

HEALTHCARE REGULATORY & COMPLIANCE COUNSELING



It is difficult to play by the rules when there are so many of them – especially when they keep changing. Husch Blackwell helps clients develop and implement programs and policies that mitigate risk and ensure compliance with the complex web of healthcare rules and regulations. From Medicare and Medicaid reimbursement to Stark Law, anti-kickback statute, HIPAA, and clinical research matters, we focus on compliance so our clients can focus on their business.

When potential violations are alleged, we are vocal advocates. Our attorneys aggressively defend clients' positions, either convincing the government to drop its pursuit or negotiating favorable resolutions for our clients.

Audit defense

When serious compliance concerns arise, Husch Blackwell represents corporate and individual providers in developing strategies to address potential violations. Our experience includes conducting internal investigations, responding to subpoenas and requests for interviews of employees, presenting defenses to the government's purported findings, and negotiating the settlement of civil and criminal charges.

Fraud and abuse

Our attorneys work with healthcare clients to minimize

“Husch Blackwell’s team of healthcare attorneys has the depth of experience we need and is extremely responsive whenever we turn to them for advice.”

— Chief Operating
Officer, Healthcare
Technology Firm —

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civil and criminal exposure to fraud and abuse – and to secure the best possible outcomes when violations are alleged. Whether developing a compliance strategy, responding to a Department of Justice (DOJ) investigation or negotiating a settlement, our Healthcare team considers not only the legal issues but also the operational and management concerns that healthcare organizations face when fraud and abuse are alleged.

Healthcare investigations and government enforcement

Our attorneys have been involved with healthcare fraud investigations not only as defense counsel but also as prosecutors, giving our team substantial insight into the government's thinking and the processes it follows in pursuing cases. Our experienced team guides clients in conducting internal investigations; responding to government enforcement actions; appealing regulatory actions; and defending civil and criminal False Claims Act, anti-kickback, and fraud allegations.

Representative Experience

Represented a multistate pharmacy benefits management company in federal grand jury investigation regarding alleged Medicare and Employee Retirement Income Security Act (ERISA) fraud.

Represented national home healthcare provider in parallel criminal and civil False Claims Act investigations. The global resolution included a deferred prosecution agreement and civil settlements with the United States and more than 30 states, as well as a corporate integrity agreement with the

OIG.

Overtaken immediate jeopardy citations and sanctions for skilled nursing facilities through the federal appeals process.

Defended pharmaceutical manufacturer in a criminal Food and Drug Administration (FDA) investigation regarding quality controls, validation of manufacturing protocols, and timeliness and accuracy of field alert submissions.

Represented nursing homes, home health agencies, and hospices in false claims investigations, including allegations of Medicare fraud.

Represented a durable medical equipment provider in federal whistleblower matter alleging fraudulent billing practices.

Represented multiple pharmacies in Medicaid false claims investigations and settlements.

Negotiated settlement with the regional office of the CMS and the U.S. Attorney's Office to avoid termination of a skilled-nursing facility.

Served as lead counsel for a health system during a four-year criminal and civil investigation by the DOJ, U.S. Attorney's Office, Federal Bureau of Investigation (FBI), and OIG on matters related to billing issues and physician relationships. The matter was ultimately resolved through settlement, and the criminal investigation of key personnel was closed with no charges being filed.

Counseled a Rocky Mountain hospital in conducting an internal investigation and voluntary disclosure to the OIG

regarding physician employment arrangements and a joint venture with physicians. The matter was resolved with a monetary settlement at a figure far below single damages exposure, and no corporate integrity agreement was imposed.

Represented a rural hospital in a local criminal investigation based on allegations of improper conduct and patient care by a formerly employed nurse.

Counseled a large hospital system during investigation by the FBI on matters related to transplant activities. The matter was closed with no charges being brought against the hospital or its employees.

Defended an organization operating a group home in a state criminal trial with charges of manslaughter and neglect related to the death of a resident. All of the organization's employees pled guilty to charges of neglect and cooperated with government prosecution, however, the jury acquitted the organization on the manslaughter charge.

Defended a large pharmaceutical business organization during investigation and revocation proceedings initiated by the Drug Enforcement Administration (DEA) related to controlled substances.

Advised a large pharmaceutical business organization during investigation by postal inspectors, OIG and U.S. Attorney related to allegations of kickbacks and other illegal conduct in the sales of prescriptive drugs.

Represented an internal medicine physician practice in

government investigation and civil litigation related to an extremely high-profile FBI case involving a Kansas City pharmacist who diluted prescription drugs.

Defended numerous healthcare clients before government and regulatory agencies and contractors, including the Department of Health and Human Services, Departmental Appeals Board, CMS, RAC, and the Zone Program Integrity Contractors (ZPIC), for alleged violations of the Social Security Act, Code of Federal Regulations, and Medicare coverage and billing policies.

Assisted institutions in evaluating compliance with federal research regulations in connection with informed consent and Institutional Review Boards (IRB) issues, NIH Grants Policy Statement, and related federal regulations and investigations in the area of pediatric and adult research.

Conducted internal compliance investigations of suspected Medicaid overpayments.

Counseled clients through audits and compliance checks by the Office of Federal Contract Compliance Programs (OFCCP), including strategies to avoid potential affected class findings with the OFCCP and the Department of Labor.

Drafted uniform medical staff bylaws for compliance with the Joint Commission standard MS.01.01.01 on behalf of a multistate health system.

Led a top-to-bottom review and enhancement of the compliance program for one of the world's leading medical device manufacturers, including its clinical trials, sales,

marketing and investigations policies, procedures, and implementation.

Prepared and reviewed clinical trial informed consent documents necessary for medical trials and experiments, particularly in life sciences, pharmaceutical, and medical device studies.

Serve as primary outside counsel for one of the nation's leading pediatric medical centers, headquartered in Kansas City, Missouri. We advise the hospital on compliance and regulatory matters, particularly dealing with state Medicaid programs and unique state requirements for disclosures and refunds.

Serve as primary outside healthcare counsel for an eight-hospital nonprofit health system headquartered in Kansas City, Missouri. We have represented the system and its facilities for more than 40 years in a wide range of matters, including regulatory compliance and research compliance.

Serve as primary outside healthcare counsel for an 11-hospital nonprofit health system that has hospitals in Kansas, Colorado and Montana. Guidance includes regulatory compliance and reimbursement matters.

Served as lead counsel for a healthcare system in conducting an internal investigation, making a self-disclosure and negotiating a settlement with the Health and Human Services' Office of Inspector General (HHS OIG) and DOJ, including defending the hospital from litigation brought by a physician included in the self-disclosure. The firm negotiated a first-of-its-kind settlement.

Settled a Stark Law violation with the Department of Justice and the HHS OIG after a multiyear internal investigation, self-disclosure, and extensive negotiations. The matter was resolved with no criminal charges, no admissions of False Claims Act violations, and no imposition of a corporate Integrity agreement or government oversight.

Developed a multi-state guardianship and consent matrix and decision tool for client currently being utilized by providers in Colorado, Kansas, Montana, Utah, and Wyoming to help front line personnel navigate sensitive and oftentimes highly controversial situations related to the terminally ill and end of life decisions, durable power of attorney and healthcare proxies, minor consent issues, and guardianship.