

# Daniel C. Fundakowski

SHAREHOLDER

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Dan Fundakowski helps health care and life sciences organizations turn complex regulatory, compliance and enforcement issues into clear, actionable strategy. Hospitals, health systems, academic medical centers and life sciences companies rely on his guidance to manage risk, respond to regulatory scrutiny and keep operations aligned with evolving legal requirements.

Dan's practice spans day-to-day regulatory counseling, compliance program development, government investigations and transactional regulatory strategy. His practice includes:

## Regulatory and Compliance Counseling

- Anti-Kickback Statute, Stark Law, False Claims Act and Civil Monetary Penalties Law
- Human subjects research regulations and the Food, Drug and Cosmetic Act
- State fraud, pricing transparency and marketing laws
- Value-based care arrangements, provider compensation models and population health collaborations
- Compliance program design, training, Corporate Integrity Agreements and post-resolution monitoring
- Licensure, telehealth and scope-of-practice issues, including advocacy before state boards and oversight agencies

## Government Investigations, Audits and Enforcement

- Internal investigations and audits involving compliance, billing practices and risk adjustment integrity
- Overpayment self-disclosures and responses to government inquiries
- Investigations and enforcement actions involving the Anti-Kickback Statute, False Claims Act, Controlled Substances Act and other fraud and abuse laws
- DOJ, HHS, CMS, FDA, state attorney general and government contractor inquiries
- Reimbursement and coverage disputes, RADV audits and CMS program integrity reviews
- Matters involving off-label promotion, kickback allegations, research misconduct, billing fraud, cost mischarging and pricing data reporting

## Capabilities

- Health Care
- Health Care Compliance
- Government Investigations
- False Claims Act Defense

## Transactional Regulatory Counseling

- Regulatory strategy and risk assessment in mergers, acquisitions, joint ventures, affiliations and other transactions
- Transactions involving providers, payors and private equity sponsors
- Structuring collaborations and arrangements to align with federal health care program requirements

## Education

- Saint Louis University School of Law (J.D., 2012)
  - Saint Louis University Law Journal, Editor
  - Health Law Certificate – Center for Health Law Studies
- Saint Louis University School of Public Health (M.H.A., 2012)
- Butler University (B.A., 2008)
  - Philosophy, Business Administration, Classical Studies

## Bar Admissions

- District of Columbia
- Missouri
- North Carolina

## Court Admissions

- U.S. District Court, District of Columbia

## Memberships

- American Bar Association, Health Law Section
- American Health Lawyers Association

## Recognition

- Named one of *Best Lawyers: Ones to Watch® in America* in Health Care Law, 2024-2026
- Recipient of the Burton Award for Distinguished Legal Writing, 2016

# Matters

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## Regulatory and Compliance Strategy

- Led regulatory strategy for a multibillion-dollar hospital system in connection with a DOJ investigation and lawsuit alleging violations of the Stark Law, the AKS and the FCA. Dan guided leadership on physician compensation realignment, compliance infrastructure enhancements and the negotiation and implementation of a Corporate Integrity Agreement.
- Supported hospitals and health systems on compliance with federal rules governing human subjects research, CME and grant-funded collaborations, and implementation of regulatory safeguards under HHS and FDA rules.
- Guided health system on Stark Law and CMP Law compliance in the context of

population health initiatives and community-based care programs. Dan conducted internal policy audits and trained executives on referral risk mitigation and safe harbor frameworks.

- Advised integrated health systems and provider groups on MACRA and Quality Payment Program participation, including MIPS reporting, alternative payment models, and compliance risks related to shared savings, care coordination incentives and quality-linked compensation.
- Structured provider compensation models and clinical collaborations that align with commercial goals and regulatory risk frameworks (e.g., the Stark Law and the AKS), including value-based care, co-management and clinical support services.
- Supported enterprise risk assessments related to provider reimbursement and audit exposure, including RADV audits, MAC overpayment findings and pre-/post-payment review strategy. Dan advised on strengthening compliance auditing functions and documentation workflows.
- Conducted HIPAA compliance reviews and enterprise security risk assessments for integrated delivery networks, with attention to EHR interoperability, data-sharing protocols and incident response planning.
- Resolved a federal investigation into a pharmaceutical manufacturer's promotional practices without any admission of wrongdoing, by aligning internal policy changes with FDA promotional guidelines and AKS safe harbor principles.
- Advised on regulatory risks under the FDCA, the AKS and the Sunshine Act related to FDA-regulated product promotion, co-branded communications, patient education and peer-to-peer marketing strategies.

## Investigations and Disputes

- Represented health systems and pharmaceutical manufacturers in FCA, AKS and FDCA investigations. Dan led internal investigations and prepared self-disclosures to CMS, the OIG and the DOJ.
- Advised a research university in responding to a lawsuit involving the alleged falsification of federally funded research data. Dan guided internal compliance strategy and risk mitigation tied to research integrity requirements.
- Advised a health system on Medicare reimbursement strategy and audit defense, including appeals before the Provider Reimbursement Review Board. Dan provided counsel on regulatory positioning, documentation standards, and administrative appeal rights involving disallowed cost report items and overpayment recoupment.
- Supported health systems and health insurers in responding to audit findings from UPICs, MACs and RADV contractors. Dan advised on corrective action planning, documentation improvements and legal strategy across all phases of the audit and appeal process.
- Counseled a health system through a multi-defendant FCA matter involving alleged violations of the Stark Law, the AKS and the FCA. Dan advised on institutional exposure, compliance remediation and parallel strategic affiliations.
- Resolved a federal investigation into a pharmaceutical manufacturer's promotional practices without any admission of wrongdoing.
- Secured a dismissal with prejudice in an FCA lawsuit involving alleged noncompliance with Paycheck Protection Program loan requirements.
- Defended a medical device manufacturer against FCA allegations of fraudulent billing practices and pursued breach-of-contract counterclaims against relators.
- Defended an operator of skilled nursing facilities in parallel investigations by Congress, the OIG and state attorneys general involving long-term care billing practices.
- Counseled a supplier of wound care products on audit defense and appeal strategy for UPIC audits, including representation through the administrative law judge hearing phase.

## **Transactional Regulatory Counsel**

- Served as regulatory counsel in mergers, joint ventures and strategic affiliations involving hospitals, academic medical centers and drug/device manufacturers. Dan evaluated licensure, billing compliance, research regulations and fraud and abuse exposure.
- Counseled on structuring collaborations to support digital health, research infrastructure and patient engagement technologies, with attention to federal health program requirements.