



Renee E. Zerbonia

SENIOR COUNSEL

DENVER, CO

PHONE: 303.749.7250

EMAIL: RENEE.ZERBONIA@HUSCHBLACKWELL.COM

KANSAS CITY, MO

PHONE: 816-983-8385

OVERVIEW

Renee provides practical and strategic solutions to complex healthcare issues.

Renee's healthcare-based practice has a significant focus on the pharmaceutical supply chain. She advises clients on issues related to the distribution, delivery, and reimbursement of drugs, including healthcare licensing, drug purchase agreements, specialty pharmacy contracting, Medicare and Medicaid matters, state pharmacy law compliance, the 340B Drug Pricing Program, and collaborations among healthcare entities. Clients turn to Renee for regulatory and strategic guidance on all aspects of drug delivery. She frequently works with retail and specialty pharmacies, health plans, pharmacy benefit managers, health systems, and disruptors in the industry.

Additionally, Renee works with health systems, hospitals, managed care companies, and other healthcare entities in their regulatory compliance and everyday operations. She has advised health systems on corporate structuring and the corporate practice of medicine, state licensure matters, Medicare and Medicaid billing and reimbursement, and preparing policies and procedures aimed at the everchanging legal landscape. She also advises telehealth companies on the unique regulatory considerations inherent in telemedicine. In addition, Renee assists clients in contract negotiations.

With extensive regulatory experience and a keen eye for detail, Renee also advises clients on healthcare mergers and acquisitions of all kinds. Her work includes managing and conducting due diligence, negotiating healthcare terms in transaction documents, and establishing efficient plans for transaction-related licensing and reporting.

Industry

Healthcare

Services

Healthcare Operations

Healthcare Providers

Healthcare Regulatory &
Compliance Counseling

Medicaid Reimbursement Strategies
Pharmacy

Psychedelics & Emerging Therapies

State Attorneys General Practice

As a former assistant attorney general in the Medicaid Fraud Control Unit (MFCU) of the Missouri Attorney General's Office, Renee counsels healthcare providers on a variety of state and federal fraud, waste, and abuse matters. She has guided providers through internal audits as well as state and federal audits and investigations. She has also assisted with establishing and auditing healthcare corporate compliance plans.

Experience

PHARMACY AND DRUG SUPPLY CHAIN

- Routinely counseled specialty pharmacy on nationwide licensing and compliance matters, including pharmacy license applications and preparing targeted legislative and regulatory updates tailored to the client's specific needs.
- Developed and implemented strategic project plan for the licensing of a specialty pharmacy in all 50 states.
- Represented an independent pharmacy solutions company in the formation of a GPO joint venture with respect to drug purchasing and participation issues.
- Advised digital health technology company on matters relating to its prescription drug savings program, including accumulator programs, copay discount cards, and Part D formulary requirements.
- Advised prescription drug services company on regulatory compliance relating to various service programs, including drug sourcing and patient assistance.
- Co-managed preparation of prescription drug rebate agreement templates and implementing amendments across hundreds of existing contracts.
- Advised pharmacy benefit manager on specialty pharmacy contracting.
- Advised health system on the state of 340B legislation and the implications of proposed and enacted laws.
- Represented drug distributor in successful appeal of complaint before the Missouri Board of Pharmacy, avoiding formal settlement and fines.

Experience

MEDICARE AND MEDICAID

- Counseled health system on reimbursement matters associated with establishing a new hospital, including provider-based billing, state licensure, and government payor enrollment.
- Routinely assisted specialty pharmacy on Medicare and Medicaid reimbursement and compliance matters, including counseling on billing requirements, drafting policies, and facilitating outreach to government agencies.
- Assisted specialty pharmacy with Medicaid program enrollment in all 50 states and advised on ongoing compliance.

TRANSACTIONS

- Assisted client in sale of specialty pharmacy to private equity company, including supporting with due diligence; negotiating healthcare related terms of transaction documents; and coordinating hundreds of licensure filings with buyer's counsel.
- Served as outside transactional and regulatory counsel to Marshfield Clinic Health System in a merger with Sanford Health, the largest rural health system in the United States. The combined system serves patients and communities across the upper Midwest, including South Dakota, North Dakota, Minnesota, Wyoming, Iowa, Wisconsin, and the Upper Peninsula of Michigan.
- Counseled nationwide HIV/AIDS healthcare system on healthcare matters in the purchase of Colorado community pharmacy.
- Led due diligence and negotiation of healthcare regulatory terms in health system's equity purchase of physician-owned hospital.
- Managed healthcare regulatory matters in sale of ophthalmology practice to private equity group, including preparing self-referral disclosure protocol (SRDP) submission to CMS.
- Delivered healthcare regulatory guidance in the merger of two large healthcare systems.

Experience

OTHER REGULATORY/COMPLIANCE

- Provided strategic legal counsel to emerging health insurance startup on market expansion plan, including insurer, third-party administrator (TPA), and utilization review entity (URE) licensure requirements in numerous states.
- Advised on regulatory and licensing matters in the establishment of a ketamine infusion clinic.
- Conducted internal corporate compliance program audit for behavioral healthcare program.
- Negotiated data privacy and security agreements, business associate agreements (BAAs), and confidential disclosure agreements (CDAs) on behalf of healthcare client.
- Assisted utilization review company with obtaining licensure in multiple states.
- Counseled nationwide health system on corporate structuring and the corporate practice of medicine (CPOM) in connection with acquisition of Colorado physician practice.
- Prepared multi-state survey of background check and related staffing requirements for Colorado assisted living facility.
- Presented multiple compliance training programs tailored to different departments of a specialty pharmacy.
- Managed team of attorneys in preparation of nationwide survey of COVID-19 related licensing waivers for telehealth services of numerous provider types.

INVESTIGATIONS AND SELF-DISCLOSURES

- Assisted with conducting internal audit and preparing Medicaid self-disclosure on behalf of Colorado home health agency.
- Aided internal investigation for healthcare staffing company in response to Department of Justice (DOJ) investigation.

Experience

- As an Assistant Attorney General, directed investigations into alleged Medicaid fraud and abuse and represented the State of Missouri in civil and criminal Medicaid fraud and abuse cases.

Education

- J.D., Saint Louis University School of Law
 - *cum laude*
 - Certificate in Health Law
 - Academic Excellence Awards in Healthcare Finance & Business Planning, Taxation, Patent Law and Legal Profession
 - *Saint Louis University Journal of Health Law & Policy*, Staff Editor
- B.A., Wake Forest University
 - Biology

Admissions

- Missouri
- Colorado