

# DOJ enforcement outlook in health care compliance for 2025

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Some predicted a drop in False Claims Act ("FCA") enforcement during the first Trump administration, but setting aside a likely pandemic-related slowdown during 2020–2022, FCA cases — both DOJ-initiated and qui tam — during the early part of the first Trump administration were consistent with the volume in the later part of the Biden administration. See FCA Statistics (<https://bit.ly/3XseNXM>).

All signs point to continued robust FCA enforcement, particularly in light of Attorney General Pam Bondi's commitment during her confirmation hearing to support vigorous enforcement of the FCA, including through whistleblowers. The healthcare and life sciences industry, which has long dominated FCA enforcement activity, will remain a focus as DOJ looks to continue to prioritize traditional areas of enforcement, such as alleged violations of the Anti-Kickback Statute ("AKS"), as well as more recent areas of interest, including private equity investment in healthcare and the use of artificial intelligence.

In 2025, industry can also expect DOJ and the whistleblowers' bar to explore new theories of liability building from the new administration's focus on eliminating Diversity, Equity, and Inclusion ("DEI") programs.

## New administration initiatives

The new administration has championed a pro-business approach and ordered all agencies to "de-prioritize actions to enforce regulations that ... impose undue burdens on small business and impede private enterprise and entrepreneurship." See Executive Order No. 14219 (<https://bit.ly/41npFrF>). Indeed, Attorney General Bondi issued an internal memo on Feb. 5, 2025, calling for the Criminal Division's Foreign Corrupt Practices Act ("FCPA") Unit to prioritize investigations related to foreign bribery that facilitate cartels and transnational criminal organizations, and to de-emphasize other types of FCPA cases.

However, all signs suggest that corporate enforcement activity through the FCA will remain active, particularly where leveraging the FCA will help achieve the new administration's goals. During her confirmation hearing, now-Attorney General Bondi stated she would "defend the constitutionality, of course, of the False Claims Act" and noted the importance of both the FCA and "the money it brings back" to the treasury.

These statements were made in response to questions posed by Senator Chuck Grassley, a long-time proponent of the FCA, who sought assurances that Bondi, if confirmed, would not undermine FCA enforcement. The exchange also comes in the wake of a recent district court decision, *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, dismissing a qui tam suit on constitutional grounds under the Appointments Clause. While some speculated that a Trump Administration DOJ might support this reading, Bondi did not suggest any sympathy to the *Zafirov* position in her confirmation hearing.

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In a Feb. 20, 2025, speech, Deputy Assistant Attorney General Michael Granston, a career lawyer who supervises the division of DOJ that enforces the FCA, proclaimed DOJ would "aggressively" enforce the FCA "consistent with the new administration's stated focus on achieving governmental efficiency and rooting out waste, fraud and abuse." (See DOJ Official Flags 'Aggressive' FCA Approach Under Trump," Law360, Feb. 20, 2025) Granston also warned "it would be a mistake to view the False Claims Act as just a healthcare fraud statute" and cited "illegal foreign trade practices" as one potential target under the FCA.

One way the Trump administration may use the FCA to advance its objectives is to target federal contractor DEI programs. On Jan. 21, 2025, President Trump issued an executive order titled "Ending Illegal Discrimination and Restoring Merit-Based Opportunity," (<https://bit.ly/4gnerlB>) ending affirmative action programs in federal government programs and giving federal agencies and contractors 90 days to come into compliance.

Among other elements, this executive order requires federal agencies to incorporate into all federal contracts or grant agreements a clause requiring the contractor or grantee to acknowledge that compliance with federal anti-discrimination laws is “material” for purposes of the FCA. The cross-reference in this executive order to an element of FCA liability suggests DOJ is gearing up to file new FCA cases against federal funding recipients that engage in DEI programs the administration concludes are unlawful, and inviting whistleblowers to pursue such cases as well.

## Continued FCA priority enforcement areas

### The Anti-Kickback Statute

The AKS remains one of DOJ’s most common drivers of FCA enforcement and recoveries. Unlike the FCPA, the AKS focuses on domestic business relationships in the healthcare industry, and changes in FCPA enforcement should not be taken as a signal that enforcement of domestic kickback concerns through the AKS will diminish.

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In particular, DOJ has recently used financial arrangements that cannot satisfy an AKS safe harbor as a vehicle for attacking arrangements it views more broadly as problematic because they are designed to drive referrals, particularly where the referrals relate to use of Durable Medical Equipment (“DME”), laboratory testing, or other items or services that are alleged to be medically unnecessary.

For example, compliance with an AKS safe harbor may not be achieved where an independent contractor arrangement is commission-based (i.e., such an agreement could be interpreted as varying with the volume or value of referrals), and over the past few years DOJ and whistleblowers have begun to more aggressively pursue such arrangements in the clinical laboratory context as AKS violations, alongside allegations that federal healthcare programs were billed for medically unnecessary tests.

In the past year, DOJ entered into an AKS settlement (<https://bit.ly/41GUpVj>) with a genetic testing provider on a theory that the provider paid commissions to independent contractors so they recommended the provider’s genetic tests to prescribers. Against the backdrop of rising criticism of pharmacy benefit managers (“PBMs”), including by President Trump (<https://bit.ly/3XsjX66>), DOJ may explore AKS-based theories of liability to target practices it views as unreasonably raising drug prices.

Some defendants may argue that certain arrangements implicating the AKS’s broad prohibitions should not be pursued where they represent common business practices and do not pose harm to federal healthcare programs, including beneficiaries. Such arguments could potentially appeal to those in the administration who hope to use the FCA as a scalpel against harmful fraud, rather

than a bludgeon that may discourage the private sector from engaging in industry-standard business activities.

### Private equity

As private equity investment in the healthcare industry increased, so too did DOJ scrutiny. In the past five years, DOJ has announced multiple FCA settlements with private equity firms, deeming them responsible for allegedly causing the submission of false claims by their portfolio companies.

Though DOJ has not clearly articulated the metes and bounds of its theory of liability, the history of prior settlement agreements suggests DOJ is at least focused on private equity firms that were aware of the alleged misconduct, had a management services agreement or other active role in management that would have given the private equity firm an opportunity to remedy the known misconduct, and who failed to do so.

It remains to be seen if the Trump administration DOJ will be as critical of private equity healthcare investment as that of the Biden administration. Even if there is a de-escalation, state FCA enforcement may pick up the torch. Recently, Massachusetts amended its state FCA to require investors in Massachusetts health care companies to disclose any investment entity’s FCA violations “within 60 days of identifying the violation.” The law does not define what it means for an investor to “identify” a violation, and similar language in the Affordable Care Act imposing reverse false claims liability under the federal FCA has spawned significant litigation.

### Use of artificial intelligence (“AI”) in federal healthcare programs

As AI has grown more prevalent across all aspects of the healthcare industry, questions and concerns have been raised about the misuse of AI, including through the use of algorithms to inappropriately deny claims. Although the focus of President Trump’s Jan. 23, 2025, AI executive order (<https://bit.ly/3EkX7Xo>) is primarily on removing barriers that inhibit AI growth — some had criticized (<https://politi.co/4bvaQas>) these Biden administration rules as “barriers to innovation disguised as safety measures” — DOJ and whistleblowers can be expected to monitor at least for traditional concerns that AI is resulting in over-billing.

For example, DOJ recently negotiated a \$23 million settlement (<https://bit.ly/41swOS9>) with an academic medical center to resolve claims that it violated the FCA when an automated coding system improperly assigned CPT codes to emergency department claims, resulting in federal healthcare programs overpaying for services. The Centers for Medicare and Medicaid Services have issued regulations over the past two years addressing use of AI by health insurers, including Medicare Advantage plans, which may create new avenues for FCA liability.

### Conclusion

The second Trump administration has already announced a slew of new policy changes across healthcare and non-healthcare industries and publicly expressed not only support for FCA enforcement and whistleblowers but also an interest in using the

FCA as a tool to advance administration objectives, including in areas that have not traditionally experienced significant FCA risk. Recipients of federal funding, particularly in areas top of mind for the new administration, should consider the potential for new FCA risk.

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### About the authors



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