

OUR PRACTICE

Health Care Enforcement Actions and Investigations

Government investigations in the health care industry are often extremely complex due to the intricate web of overlapping health care statutes, regulations, executive orders, and state licensing and practice of medicine laws, as well as a burgeoning body of False Claims Act (FCA) case law. The financial burden of a drawn-out investigation behind the "seal" of a *qui tam* action provides whistleblowers and the government with a blunt instrument that can threaten the survival of a company. Companies also face the threat of criminal investigation with potential exposure for individual officers and executives. Baker Donelson's Health Care Enforcement and Investigations Team, comprised of health care regulatory lawyers and former government attorneys, former federal and state prosecutors, lawyers with unique industry insights and knowledge, and experts in project management and electronic discovery, has the knowledge and experience to help clients navigate the layers of potential criminal, civil, and administrative risks.

Our team defends investigations for a wide variety of health care entities and individuals, including academic medical centers, ambulatory surgical centers, device manufacturers, hospices, hospitals, long term care providers, pharmacies, pharmaceutical companies, and physician practices and individual physicians and executives against alleged violations involving:

- **FCA violations** resulting from filing false claims with government health care programs, including upcoding and unbundling, services not rendered, lack of medical necessity, and inflated cost reporting;
- **Medicare, Medicaid, and TRICARE medical billing fraud**, including double billing, mischarging, unbundling, and upcoding;
- **Stark Law Violations, Anti-Kickback Statute (AKS), and Civil Monetary Penalties (CMP)** as a result of offering or receiving kickbacks and other financial inducements;
- **Off-label marketing of drugs and devices** in violation of the federal Food, Drug, and Cosmetic Act;
- **Negotiating and monitoring corporate integrity agreements or certification of compliance agreements** and assisting with related compliance and reporting activities;
- **Congressional Inquiries relating to Health Care**, including written responses and live testimony; and
- **Federal and State Surveys**: administrative investigation that can often lead to serious adverse administrative actions as well as follow-on criminal and civil investigations

Our Health Care Government Investigations Team focuses on handling such complex cases. Clients benefit from the seamless combination of our nationally-recognized health care regulatory attorneys, who bring extensive prior government and industry experience from their years of service in the Department of Health & Human Services (HHS), and the litigation and trial advocacy experience of the former prosecutors, judges and agents, and white-collar defense attorneys in our Government Enforcement and Investigations Group. Team

members have decades of experience helping health care providers navigate the nuances and requirements of the Department of Justice (DOJ) and its agencies and contractors.

In addition, Baker Donelson attorneys work closely with our health care clients and their counsel to identify and assess the areas of potential risk of future disputes or enforcement actions, and often assist with developing and implementing proactive, sustainable risk mitigation solutions.

Baker Donelson understands that positive outcomes in health care investigations are not only dependent on the skills and experience of its attorneys, but on the services that help facilitate effective responses, including eDiscovery, ESI management tools, and full-service project management. Our streamlined approach to eDiscovery and document production creates a smooth interface with government agencies, and our proven project management processes offer our clients more predictability in terms of time and expense.

Health Care Fraud Prevention Training and Planning

The U.S. government dedicated trillions of dollars to containing and treating the coronavirus (COVID-19) and stimulating the national economy. It also waived many federal health program requirements to allow providers greater flexibility to address the pandemic. Now that the dust has settled, however, the use of those dollars and actions taken under loosened restrictions have come under increased scrutiny.

While the absence of on-the-ground oversight and investigation may have delayed the identification and remediation of potential corruption, bribery, and fraud, we are now seeing a significant increase in FCA claims and other alleged violations of federal and state rules and regulations. Baker Donelson's attorneys are able to advise clients on proactive steps they should take now to strengthen their compliance infrastructure and improve compliance hygiene to avoid missteps.

Our team designs and implements compliance plans and guides clients on all aspects of compliance with federal and state fraud and abuse statutes. We provide comprehensive compliance analysis and training, including risk areas where health care law overlaps with privacy and security, labor and employment, insurance, and regulatory requirements. Our lawyers advise on reimbursements under government contracts, plan responses on whistleblower issues, and defend against debarment and exclusion from federal programs.

Case Studies

Results may vary depending on your particular facts and legal circumstances.

- [False Claims Act Allegations Against National Hospice Chain Dismissed](#) - False Claims Act
- [Baker Donelson Obtains Motion for Summary Judgment for Hospital Client](#) - Health Care False Claims Act

Representative Matters

Results may vary depending on your particular facts and legal circumstances.

- Obtained dismissal of relator's complaint asserting various claims under the False Claims Act, Anti-Kickback Statute, Stark Law, and Louisiana Medical Assistance Programs Integrity Law on behalf of several related health care provider entities relating to wound care services.
- Represented a nationwide DME appeals contractor in an action alleging false claims in connection with determination of second-level appeals. The Firm took the lead in drafting and arguing a motion to dismiss based on the FCA prior public disclosure bar, arising out of Medicare appeals by the relator. Following a favorable ruling in the Eastern District of Pennsylvania, relator appealed to the U.S. Court of Appeals for the Third Circuit. The Court of Appeals upheld the dismissal, finding that the relator's participation in the underlying Medicare administrative appeals constituted a prior public disclosure of the alleged failure to properly adjudicate appeals.

- Represented a national chain of long term care facilities in responding to requests for information from Congress relating to COVID-19 preparation and response.
- Represented a large medical device manufacturer in an FCA *qui tam* case brought by a former employee in NDGA under a false certification theory, resulting in declination by the United States and dismissal of civil damages case.
- Represented a medical device manufacturer in an FCA *qui tam* case brought in NDGA under a false certification theory, resulting in declination by the United States and settlement for a nominal amount approved by the court.
- Represented a pharmacist in relation to a state attorney general criminal RICO prosecution involving alleged elderly abuse and other allegations under the state law counterpart to the FCA, which resulted in a plea to a lesser offense and a probation-only sentence.
- Defended the largest physician-owned (1,300+) Medicare Advantage HMO in the country in parallel criminal and civil investigations alleging failure to provide member care. After a multi-year investigation by the U.S. Attorney's Office for the Eastern District of Louisiana, the parallel criminal and civil cases were declined without action.
- Represented providers in responding to investigations that are part of national Office of Inspector General (OIG) initiatives.
- Represented suppliers and providers in implementing compliance programs, responding to civil investigative demands and negotiating CIAs.
- Represented clients in OIG enforcement efforts, including under Operation Restore Trust and Operation Lab Scam. Oversaw self-disclosures, negotiated settlements and CIAs and supervised annual reporting under the CIAs.
- Obtained favorable OIG Advisory Opinions for privately-financed ventures.
- Helped conduct and respond to interview and document requests during an investigation of pharmacies by the U.S. Attorney's Office in the Southern District of Florida, no charges resulting.
- Successfully represented a physician in a government investigation involving federal anti-kickback and false claims law.
- Represented a hospital in a psychiatric and outpatient partial hospitalization program civil and criminal investigation.
- Represented a health maintenance organization in *qui tam* and governmental investigations alleging a pharmaceutical company switch program.
- Represented a hospital in a civil and criminal false claim investigation regarding cardiac interventional procedures.