

# As Health Care Enforcement Surges, Buckle Up for a Bumpy Ride

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As the saying goes, the more things change, the more they stay the same – and the world of health care fraud enforcement is no exception. Recent years have seen a wave of novel technologies, emerging threats to our nation’s health, and a regulatory and statutory regime struggling to keep up. Yet at least one constant has been in the periphery of the health care industry without fail: the U.S. Department of Justice (DOJ). And, while recent actions by DOJ may lead some to believe there will be less health care fraud enforcement under the Trump Administration, that could not be further from the truth. If anything, health care fraud enforcement is likely to be invigorated while, at the same time, companies will have to navigate a much more uncertain regulatory landscape.

DOJ (and its local equivalents) have hunted for wrongdoing in the health care industry for as long as the government has had a hand in paying for it. And unlike some other DOJ components, those tasked with rooting out health care fraud typically enjoy bipartisan support for those efforts. For example, President Obama’s signature Affordable Care Act strengthened enforcement with its provision creating per se False Claims Act liability for any violation of the Anti-Kickback Statute; on the other side of the aisle, Senator Charles Grassley (R-IA) has been a vocal advocate for whistleblower incentives since the 1980s and continues to advance that cause today. Both of those endeavors measurably advanced health care fraud enforcement, with generally favorable responses from the electorate of both parties.

The appeal of health care fraud enforcement is no mystery; in the last 10 years, the DOJ Criminal Health Care Fraud Unit has charged over \$30 billion worth of fraud, while the Civil Division’s health care fraud

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group has actually *recovered* over \$20 billion in that same period. In other words, these prosecutions look great on a balance sheet.

The Trump Administration has made its mark by defying traditional expectations in many respects – but when it comes to health care fraud, the Trump DOJ appears likely to continue the trend of vigorous enforcement. In fact, the units charged with investigating and prosecuting these cases have *increased* in headcount and investigative capacity. Trial attorneys from areas of reduced DOJ enforcement (Foreign Corrupt Practices Act, for example) have seen much of their census reallocated to criminal health care fraud investigations in recent months. With the recent disbanding of the National Cryptocurrency Enforcement Team, additional DOJ trial attorneys may be swelling those ranks even more. This should serve as a signal to everyone in the health care industry that increased scrutiny is likely on its way. Indeed, with so many more experienced trial attorneys shifting their focus to health care fraud, prospective defendants that might have flown under DOJ's radar last year could find themselves under its microscope this year.

Of course, there are other factors that health care industry players must navigate, such as impacts from the leadership shake-up at the U.S. Department of Health and Human Services (HHS), which has had an Acting Inspector General since Christi Grimm was removed from that position in January (along with a group of Inspectors General from various other agencies). HHS-OIG is a primary enforcement partner of DOJ when it comes to health care fraud, along with FBI, so uncertainty at the agency level may cause cases to drag out.

The landscape of health care is also rapidly shifting, as issues such as vaccination, research, and drug pricing are brought to the forefront of the public discourse. Artificial intelligence (AI), moving at light speed into the world of health care provision, was previously the subject of scrutiny by the Biden Administration. But the Trump Administration on January 20 revoked Biden's Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence – and the next day, President Trump announced "Project Stargate," a \$500 billion private-sector initiative promoting AI technology. Health care providers have been left uncertain whether they can rely on the security, impartiality, or accuracy of new technologies.

The present uncertainty extends beyond technology, leaving those in the industry to speculate as to when and where the enforcement hammer may swing next. As one example, in the area of reproductive health, it is conceivable that emboldened states may seek to impose restrictive policy goals through the existing fraud enforcement mechanisms if their more direct efforts are stymied by courts or voters. Likewise, drug pricing, rebate programs, and pharmacy benefit manager arrangements may find their way into more criminal or civil complaints soon, as the hunt for fraud, waste, and abuse turns its eye towards pharmaceuticals. And, on an even more basic level, the health care sector must navigate the shifting policy landscape around diversity and inclusion in a way that serves patients and protects employees.

Keeping up with these evolutions is critical for compliance officers and in-house counsel. Given the heightened wave of enforcement forecast here, it may be prudent to conduct holistic reviews of your organization's policies, practices, and audit functions. Health care fraud risks from reliance on AI are an emerging area well worth taking the time to assess by ensuring that your organization is securing data, seeding the models with accurate information, and educating employees on the appropriate usage of the technology. Internal

whistleblower programs are another area that organizations will be well-served by revisiting and revamping to ensure your employees are heard and action is taken. With more government attorneys ready to run with new tips and an appetite for enforcement, it wouldn't take much for a squeaky wheel on the inside to become a thorn in your organization's outside.

Wiley's Health Care and White Collar Defense practices are adept in helping clients implement the steps recommended here, tailored to the specific needs of each organization. Working in collaboration with the firm's seasoned employment, life sciences, and intellectual property attorneys, we are available to consult and assist on any issues in this time of increased enforcement. After all, while the landscape may be changing every day, the importance of ensuring compliance across the board is the same as it ever has been.