joining the firm, Andrew counseled hospitals, pharmaceutical and medical device companies, and Medicare Advantage plans on a range of Medicare and Medicaid regulatory, litigation, and transactional matters. He advised on strategic issues surrounding coverage, reimbursement, and compliance, as well as drug pricing and price reporting. He defended clients in investigations by the US Attorney's Office and the Department of Health and Human Services Office of Inspector General. He has also appeared before several regulatory tribunals, such as the Provider Reimbursement Review Board and the HCPCS Committee.

ACHIEVEMENTS

- Recognized by *The Best Lawyers in America*® for Health Care Law in Washington, DC, 2027
- Recognized by *Chambers USA* for Healthcare in District of Columbia, 2024-2026
- Recognized by *The Legal 500 United States* as a Recommended Lawyer for Life Sciences, 2025-2026

SPEAKING ENGAGEMENTS

- "Understanding How Co-Pay Coupons, Accelerators, and Maximizers Impact Medicaid and Medicare Pricing and Rebates," *American Conference Institute*, 20 November 2025
- ACI's Drug Pricing Virtual Series, *American Conference Insitute*, 20 November 2024
- "Top Ten 2024: Drug Pricing—340B Developments to Watch," *American Health Law Association*, 15 March 2024
- "Medicare Part B Drug Pricing," *American Conference Institute*, 13 November 2023
- "21st Annual Rx Drug Pricing Boot Camp," *American Conference Institute,* May 4 – 5, 2023
- "Understanding How Co-Pay Coupons, Accelerators, and Maximizers Impact Medicaid and Medicare Pricing and Rebates," *American Conference Institute*, 17 November 2022
- "Medicare Part B Drug Pricing," *American Conference Institute*, 8 November 2022

- "Fraud & Abuse in the Sales and Marketing of Drugs & Medical Devices," *American Conference Institute*, 20 July 2022
- "Hospital Charges under the Microscope: Impact of Price Transparency Rule and No Surprises Act," *AHLA Annual Meeting*, 27-29 June 2022
- ACI's Annual RX Drug Pricing Boot Camp, *American Conference Institute*, 11 and 12 May 2022
- ACI's "BIG FOUR" Pharmaceutical Pricing Boot Camp, *American Conference Institute*, 18 and 19 May 2022
- "Provider-Based Status, Under Arrangements, Enrollment, and Related Medicare Requirements," *AHLA Institute on Medicare and Medicaid Payment Issues*, 23-25 March 2022
- "Medicare Part B Drug Pricing," *American Conference Institute*, 17 November 2020
- "Price Transparency Rule Compliance, Informing the Patient, and Protecting the Hospital's Commercial Interests: Mutually Exclusive Concepts?" *AHLA Physicians and Hospitals Law Institute*, 10-11 February 2020
- "Limits on Agency Action by the Department of Health and Human Services: Impact on Providers in 2020 and Beyond," *American Health Law Association*
- "Provider-Based Status, Under Arrangements, Enrollment, and Related Medicare Requirements," *AHLA Institute on Medicare and Medicaid Payment Issues*, 20-22 March 2019
- "Provider-Based Status, Under Arrangements, Enrollment, and Related Medicare Requirements," *AHLA Institute on Medicare and Medicaid Payment Issues*, 21-23 March 2018
- "60-Day Repayment Rule: Implications for Internal and External Audits," *AHLA Annual Meeting*, June 2018
- "What's the Future of the CMS 60-Day Repayment Rule?" *AHLA Physicians and Hospitals Law Institute*, February 2018
- "Don't put the CAR-T before the Horse: Proper Planning for Novel Gene Therapies in an Uncertain Regulatory Environment"
- "Provider-Based Status under Siege: Do the Benefits Justify the Costs of Compliance?" *Fraud and Compliance Forum*, October 2017
- "Hospital-Based Status Post BBA Section 603: Is Expansion Still Possible?" *AHLA Annual Meeting*, June 2017
- "Provider-Based Status: What a Long, Strange Trip It's Been!" *AHLA Institute on Medicare and Medicaid Payment Issues*, 23-31 March 2017
- "What Every AMC Needs to Know About the 340B Program," *AHLA Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions*, 9-10 March 2017
- "Medicare Part B: Drug Pricing, RX Drug Pricing Master Course," *American Conference Institute,* 1-2 November 2016

EDUCATION

- J.D., Case Western Reserve University School of Law, 1996
- A.B., Wesleyan University, 1987

ADMISSIONS

- Bar of District of Columbia
- Bar of New York
- United States District Court for the District of Columbia

THOUGHT LEADERSHIP *POWERED BY HUB*

- 3 August 2026, CMS CY 2027 OPPS/ASC Proposed Rule: Key Payment and Policy Changes for Hospitals, Health Systems, and ASCs
- 21 April 2026, Next Steps for Provider-Based Departments After the Consolidated Appropriations Act of 2026
- 25 March 2026, The 2026 OPPS Drug Acquisition Cost Survey: Response Deadline Extended
- 6 March 2026, The 2026 OPPS Drug Acquisition Cost Survey: Additional Considerations as Deadline Nears
- 1 December 2025, The 2026 OPPS Final Rule: Hospitals Now at a Decision Point Regarding Drug Acquisition Cost Survey
- October 2025, September and October 2025 Accolades
- March 2025, Loper Bright: Navigating the New Regulatory State and Implications for the Trump Administration Agenda
- October 2024, The Potential Impact of the 2024 Elections on the 340B Drug Pricing Program
- 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?
- 15 December 2022, Recent Developments to the 340B Drug Pricing Program
- 17 November 2022, New Data Available Under the Hospital Price Transparency Rule
- 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
- 31 January 2022, Medicare Reimbursement for Community Hospital Residency Programs

- 8 November 2021, 2022 OPPS Final Rule Overview: CMS Finalizes Policies on 340B, Hospital Price Transparency, and Inpatient Only List
- 21 October 2021, An Update on the CMS Hospital Price Transparency Rule
- 19 October 2021, 2021 Hot Topics in the 340B Drug Pricing Program
- 22 July 2021, CMS Proposes to Increase Penalties for Hospital Price Transparency Noncompliance
- 8 July 2021, 340B Update: Supreme Court Accepts Certiorari in 340B Payment Reduction Case
- 7 July 2021, 340B Update: Delaware Court Denies 340B Program Statute Requiring Contract Pharmacy Arrangements
- 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 March 2021, 340B Drug Pricing Program 2021 Outlook
- 24 December 2020, COVID-19: Reimbursement Corner: Graduate Medical Education Gets Major Boost from Congressional Appropriations Bill
- 3 December 2020, 340B Update: HRSA Moves Forward with 340B ADR Rule as Covered Entities Challenge Contract Pharmacy Actions
- 2 December 2020, OIG Finalizes Rebate Rules: Removal of Safe Harbor Protections for Rebates and Creation of New Safe Harbors for Other Discounts and Service Fees
- 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
- 28 September 2020, K&L Gates Reimbursement Corner: CMS's Proposed Phase-Out of the Inpatient Only List is Not Entirely Welcome News
- 25 September 2020, 340B Update: Congress and the Administration Respond to Drug Manufacturers' 340B Contract Pharmacy Actions
- 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
- 27 July 2020, President Trump Signs Drug Pricing Executive Orders Reinforcing the Administration's Priorities
- 23 July 2020, K&L Gates Triage: Recent Developments in the 340B Drug Pricing Program

- 21 July 2020, 340B Update: HRSA Indicates it Lacks Authority to Enforce 340B Program Guidance

OTHER PUBLICATIONS

- "Top Ten Issues in Health Law 2024," *American Health Law Association,* 1 January 2024
- "The Medicare Final Rule Regarding 340B Underpayment," *American Health Lawyers Association*
- "Strategic Planning for Physician Practice Acquisitions in the Post-Site Neutrality Payment Era," *American Health Lawyers Association*
- Editor, "Price Transparency Rules," *American Health Lawyers Association*
- "60-Day Repayment Rule: Implications for Internal and External Audits," *American Health Lawyers Association*
- "60-Day Overpayment Rule Medicare Parts A and B," *American Health Lawyers Association*
- "Don't put the CAR-T before the Horse: Proper Planning for Novel Gene Therapies in an Uncertain Regulatory Environment," *American Health Lawyers Association*
- "Provider-Based Status, Under Arrangements, Enrollment and Related Medicare Requirements," *American Health Lawyers Association*
- "Provider-Based Status under Siege: Do the Benefits Justify the Costs of Compliance?" *American Health Lawyers Association*
- "What Every AMC Needs to Know about the 340B Program," *American Health Lawyers Association*

NEWS & EVENTS

- 8 July 2026, K&L Gates Advises The J. Molner Company on Acquisition of Pharmaceutical Portfolio From Nordic Pharma, Inc.
- 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
- 11 March 2025, Nearly 50 K&L Gates Lawyers Receive Global Recognition in *Thomson Reuters*' Stand-out Lawyers List
- 6 June 2024, K&L Gates Receives More Than 200 Firm, Individual Rankings in 2024 *Chambers USA* Guide
- 14 December 2023, Chambers Asia-Pacific 2024 Guide Recognises K&L Gates
- 26 June 2023, AHLA Annual Meeting, Hosted by AHLA
- 1 June 2023, K&L Gates Receives Firm, Individual Rankings in 2023 *Chambers USA* Guide
- 31 January 2023, Physician and Hospital Law Institute 2023, Hosted by AHLA

- 20 July 2022 , Navigating the Latest Fraud & Abuse Risks Associated with Payor Relationships, Value-Based Arrangements, and Market Access Agreements, Hosted by ACI Fraud & Abuse in the Sales and Marketing of Drugs & Medical Devices
- 27 June 2022, Hospital Charges Under the Microscope: Operational Implications of the Price Transparency Rule and No Surprises Act, Hosted by the American Health Law Association
- 23 March 2022, Provider-Based Status, Under Arrangements, Enrollment, and Related Medicare Requirements, Hosted by American Health Law Association
- 22 March 2022 , Institute on Medicare and Medicaid Payment Issues 2022 Hosted by Health Care and FDA
- 2 February 2022, Physicians and Hospitals Law Institute 2022, Hosted by the American Health Law Association
- 17 November 2021, Understanding How Co-Pay Coupons, Accelerators, and Maximizers Impact Medicaid and Medicare Pricing and Rebates, hosted by American Conference Institute
- 17 November 2021, Rx Drug Pricing & Rebate Fundamentals, hosted by American Conference Institute
- 17 November 2021, Understanding How Co-Pay Coupons, Accelerators, and Maximizers Impact Medicaid and Medicare Pricing and Rebates, hosted by American Conference Institute
- 17 November 2021, Rx Drug Pricing & Rebate Fundamentals, hosted by American Conference Institute
- 8 November 2021, Medicare Part B: Coverages and Rebate and Pricing Essentials, hosted by American Conference Institute
- 7 July 2020, K&L Gates Continues Health Care Practice Growth With Washington, D.C., Partner Addition

AREAS OF FOCUS

- Healthcare and FDA
- 340B Program and Pharmacy
- Food, Drugs, Medical Devices, and Cosmetics (FDA)
- Healthcare Fraud and Abuse (US)
- Healthcare Payor-Provider Disputes (US)

INDUSTRIES

- Healthcare
- Life Sciences
- Pharmaceuticals, Biologics, and Medical Devices