ArentFox Schiff LLP
Attorneys

Stephanie Trunk

PARTNER

Stephanie focuses her practice on counseling pharmaceutical and device manufacturers, distributors and their customers on regulatory, reimbursement and compliance matters.

Industries

Health Care
Life Sciences

Practices

Privacy, Data Protection & Data Security

Education

The George Washington University Law School, JD, highest honors, 2003

The George Washington University School of Public Health, Graduate Certificate in Health Management, Graduate Certificate in Health Management, 2003

University of Maryland, BS, summa cum laude, 1997

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Her practice extends to counseling on drug pricing and government price reporting, HIPAA and privacy matters, counseling on Medicare Part D, developing corporate compliance programs, representing clients in contract negotiations and providing transactional support to her clients. Stephanie is a member of the firm's Life Sciences Industry Group.

Client Work

Stephanie represents pharmaceutical manufacturers of both pioneer and generic drugs as well as wholesale distributors of prescription drugs and devices. Her recent work has included:

- Developing a training program on government price reporting, including ASP, AMP and Best Price, ceiling and sub-ceiling price reporting to support the Public Health Service 340B program and non-FAMP and FCP reporting to FA/FSS for a pharmaceutical manufacturer.
- Conducting a "gap analysis" related to a pharmaceutical manufacturer's existing government price reporting methodologies and documentation.
- Conducting a review of a pharmaceutical manufacturer's interactions with managed care and pharmacy benefit management customers.
- Structuring a limited distribution arrangement through a "hub" and limited specialty pharmacies for a newly approved brand name drug.
- Obtaining an OIG Advisory Opinion for a charitable patient assistance program.
- Creating a compliance program for a small generic drug manufacturer.
- Counseling various pharmaceutical manufacturers related to federal Sunshine Act compliance.
- Drafting proposed comments to Medicare Part D regulations proposed by CMS for various interested stakeholders.
- Counseling a pharmacy benefit manager on Medicare Part D compliance and assisting with

preparation for a CMS audit.

- Assisting a device manufacturer in assessing fraud and abuse risks associated with contemplated sales and marketing activities and promotional or educational programs.
- Auditing a patient assistance foundation.
- Drafting and negotiating HIPAA Business Associate Agreements for various clients, including an electronic health records vendor.
- Drafting annual compliance training for a pharmacy benefit management company and a medical device manufacturer.
- Reviewing and updating rebate agreements for a pharmaceutical company.
- Drafting distribution agreements for a device manufacturer.

Previous Work

Prior to joining ArentFox Schiff, Stephanie was legal counsel to a pharmacy benefit management company where she provided legal guidance to the company on a variety of matters, including: Medicare Part D, HIPAA and privacy, corporate compliance, fraud and abuse, and licensing/regulatory. Additionally, upon completion of law school, Stephanie was an associate in the DC office of a leading national law firm, where she primarily counseled pharmaceutical and device manufacturers on both reimbursement and fraud and abuse matters.

Prior to attending law school, Stephanie practiced as a Certified Public Accountant in the assurance and advisory business services division of a national accounting firm, primarily providing auditing services to entities throughout the health care industry.

Professional Activities

Stephanie is a member of the American Health Lawyers Association and the American Bar Association's Health Law Section. She is also be a member of the BNA Pharmaceutical Law & Industry Advisory Board.

Publications, Presentations & Recognitions

Stephanie speaks and writes frequently on legal and regulatory issues impacting pharmaceutical manufacturers, pharmacies, wholesalers, PBMs and other stakeholders to the pharmaceutical supply chain. Some of Stephanie's recent speeches and webinars include:

- Overview of the Rapidly Shifting Reimbursement Policy Landscape, Healthcare Distribution Alliance (HDA) 2023 Distribution Management Conference; Indianapolis, IN (03.13.2023)
- An Overview of Reimbursement and Coverage Basics for Medical Devices, Lawline Webcast (12.20.2022)
- Medicare Pricing and Rebate Essentials, American Conference Institute (ACI) Passport to Proficiency on Rx Drug Pricing & Rebate Fundamentals Course; Online (11.08.2022)
- Drug Pricing and Rebate Essentials and Introduction to Medicaid, American Conference Institute (ACI) Passport to Proficiency on Rx Drug Pricing & Rebate Fundamentals Course; Online (11.01.2022)
- Ask the Attorneys – What Keeps Them Up at Night?; Closed-Door Executive Strategy Summit, Informa Medicaid Drug Rebate Program Summit; Chicago, IL (10.12.2022)
- State Drug Price Transparency Reporting (SPTR): State-By-State Review of Legal Requirements and Operational Challenges; External Counsel Roundtable – The Washington Outlook, 2022 Informa Connect Medicaid & Government Pricing Congress; Philadelphia, PA (05.23.2022)
- American Conference Institute (ACI) 20th Annual Rx Drug Pricing Boot Camp; Online (05.11.2022)
- Overview of the Rapidly Shifting Reimbursement Policy Landscape, Healthcare Distribution Alliance (HDA) 2022 Distribution Management Conference; Austin, TX (03.08.2022)
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Medicare Part D: Coverages and Rebate Pricing Essentials; Views from the Hill: The Latest Proposals on Drug Pricing and Reporting and What They May Signify, American Conference Institute (ACI) Passport to Proficiency on Rx Drug Pricing and Rebate Fundamentals Course; Online (11.17.2021)

- Drug Pricing and Reimbursement Legislation and Proposals in 2021, Association for Accessible Medicines (AAM) Legal Town Hall 2021; Online (05.25.2021)
- Explore the Evolving Role of the PBM and the Verticalization of the Pharmaceutical Industry, Dynamic Global Events Rx Pricing and Reimbursement Summit; Online (05.24.2021)
- Government Pricing & Reimbursement Update – What You Should Know for 2021 and Beyond, ArentFox Schiff & Federal Compliance Solutions Lunch & Learn; Online (05.03.2021)
- Biden's First 100 Days: What Does It Mean for Life Sciences Companies?, ArentFox Schiff Webinar; Online (04.29.2021)
- What the Biden Administration Means for Drug Pricing, Coverage and Reimbursement, Lawline Webcast (04.12.2021)
- Understanding How Co-Pay Coupons, Accelerators, and Maximizers Impact Medicaid and Medicare Pricing and Rebates; Post-Election Analysis: New Legislative, Regulatory, and Enforcement Trajectories for Drug Manufacturers Under a New Administration, American Conference Institute (ACI) Proficiency Series on Rx Drug Pricing & Rebate Fundamentals; Online (11.19.2020)
- External Counsel Fireside Chat, Informa Connect Medicaid Drug Rebate Program; Online (09.18.2020)
- Hub Services and Foundation Support – Why and How to Keep Them Separate and Distinct, 21st Annual Patient Assistance & Access Programs; Online (08.07.2020)
- Pharmaceutical Pricing?How Much Is Too Much? Policy and Enforcement Perspectives; AHLA Annual Meeting; Boston, MA (06.25.2019)
- Navigate the Complexities of the Specialty Market and Copay Collaboration with Hubs and Specialty Pharmacies; World Congress' Copay Summit; Philadelphia, PA (07.23.2018)
- Risky Business – Off-Label Compliance and Effectively Navigating Safe Harbors in the Medical Device Industry, CBI's 14th Annual Medical Device Compliance Congress; Chicago, IL (06.14.2018)
- The Latest Developments in State Pricing Transparency and Disclosure, CBI's 20th Annual Medicaid and Government Pricing Congress; Orlando, FL (05.21.2018)
- Pharmacy Benefit Managers: Understanding Pharmaceutical Supply Chain Middlemen, Lawline Webcast (04.09.2018)
- Navigate the Legal & Regulatory Landscape: Discuss Top Regulations Impacting Oncology Market Access and Commercialization, Oncology Market Access and Commercialization Summit ; Philadelphia, PA (02.05.2018)
- Addressing Medicaid and Medicare Pricing Concerns Relative to Value Based Arrangements, Health Outcomes Data Communications, Market Access, and Contracting Conference; Philadelphia, PA (01.22.2018)
- Address the Benefits and Inherent Risks Associated with Patient Advocates and Ensure Compliant Message Delivery, CBI Bio/Pharma Compliant Patient Support Programs East Conference, Philadelphia, PA (12.04.2017)
- Understanding Intermediaries: Group Purchasing Organizations, FTC Workshop Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics, Washington, DC (11.08.2017)
- Assessing the Impact of Pricing Pressures on the Pharmaceutical Industry, Life Science CEO Forum; San Diego, California (03.24.2017)
- The Convergence of Technology and Healthcare, Life Science CEO Forum; San Diego, California

(03.24.2017)

- Perspectives on Reimbursement Landscape, Healthcare Distribution Management Association (HDMA) Distribution Management Conference; Palm Desert, California (03.07.2017)
- Reimbursement Framework for Biosimilars, Lawline Webcast (02.24.2017)
- Mitigate Risk by Understanding Trends in False Claims and Anti-Kickback Risks, CBI Pharmacy Benefit Oversight and Compliance Congress; Scottsdale, Arizona (11.14.2016)
- The Final AMP Rule: An Analysis for New Pricing Challenges, ACI 16th National Rx Drug Pricing Master Course; New York, New York (11.01.2016)
- The Evolution of Value-based Purchasing Arrangements & Government Pricing Challenges Associated Therewith, Medicaid Drug Rebate Program (MDRP) Summit, Institute for International Research; Chicago, Illinois (9.22.2016)
- Reimbursement Framework, GPhA Biosimilars Council Conference; North Bethesda, Maryland (09.07.2016)
- The AMP Final Rule Recap: Operationalities, Legalities, Realities and Practicalities, American Conference Institute (ACI) Final AMP Rule Boot Camp - East Coast Edition; New York, New York (5.23.2016)
- Final AMP Rule: An Overview for Stakeholders, AHLA Enterprise Risk Management Task Force (ERM TF), Education Call (4.14.2016)
- Huron GP Insights Round Table, Huron Consulting Group, Conference Call (4.6.2016)
- Payer Perspectives on Reimbursement and Other Regulatory Issues, Healthcare Distribution Management Association (HDMA) Distribution Management Conference; San Antonio, Texas (3.7.2016)
- A Closer Look at AMP and Other Regulations: The Impact on Generics, Webinar (2.18.2016)
- Deciphering the Final AMP Rule, Webinar (2.4.2016)
- Generics and Biosimilars - Impact of Changes in Market Share and Pricing, CBI Pharmacy Benefit Oversight & Compliance Conference; Scottsdale, Arizona (11.13.2015)
- Overview of Medicaid Price Calculations and Rebates: The Basic Building Blocks, ACI National Rx Drug Pricing Master Course; New York, New York (11.5.2015)
- The Evolution of Medicaid After the Affordable Care Act, Medicaid Drug Rebate Program (MDRP) Summit, Institute for International Research; Chicago, Illinois (9.30.2015)
- Legal Considerations, Contract Terms, and Language of PBM Contracting, CBI Pharmacy Benefit Management and Contracting Conference; Chicago, Illinois (8.21.2015)
- Affordable Care Act Implications on Pricing, Class of Trade, Membership and Eligibility, CBI Commercial Contracts and Chargeback Management Conference; Philadelphia, Pennsylvania (6.22.2015)
- Medicaid Expansion, Accurately Forecasting and Accruing for Medicaid and Rebate Liability in the Wake of PPACA and Medicaid Expansion, Government Programs Summit, Institute for International Research; Arlington, Virginia (3.23.2015)
- Manufacturer Legal Risk and Compliance Relating to the 340B Program, Government Programs Summit, Institute for International Research; Arlington, Virginia (3.23.2015)
- Bona Fide Service Fees and Fair Market Value, Government Drug Pricing Forum, The Conference Forum; Washington, DC (2.2.2015)
- Implications of Health Insurance Exchanges and State Law Trends on Pharmacy Benefit Management, CBI Pharmacy Benefit Oversight & Compliance; Chicago, Illinois (11.12.2014)
- Legal and Policy Update for Pharmacies and PBMs, Health Market Science Advisory Board 2013, Health Market Science; Chicago, Illinois (10.22.2013)

Stephanie is the author of the following book chapters:

- Controlling Fraud, Waste and Abuse in the Medicare Part D Program, published in the ABA/BNA's *Health Care Fraud and Abuse: Practical Perspectives*, edited by Linda A. Baumann
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Medicare Part D Covered Drugs published in the Thomson Reuters Regulation of Medicare Part D Plans

- Fraud and Abuse Litigation in the Pharmaceutical Industry published in Health Care Litigation and Risk Management Answer Book, edited by David S. Greenberg and Brian D. Schneider
- The Federal Anti-Kickback Statute published in Health Care Litigation and Risk Management Answer Book, edited by David S. Greenberg and Brian D. Schneider

While in law school, Stephanie was a member of the *George Washington University Law Review*, where she published the following articles:

- "Agency Interpretation of the Medicaid Statute: When Does It Deserve Deference?" 70 Geo. Wash. L. Rev. 405 (2002).
- "Sounding the Death Toll for Health Care Providers: How the Civil False Claims Act has a Punitive Effect and Why the Act Warrants Reform of its Damages and Penalties Provision." 71 Geo. Wash. Rev. 159 (2003).

She was also elected to the Order of the Coif and is the 2003 Recipient of the Excellence in Health Law Award from the American Bar Association Health Law Section and Bureau of National Affairs.

Life Beyond the Law

When not working, Stephanie enjoys spending time, especially outdoors, with her 2 children and cheering on the Baltimore Ravens.

Bar Admissions

District of Columbia
Virginia