What the Health Care and Life Sciences Industry Should Know About the DOJ's False Claims Act Working Group

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With any new presidential administration, businesses across industries must assess how shifts in regulation and enforcement priorities impact the way their organization operates. While fiscal year 2024 saw settlements and judgments under the False Claims Act (FCA) exceed $2.9 billion—the highest number of qui tam actions filed in history—the second Trump administration is looking to double down on fighting fraud through the FCA.

In July 2025, the Department of Justice (DOJ), alongside the U.S. Department of Health and Human Services (HHS), announced[1] the formation of a working group to leverage the FCA to better combat health care fraud. The DOJ listed six priority areas targeted for FCA enforcement, all intensely focusing on the health care and life sciences sectors, including:

- Medicare Advantage
- Drug, device or biologics pricing, including arrangements for discounts, rebates, service fees and formulary placement and price reporting
- Barriers to patient access to care, including violations of network adequacy requirements
- Kickbacks related to drugs, medical devices, durable medical equipment and other products paid for by federal healthcare programs
- Materially defective medical devices that impact patient safety
- Manipulation of Electronic Health Records systems to drive inappropriate utilization of Medicare covered products and services.

During Buchanan's Life Sciences + Healthcare Summit this October, we shared key insights on how this new working group, and other new regulatory priorities, would affect organizations in the sectors.

Higher likelihood for civil and criminal penalties

While the FCA has traditionally been used mostly to secure civil penalties from violators, recent trends show that the DOJ is increasingly seeking criminal penalties for defendants as well. Typically, these criminal charges are pursued in matters involving allegations of bribery and/or kickbacks.

Further complicating matters is the fact that the DOJ can begin an FCA investigation as a civil case, take testimony, and later use those statements as evidence in a criminal case. As with any investigation, having experienced legal representation in these matters is essential.

Leveraging FCA to crack down on cybersecurity customs violations

The DOJ has, in recent years, expanded the use of the FCA beyond traditional healthcare fraud. That includes increasing enforcement on companies with government contracts who fail to comply with their contractual cybersecurity regulations. These DOJ lawsuits have ramped up in the past 18 months and are expected to continue under this administration.

Additionally, the DOJ is leveraging the FCA to target companies seeking to dodge customs or duties for imported goods. With most durable medical equipment and medical consumables being manufactured overseas, those in the health care and life sciences sectors must ensure their practices are in full compliance with all customs requirements to avoid potential penalties under the FCA.

The Need for Experienced Legal Counsel

With a White House seeking to affect how the DOJ operates more than previous administrations and significant turnover happening at all levels of the DOJ, government enforcement is as unpredictable as ever. At Buchanan, our experienced attorneys can assess your risk potential, address compliance issues, and support you through any investigation or litigation you may face.

[1]https://www.justice.gov/opa/pr/doj-hhs-false-claims-act-working-group

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