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July 9, 2025

# DOJ and HHS Reestablish False Claims Act Working Group

On July 2, 2025, the U.S. Department of Justice (“DOJ”) and the U.S. Department of Health and Human Services (“HHS”) [announced](#) the renewal of the DOJ-HHS False Claims Act Working Group (the “Working Group”). The Working Group is aimed at strengthening ongoing collaboration between DOJ’s Civil Division and HHS to investigate health care fraud and enforce the False Claims Act (“FCA”), with a focus on priority areas such as Medicare Advantage, drug pricing, kickbacks, and electronic health record manipulation.<sup>1</sup> This Working Group reestablishes a prior DOJ-HHS False Claims Act Working Group formed in December 2020 during the first Trump Administration. That group’s priorities focused on combatting health care fraud arising from the COVID-19 pandemic. The Working Group is also likely to focus on other priorities recently set out by the Civil Division, such as combatting discriminatory practices and policies, ending antisemitism, and protecting women and children.

## Working Group Structure and Leadership

Signaling a more collaborative approach to FCA investigations and enforcement, the Working Group will be jointly led by HHS’s General Counsel (Sean Keveney, acting General Counsel), the Chief Counsel to HHS-OIG (Susan Edwards, acting Chief Counsel), and the Deputy Assistant Attorney General of the Commercial Litigation Branch (DAAG Brenna Jenny).

The divisions of DOJ and HHS represented in the Working Group include:

- HHS-OIG (Office of Inspector General);
- HHS-OGC (Office of General Counsel);
- Centers for Medicare & Medicaid Services Center for Program Integrity;
- DOJ Civil Division; and
- Various U.S. Attorney’s Offices.<sup>2</sup>

To promote dialogue, the Working Group will begin meeting monthly starting in July.

## Working Group Key Enforcement Priorities

The Working Group’s stated priority enforcement areas are:

- Medicare Advantage;

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<sup>1</sup> Press Release, *DOJ-HHS False Claims Act Working Group*, U.S. Dep’t of Just. (July 2, 2025), available [here](#); see also American Health Law Association, *Breaking News from HHS and DOJ at AHLA’s Annual Meeting*, YouTube (July 2, 2025), available [here](#).

<sup>2</sup> *Id.*

- Drug, device and biologics pricing, including arrangements involving discounts, rebates, services fees, formulary placement and price reporting;
- Barriers to patient access, including violations of network adequacy requirements;
- Kickbacks;
- Materially defective medical devices; and
- Manipulation of electronic health records to drive inappropriate Medicare utilization.<sup>3</sup>

While the Working Group's priority enforcement areas include traditional FCA targets, such as fraud and kickbacks, they also cover new and evolving areas under the FCA. For instance, DOJ has not traditionally used the FCA as a vehicle to address "barriers to patient access," and it remains to be seen how DOJ will pursue FCA enforcement in this area. However, notably, on May 1, 2025, DOJ filed an FCA complaint against three of the largest U.S. health insurance companies alleging unlawful kickbacks and discrimination against disabled individuals.<sup>4</sup> This lawsuit may provide some insight into how aggressively DOJ will use the FCA as an enforcement tool in these novel areas, as well as the potential targets of such enforcement actions. Similarly, the inclusion of drug pricing likely reflects that states and the federal government are increasingly focused on prescription drug benefit managers' rebating practices.<sup>5</sup>

The press release announcing the Working Group makes clear that the above priority enforcement areas are in addition to the FCA priorities previously announced in a June 11, 2025 memorandum from Assistant Attorney General Brett Shumate to DOJ Civil Division employees (the "Civil Division Memorandum"). Specifically, the Civil Division Memorandum directed DOJ attorneys to prioritize investigations and enforcement actions addressing five areas of concern: (1) combatting discriminatory practices and policies; (2) ending antisemitism; (3) protecting women and children; (4) ending sanctuary jurisdictions; and (5) prioritizing denaturalization.<sup>6</sup> In its discussion of items (1) and (2), the memorandum referred to the Civil Division's authority to bring suit under the FCA to "aggressively investigate and, as appropriate, pursue False Claims Act violations against recipients of federal funds that knowingly violate civil rights laws."<sup>7</sup>

Similarly, in discussing item (3), the Civil Division Memorandum referred to Attorney General Bondi's directive "to pursue investigations under the False Claims Act of false claims submitted to federal health care programs for any non-covered services related to radical gender experimentation."<sup>8</sup> In line with that directive, the Civil Division Memorandum affirmed that the Civil Division would "aggressively pursue claims under the False Claims Act against health care providers that bill the federal government for impermissible services," specifically including "providers that attempt to evade state bans on gender dysphoria treatments by knowingly submitting claims to Medicaid with false diagnosis codes."<sup>9</sup> The Civil Division Memorandum stated that in pursuing these enforcement goals, "[t]he Civil Division will work with the Civil Rights Division, relators, other whistleblowers, and federal agencies to advance these efforts."<sup>10</sup>

Explicit reference to the Civil Division Memorandum in the press release announcing the Working Group, as well as the timing of the Working Group announcement—which comes only weeks after the June 11 Civil Division Memorandum—signals that the Working Group may be involved in investigating and carrying out some of the Civil Division's enforcement priorities. By doing so, the Working Group would be assisting with FCA investigations and enforcement in new areas not previously associated with fraud enforcement (e.g., DEI initiatives, antisemitism and transgender issues).

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<sup>3</sup> *Id.*

<sup>4</sup> Press Release, *The United States Files False Claims Act Complaint Against Three National Health Insurance Companies and Three Brokers Alleging Unlawful Kickbacks and Discrimination Against Disabled Americans*, U.S. Dep't of Just. (May 1, 2025), available [here](#).

<sup>5</sup> For example, the Federal Trade Commission initiated a lawsuit against prescription drug benefit managers in *In the Matter of Caremark Rx, LLC, et al.*, available [here](#).

<sup>6</sup> Memorandum from Assistant Att'y Gen. Brett A. Shumate, *Civil Division Enforcement Priorities*, U.S. Dep't of Just. (June 11, 2025), available [here](#).

<sup>7</sup> *Id.* at 1.

<sup>8</sup> *Id.* at 2.

<sup>9</sup> *Id.* at 3.

<sup>10</sup> *Id.* at 1.

## Working Group Collaboration and Use of Data Mining

As part of its collaboration, the Working Group press release states that it will expedite ongoing investigations in priority enforcement areas and “identify new leads” by “leveraging HHS resources through enhanced data mining and assessment of HHS and HHS-OIG report findings.”<sup>11</sup> By utilizing such resources, the Working Group intends to initiate FCA actions backed by data, rather than relying primarily on whistleblowers. Nevertheless, the press release announcing the Working Group still encouraged “whistleblowers to identify and report violations of the federal False Claims Act involving priority enforcement areas.”<sup>12</sup>

The Working Group will also discuss when to “implement a payment suspension pursuant to 42 C.F.R. § 405.370 *et seq.* or whether DOJ shall move to dismiss a *qui tam* complaint under 31 U.S.C. § 3730(c)(2)(A), consistent with Justice Manual Section 4-4.111.”<sup>13</sup> The latter point—assessing potential dismissals of *qui tam* suits—appears to be a response to a February 7, 2025 letter from Senator Chuck Grassley to Attorney General Bondi.<sup>14</sup>

In that letter, Senator Grassley asked Attorney General Bondi to pause potential DOJ dismissals of *qui tam* actions. The Supreme Court’s June 16, 2023 decision in *United States Ex Rel. Polansky v. Executive Health Resources, Inc., et al.* held that DOJ may dismiss a *qui tam* case at any point, so long as DOJ first intervenes.<sup>15</sup> Doing so, however, could undermine the *qui tam* system, which Senator Grassley noted had recovered \$2.4 billion in 2024.<sup>16</sup> Though the Biden Administration had not been providing any data to Senator Grassley regarding which cases it moved to dismiss under *Polansky*, the Working Group’s mention of this issue may signify that an increase in dismissals of *qui tam* complaints over relators’ objections is coming; however, it is still too early to say. Under the first Trump administration, DOJ issued guidance encouraging the dismissal of *qui tam* suits upon consideration of factors including: (1) curbing meritless *qui tam* actions; (2) preventing parasitic or opportunistic *qui tam* actions; (3) preventing interference with agency policies and programs; (4) controlling litigation brought on behalf of the United States; (5) safeguarding classified information and national security interests; (6) preserving government resources; and (7) addressing “[e]gregious” procedural errors.<sup>17</sup> Even in the face of a possible increase in *qui tam* dismissals, companies should remain prepared for activity from the sophisticated *qui tam* bar, which may be emboldened to take advantage of a more encouraging DOJ to pursue lucrative actions and settlements.

## Enforcement Focus on Healthcare

The Working Group’s focus on health care is consistent with recent enforcement trends.

In 2024, DOJ collected a total of \$2.9 billion from 558 FCA settlements and judgments, \$1.67 billion of which related to matters involving the health care industry.<sup>18</sup> The \$1.67 billion only reflects recoveries arising from federal losses, but, in many of these cases, DOJ was instrumental in recovering additional amounts for state Medicaid programs.<sup>19</sup>

Guidance from the DOJ Criminal Division underscores the current Administration’s continued focus on FCA healthcare enforcement. On May 12, 2025, the Head of the Criminal Division issued a memorandum outlining the Criminal Division’s enforcement priorities and reaffirming the Criminal Division’s commitment to combatting health care fraud (the “Criminal Division Memorandum”).<sup>20</sup> Specifically, the Criminal Division Memorandum identified areas of focus that the Criminal Division will prioritize, including three FCA enforcement areas: (1) “[w]aste, fraud, and abuse, including health care fraud and federal

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<sup>11</sup> DOJ-HHS False Claims Act Working Group, *supra* note 1.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> Letter from Sen. Chuck Grassley to Att’y Gen. Pam Bondi (Feb. 7, 2025), available [here](#).

<sup>15</sup> 599 U.S. 419, 424 (2023).

<sup>16</sup> Letter from Sen. Chuck Grassley to Att’y Gen. Pam Bondi, *supra* note 14. Relatedly, in a decision on June 25, 2025, the Ninth Circuit issued a decision confirming that *qui tam* actions under the FCA are available for private parties to enforce payment of customs duties, suggesting a possible upcoming increase in *qui tam* lawsuits against importers who evade tariffs. See *Island Indus., Inc. v. Sigma Corp.*, No. 22-55063, 2025 WL 1730271 (9th Cir. June 23, 2025).

<sup>17</sup> Memorandum from Michael D. Granston, Director of the Commercial Litigation Branch, Fraud Section, *Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)*, U.S. Dep’t of Just. (Jan. 10, 2018), available [here](#).

<sup>18</sup> Press Release, *False Claims Act Settlements and Judgments Exceed \$2.9B in Fiscal Year 2024*, U.S. Dep’t of Just. (Jan. 15, 2025), available [here](#).

<sup>19</sup> *Id.*

<sup>20</sup> Memorandum from Head of the Crim. Div., *Focus, Fairness, and Efficiency in the Fight Against White-Collar Crime*, U.S. Dep’t of Just. (May 12, 2025), available [here](#).

program and procurement fraud that harm the public fisc”; (2) “[t]rade and customs fraud, including tariff evasion”;<sup>21</sup> and (3) “[v]iolations of the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act (FDCA), including the unlawful manufacture and distribution of chemicals and equipment used to create counterfeit pills laced with fentanyl, and unlawful distribution of opioids.”<sup>22</sup> The Criminal Division Memorandum also notes that “[r]ampant health care fraud and program and procurement fraud drain our country’s limited resources.”<sup>23</sup>

Finally, on June 30, DOJ announced the results of its 2025 National Health Care Fraud Takedown (the “Takedown”), which is the largest DOJ health care fraud takedown in history with: (1) criminal charges against 324 defendants, including 96 doctors, nurse practitioners, pharmacists and other licensed medical professionals, in 50 federal districts and 12 State Attorney General’s Offices across the United States, for their alleged participation in various health care fraud schemes involving over a purported \$14.6 billion in intended losses; (2) civil charges against 20 defendants for \$14.2 million in alleged fraud; and (3) civil settlements with 106 defendants totaling \$34.3 million. The Takedown was a coordinated nationwide law enforcement operation, consisting of collaboration between the Criminal Division’s Health Care Fraud Unit, various U.S. Attorney’s Offices, State Attorneys General’s Offices, the Federal Bureau of Investigation, HHS-OIG, the Drug Enforcement Administration and Centers for Medicare & Medicaid Services.

### Pending Litigation Over the Constitutionality of *Qui Tam* Provisions of the FCA

Meanwhile, there is looming uncertainty surrounding recent FCA jurisprudence. In *United States ex rel. Zafirov v. Florida Medical Associates*, the Middle District of Florida ruled that 31 U.S.C. § 3730(b)(1), the provision of the False Claims Act permitting *qui tam* actions, violates the Appointments Clause of Article II of the Constitution by permitting *qui tam* relators to act as officers of the United States without presidential appointment.<sup>24</sup> The decision flows from a set of opinions questioning the validity of the *qui tam* provision authored by Justices Thomas, Kavanaugh and Barrett.<sup>25</sup> An appeal is currently pending in the Eleventh Circuit.<sup>26</sup>

### Looking Ahead: Practical Implications & Considerations

With the Working Group reestablished, companies operating in the health care space, especially those participating in federal health care programs such as Medicare or Medicaid, should remain vigilant. To minimize FCA liability, companies in the health care space and beyond should reevaluate and, where appropriate, enhance their compliance programs in light of DOJ’s current priorities and engage in ongoing monitoring of those programs. Proactive audits are a powerful strategy for evaluating such compliance programs and addressing any deficiencies before risks materialize.

Additionally, the announcement of the Working Group and DOJ’s recent memoranda discuss the important role that whistleblowers play in reporting misconduct.<sup>27</sup> Companies should consider creating, enhancing and promoting existing whistleblower reporting hotlines and fostering other avenues for potential whistleblowers to raise issues and concerns internally. Companies should also maintain and ensure compliance with protocols for handling whistleblower complaints. Best practices in addressing whistleblower complaints include protections against retaliation, meaningful engagement with whistleblowers and prompt investigation into complaints.

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<sup>21</sup> While tariff compliance is a newer area of government enforcement, in remarks at the Federal Bar Association’s annual *qui tam* conference in February 2025, former Deputy Assistant Attorney General Michael Granston stated that the FCA is a “powerful tool” to enforce tariffs. See Daniel Wilson, *DOJ Official Flags ‘Aggressive’ FCA Approach Under Trump*, Law360 (Feb. 20, 2025), available [here](#).

<sup>22</sup> *Id.* at 4.

<sup>23</sup> *Id.* at 2.

<sup>24</sup> *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, 751 F. Supp. 3d 1293 (M.D. Fla. 2024).

<sup>25</sup> See *id.* at 1324.

<sup>26</sup> Paul, Weiss represents defendant-appellees Florida Medical Associates, Physician Partners and Anion Technologies in the appeal.

<sup>27</sup> DOJ-HHS False Claims Act Working Group, *supra* note 1; Civil Division Memorandum, at 1; Criminal Division Memorandum, at 5.

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This memorandum is not intended to provide legal advice, and no legal or business decision should be based on its content. Questions concerning issues addressed in this memorandum should be directed to:

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