

**McGuireWoods**

# HEALTHCARE ENFORCEMENT



## HEALTHCARE ENFORCEMENT



McGuireWoods is a national leader in representing healthcare companies that are subject to government fraud enforcement investigations and actions. Relying on our industry-leading regulatory attorneys with their extensive knowledge regarding the laws and regulations impacting the provision of healthcare as well as the sale and promotion of drugs and medical devices; and the wealth of experience navigating high-risk matters offered by McGuireWoods' nationally recognized litigation and white-collar defense team, time and again clients have called upon McGuireWoods when confronted with an inquiry, subpoena or complaint from the government or one of its intermediaries.

Our Healthcare Enforcement Team includes members of our Government Investigations and White Collar Litigation Department, which has been recognized twice as a Law360 Group of the Year, includes former U.S. attorneys, more than a dozen federal prosecutors and other former enforcement officials; as well as members of the Healthcare Department, whose lawyers have been recognized by Chambers USA, Best Lawyers in America, Legal Elite and Super Lawyers as among the top legal service providers in the nation. The team, many of whom have significant experience working for the enforcement agencies that bring investigations and initiate litigation against our clients, maintains strong personal and professional relationships with investigating agencies and, as a result, we bring credibility to any representation. This extensive experience, as well as our attorneys' close relationships with prosecutors and regulators, provide unique insights into the government's tactics and policy concerns. That insight is critical in helping to persuade prosecutors to decline to file a complaint or intervene in a qui tam (whistleblower) suit, dismiss a qui tam complaint outright, or take other actions that lead to a favorable outcome for a client.

When fraud allegations arise in the administrative, civil or criminal context, our experienced Healthcare Enforcement Team leverages a storied history of helping corporate clients and individuals navigate the complexities of potentially-perilous investigations and enforcement actions and attain favorable resolutions with minimal impact on business operations. The multidisciplinary team includes numerous former federal prosecutors with extensive experience prosecuting healthcare fraud cases at DOJ, and seasoned trial attorneys who have defended numerous fraud actions in the healthcare sector. Representation of clients is also enhanced by combining this enforcement and litigation experience with McGuireWoods' recognized regulatory experience in a broad range of sub-sectors in the healthcare industry.



The Healthcare Enforcement Team routinely advises clients on regulatory matters which arise during audits, investigations and enforcement proceedings initiated by various federal and state agencies including the Centers for Medicare and Medicaid Services (CMS) and its intermediaries, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS), the Department of Justice (DOJ), and state health departments, attorneys general and professional licensing boards.

We also advise participants throughout the healthcare and life sciences industries on compliance matters, including the establishment of compliance programs, the adoption of policies and procedures, compliance training, and the resolution of compliance reports and investigations. Our focus on assisting clients with the implementation and operation of effective compliance programs based on applicable law, regulations, and guidance allows our clients to identify and resolve regulatory risks before they become significant issues.

## HOW WE HELP

The Healthcare Enforcement attorneys at McGuireWoods have the knowledge and experience that healthcare providers and insurers need to deftly handle high-risk enforcement investigations and action and achieve compliance with federal and state-specific regulatory requirements. Our team represents and advises clients with respect to a full range of regulatory areas, including:

Federal and state criminal fraud and abuse provisions

False Claims Act (FCA) and state equivalents

Federal and state anti-kickback laws, including the federal Anti-Kickback Statute

Federal and state self-referral laws, including the federal Stark law

Federal and state privacy laws, including HIPAA

Food and Drug Administration (FDA) regulations

Corporate practice of medicine restrictions

Medicare and Medicaid conditions of participation

Telehealth regulations

Federal procurement laws and regulations



Beyond responding to investigations and enforcement actions, we also assist clients in proactively reducing risk by:

Conducting internal audits and investigations

Developing and implementing compliance programs

Facilitating enterprise-wide risk management solutions

C-suites of Fortune 500 companies, senior executives, boards of directors and high-profile individuals rely on McGuireWoods to handle responses to healthcare fraud investigations from inception to resolution. We focus on minimizing the business and personal interruptions an investigation can cause. By developing strategies to reduce civil, criminal and administrative exposure, we help to navigate a cumbersome, time-consuming process while limiting the consequences of an investigation or action. More specifically, our experienced Healthcare Enforcement attorneys will:

Employ its close relationship with prosecutors to attempt to glean details about potentially under-seal matters and confidential investigations and limit the scope and breadth of discovery requests.

Confer with McGuireWoods premier regulatory experts to quickly master the relevant industry-specific legal regime, program and reimbursement rules, standards and practices.

Formulate and execute a comprehensive internal investigation and defense strategy to quickly and efficiently learn the relevant facts and circumstances, so we can minimize risks and maximize the chances of a quick and favorable outcome for the client.

Navigate ancillary risks and attendant negotiations such as corporate integrity or monitoring agreements and potential suspension, exclusion or revocation from federal healthcare programs.

We also work closely with our [Strategic Risk & Crisis Management](#) Team to manage related issues, including board and shareholder relations, media inquiries and other crisis management matters.



## OUR TEAM

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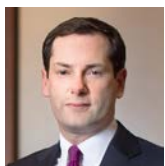
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## REPRESENTATIVE MATTERS

- McGuireWoods is serving as Special Counsel for Opioid Litigation for Purdue Pharma, the maker of OxyContin, helping lead the company through litigation and government investigations related to the opioid crisis.
- Representation of a pain specialist currently under investigation by the U.S. Attorney's Office in the Eastern District of Virginia (Richmond) for violating the Anti-Kickback Statute for receiving speaker fees from fentanyl manufacturer, INSYN, and for violating rules governing prescribing of opioids.
- Represented the largest private operator of healthcare facilities in the world in defense of allegations by a qui tam plaintiff that the company fraudulently billed Medicare and Medicaid for unnecessary medical procedures.
- Represented a significant physician practice that had a relationship with a local health system that was alleged to have been in violation of the Anti-Kickback Statute and the False Claims Act (FCA).
- Representation of a telemedicine provider in a qui tam case investigated by the federal government based on alleged incorrect billing of services provided to Medicare patients.
- Represented a physical therapist and a related entity in a federal FCA investigation alleging improprieties in connection with the provision of therapy services and related billing.
- Represented the former manager of a nursing home in negotiating a settlement of a federal FCA lawsuit alleging the submission of false claims for services provided to nursing home residents.
- Represented a national dialysis chain in a federal FCA investigation involving alleged billing issues.
- Representing a health care services processing company in a multi-agency inspectors general investigation related to manufacturing issues allegedly in violation of the FCA.
- Represented a medical device company executive in connection with a qui tam lawsuit alleging kickbacks and overcharging on Medicare-related payments.
- Representation of an Ambulatory Surgical Center executive in connection with a criminal investigation related to medically unnecessary procedures.
- Represented a medical school in an FCA investigation relating to billing for resident services.
- Represented the former owners of a pharmacy company in a joint federal and state FCA investigation and federal criminal investigation related to allegations of improper provision of pharmaceuticals to nursing home patients and illegal kickbacks in connection with customer contracts and sale of business.
- Represented physician group in a federal FCA case regarding allegations of illegal kickbacks.
- Represented a health insurance company in a contentious lawsuit that was filed in the Southern District of Texas alleging violations of the federal FCA.
- Represented a mail order pharmacy in connection with allegations that it had engaged in improper marketing activities that allegedly violated statutes and gave rise to FCA liability.
- Represented an electronic medical record vendor in connection with an FCA allegation in which a relator had alleged that the software purportedly caused an upcoding of medical claims.



- Represented several large pharmaceutical companies in congressional probes into the opioid crisis.
- Represented university as a plaintiff in recovering overcharges for student health insurance premiums under Virginia's Fraud Against Taxpayers Act.
- Representing a health care services processing company in a multi-agency inspectors general investigation related to manufacturing issues allegedly in violation of contractual requirements implicating the FCA and other statutory requirements.

## INSIGHTS

The  
**FCA INSIDER**  
INSIGHTS AND UPDATES ON FALSE CLAIMS ACT LITIGATION

***The FCA Insider***, a False Claims Act blog published by a multi-disciplinary team of McGuireWoods' attorneys, aims to keep you abreast of False Claims Act developments. The blog provides insights and updates on False Claims Act litigation impacting a variety of industries — including healthcare, government contracts and financial services — and on developing rules, laws, guidance and DOJ settlements that *influence* the fraud and abuse landscapes.

GOVERNMENT INVESTIGATIONS AND WHITE COLLAR LITIGATION GROUP  
**SUBJECT to INQUIRY**  
THE LATEST ON GOVERNMENT INQUIRIES AND ENFORCEMENT ACTIONS

***Subject to Inquiry*** is a blog published by the Government Investigations and White Collar Litigation Department of McGuireWoods since 2010. The blog explores topics, trends and cases related to government enforcement investigations and actions.

**THE HEALTHCARE INVESTOR**  
Insights on Issues & Trends that Impact Investments in Healthcare & Life Science Businesses

***The Healthcare Investor*** is our Healthcare blog providing insights on issues and trends that impact investments in Healthcare and Life Science businesses.

## ABOUT OUR GOVERNMENT INVESTIGATIONS & WHITE COLLAR LITIGATION DEPARTMENT

The Government Investigations & White Collar Litigation Department at McGuireWoods is a nationally recognized team of more than 80 attorneys representing Fortune 100 and other companies and individuals in the full range of civil and criminal investigations and enforcement matters at both the federal and state level. Our senior team is comprised of a deep bench of former federal officials, including former U.S. Attorneys, more than a dozen federal prosecutors, and an Associate Counsel to the President of the United States. Strategically centered in Washington, our Government Investigations & White Collar Litigation is proud to be recognized as an elite practice, most recently honored by Chambers USA with a highly regarded nationwide ranking for Corporate Crime & Investigations, honored twice as White Collar Practice Group of the Year by Law360, and consistently ranked among the world's leading investigations firms on the Global Investigations Review 100 guide to top cross-border investigations practices. The Legal 500 United States, a premier list of the country's best law firms, also commended McGuireWoods for the "exceptional quality" of our powerhouse white collar litigation practice.

For more information about the breadth of the capabilities of the Government Investigations & White Collar Litigation Department, please contact department chair Jason H. Cowley at [jcowley@mcguirewoods.com](mailto:jcowley@mcguirewoods.com) or at +1 704 343 2030.

## ABOUT MCGUIREWOODS' HEALTHCARE DEPARTMENT

With more than 60 experienced, industry-focused lawyers, our national Healthcare Department is consistently ranked as one of the top U.S. healthcare practices. Our healthcare attorneys have the knowledge and experience that healthcare providers and insurers need to achieve compliance with federal and state-specific regulatory requirements. Our group advises clients on a full range of regulatory and policy issues enforced by the U.S. Government. Clients have recognized the value of our depth in regulatory, litigation and transactional matters, noting our "great commercial awareness" and have described us as "very skilled," "extremely knowledgeable, practical and accessible." Our healthcare group and individual lawyers from across the country are recognized by *Chambers USA*, *Best Lawyers in America*, *Legal Elite* and *Super Lawyers* as among the top legal providers in the nation.

## ABOUT MCGUIREWOODS

McGuireWoods has 1,100 lawyers in 21 offices across the United States and other countries. Over its 187-year history, we have earned the loyalty of our many longstanding clients with deep understanding of their businesses and broad skills in complex regulatory and compliance matters, high-stakes disputes, and transactional matters. For more than a decade, McGuireWoods has been ranked on BTI Consulting Group's "Client Service 30" list of law firms serving Fortune 1,000 companies — elite firms singled out for client service excellence based on unprompted feedback from corporate counsel. Its full-service public affairs arm, McGuireWoods Consulting LLC, offers infrastructure and economic development, strategic communications and grassroots advocacy, and government relations solutions. For more information, visit [www.mcguirewoods.com](http://www.mcguirewoods.com).

# McGuireWoods



**Nationwide highly regarded  
ranking for Corporate Crime &  
Investigations**



**Ranked among the world's top 100  
firms for five consecutive years for our  
“heavyweight team of white-collar  
investigators that bring decades of  
high-stakes work experience.”**



**Named “Best Law Firms” for Healthcare  
2020 & 2021**

**Best Lawyers**

**Nationwide ranking for corporate  
investigations and white collar  
criminal defense**



**Honored as a top firm for Healthcare  
Insights in Readers’ Choice Awards**



**Nationwide highly regarded  
ranking for corporate crime  
and investigations. Nationwide,  
State, and Individual rankings in  
Healthcare**



**Multiple government investigations  
partners named “Lawyers of the Year”**

**Best Lawyers**

**Named to the “Client Service  
A-Team”**



**Named a Practice Group of the Year**



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