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Healthcare Alert

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DOJ-HHS False Claims Act Working Group re-established

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Individuals and entities participating in federal healthcare programs should anticipate increased collaboration among and oversight by federal agencies.

What's the impact?

- DOJ and HHS leadership are reviving and reworking the False Claims Act (FCA) Working Group, which recently announced its initial priority enforcement areas.
- Stakeholders should expect the FCA Working Group to rely upon the newly created Health Care Fraud Data Fusion Center to drive decision-making and future enforcement priorities.
- Re-establishment of the FCA Working Group may signal that the government intends to take a more active role in exploring and evaluating § 3730(c)(2)(A) dismissals.

On July 2, 2025, the U.S. Department of Health and Human Services (HHS) and U.S. Department of Justice (DOJ) jointly announced the establishment of the False Claims Act Working Group (FCA Working Group). HHS previously created an FCA Working Group at the end President Trump's

first term, but little information was publicized about the FCA Working Group's activities during the Biden administration.

Enforcement priorities

In announcing the FCA Working Group, HHS and DOJ expressed their commitment to strengthen their ongoing collaboration to advance priority enforcement areas. DOJ identified some of these general enforcement priorities in a June 11, 2025, internal DOJ memorandum from the Assistant Attorney General for DOJ's Civil Division. These included: (1) combatting discriminatory practices and policies; (2) ending antisemitism; (3) protecting women and children; (4) ending sanctuary jurisdictions; and (5) prioritizing denaturalization.

In addition to these general priorities, the FCA Working Group announced and described the following priority enforcement areas.

- ***The Medicare Advantage Program***, also known as Medicare Part C, in which Medicare beneficiaries enroll in private health insurance plans that offer Medicare benefits, which are paid on a per-person basis to provide Medicare-covered benefits to enrolled beneficiaries;
- ***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, which ensure that health insurance plans have enough qualified healthcare providers in their network to meet the needs of their members;
- ***Kickbacks*** related to drugs, medical devices, durable medical equipment (DME), and other products paid for by federal healthcare programs;
- ***Materially defective medical devices*** that affect patient safety; and
- ***Manipulation of Electronic Health Records systems*** to drive inappropriate use of Medicare-covered products and services.

DOJ highlighted several representative matters relating to some of these priority areas this past winter in the HHS-DOJ FY2023 Health Care Fraud and Abuse Control Program Annual Report, and in connection with its announcement that FCA settlements and judgments exceeded $2.9 billion in the fiscal year ended September 30, 2024.

FCA working group membership

The composition of the newly established FCA Working Group has changed slightly since Trump's first term. The previous group comprised former DOJ FCA and healthcare fraud prosecutors, former private counsel for healthcare and life sciences companies, and experienced HHS attorneys. The new FCA Working Group is more government-centric and will be jointly led by the HHS general counsel, chief counsel to the HHS Office of Inspector General (HHS-OIG),

and deputy assistant attorney general of the Commercial Litigation Branch. Membership will include leadership from the HHS Office of General Counsel, Centers for Medicare & Medicaid Services Center for Program Integrity, Office of Counsel to HHS-OIG, and DOJ's Civil Division. Designees will represent U.S. Attorneys' offices.

Use of data mining & analytics

The announcement provides that the FCA Working Group will maximize cross-agency collaboration and identify new leads through enhanced data mining and analytics, which have also been drivers of governmental investigations in recent years.

DOJ and HHS-OIG both have publicly acknowledged the increasing use of advanced data analytics and algorithmic methods to identify, monitor, and target potential fraud, waste, and abuse affecting HHS programs. Indeed, the government has relied upon analytics to identify newly emerging healthcare fraud schemes, aberrant billing levels, and suspicious billing patterns, which have led to some of the largest criminal and civil FCA cases and initiatives.

On June 30, 2025, in connection with its national healthcare fraud takedown in which 324 defendants were charged in connection with more than $14.5 billion in alleged healthcare fraud, DOJ highlighted the importance of cutting-edge data analytics to identify and support the investigations that led to the charges. DOJ further announced its collaboration with HHS-OIG and other federal agencies to create the Health Care Fraud Data Fusion Center to bring together experts from DOJ's Criminal Division, Fraud Section, Health Care Fraud Unit Data Analytics Team; HHS-OIG; the FBI; and other agencies to leverage cloud computing, artificial intelligence, and advanced analytics to increase efficiency, detection, and rapid prosecution of emerging healthcare fraud schemes.

While the Health Care Fraud Data Fusion Center is newly established, stakeholders should expect its findings to have an impact on future FCA Working Group enforcement priorities.

On July 14, 2025, xAI, the artificial intelligence company founded by Elon Musk, also announced Grok for Government, a new suite of tools which aims to provide federal, local, and state agencies with access to advanced AI technologies. In making the announcement, xAI highlighted that the initiative would make unique capabilities available to the government, including custom AI-powered applications to accelerate use cases in health care. Although it remains to be seen whether the Health Care Fraud Data Fusion Center or the FCA Working Group will leverage any xAI applications, xAI's announcement provides that every federal agency — including DOJ and HHS — may procure xAI's products.

Evaluations of credible allegations of fraud to suspend payments

The announcement further provides that the FCA Working Group will discuss considerations bearing on whether HHS should implement a payment suspension pursuant to 42 C.F.R. § 405.370, *et seq*. 42 CFR 405.371(a)(2) provides the regulatory authority for CMS and Medicare contractors to suspend Medicare payments to providers and suppliers in cases of suspected fraud if CMS or the Medicare contractor, after consulting with HHS-OIG and DOJ, determines that a credible allegation of fraud exists against the provider or supplier (unless there is good cause not to suspend payments).

42 CFR 405.370(a) further defines "credible allegation of fraud" as "an allegation from any source, including but not limited to the following: (1) fraud hotline tips verified by further evidence; (2) claims data mining; and (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability."

While the FCA Working Group did not set forth its specific process for assessing considerations about payment suspensions in its announcement or the frequency of group meetings, the announcement suggests that it will serve as at least one forum for evaluating whether a payment suspension is warranted, as provided in 42 CFR 405.371(a)(2).

31 U.S.C. § 3730(c)(2)(A) dismissals

In FCA actions brought by relators (i.e., whistleblowers), the government remains the real party in interest. Accordingly, the FCA provides, in 31 U.S.C. § 3730(c)(2)(A), that DOJ may move to dismiss a FCA qui tam action notwithstanding the objections of a relator if the DOJ notifies the relator of the filing of the motion, and the court provides the relator with an opportunity for a hearing on the motion.

Historically, DOJ rarely leveraged its authority under § 3730(c)(2)(A) to dismiss a qui tam action. However, in 2018, Michael D. Granston, then-director of DOJ's Civil Fraud Section (and leader of DOJ's Civil Division's Commercial Litigation Branch from 2019 to 2025), issued the Granston Memorandum, which set forth a non-exhaustive list of factors for evaluating dismissals pursuant to § 3730(c)(2)(A). These factors were later memorialized in Section 4-4.111 of the Justice Manual, which provides that DOJ attorneys should evaluate the following when determining whether to seek a § 3730(c)(2)(A) dismissal.

- Curbing meritless qui tams that facially lack merit (either because the relator's legal theory is inherently defective or the relator's factual allegations are frivolous);
- Preventing parasitic or opportunistic qui tam actions that duplicate a pre-existing government investigation and add no useful information to the investigation;

- Preventing interference with an agency's policies or the administration of its programs;
- Controlling litigation brought on behalf of the United States, to protect the department's litigation prerogatives;
- Safeguarding classified information and national security interests;
- Preserving government resources, particularly where the government's costs (including the opportunity costs of expending resources on other matters) are likely to exceed any expected gain; and
- Addressing egregious procedural errors that could frustrate the government's efforts to conduct a proper investigation.

Recently, in *U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419 (2023), the U.S. Supreme Court held that the government may move to dismiss an FCA action under § 3730(c)(2)(A) whenever it intervenes, regardless of whether such intervention occurred during or subsequent to the period in which the qui tam action was sealed. The US Supreme Court further held that district courts should apply standard procedural rules governing voluntary dismissal of civil suits when evaluating a motion to dismiss pursuant to § 3730(c)(2)(A). In so holding, the Supreme Court stated that a § 3730(c)(2)(A) motion will satisfy such procedural rules "in all but the most exceptional cases." Accordingly, DOJ's § 3730(c)(2)(A) authority remains a powerful way for the government to halt qui tam actions that it deems deserving of dismissal.

While it remains to be seen whether DOJ will leverage its authority to dismiss FCA qui tam actions more frequently (a record 979 qui tam lawsuits were filed in fiscal year 2024), the specific reference to DOJ's § 3730(c)(2)(A) dismissal authority in the announcement of the FCA Working Group suggests that the government may take a more active role in exploring and evaluating dismissals, and that the FCA Working Group will be instrumental in those decisions.

Prioritize compliance to mitigate FCA exposure

The increasing reliance on the FCA (by both the government and relators) to pursue relief against federal healthcare program participants requires stakeholders to closely monitor enforcement activity and be proactive with respect to compliance. On November 6, 2023, HHS-OIG released its updated General Compliance Program Guidance, a reference guide for the healthcare compliance community to use to develop and evaluate compliance programs. Further, HHS-OIG is developing updated supplemental compliance program guidance documents targeting specific industry segments (ICPGs). HHS-OIG published the first updated ICPG targeting nursing facilities on November 20, 2024, and ICPGs targeting Medicare Advantage (a priority enforcement area), hospitals, and clinical laboratories are scheduled for publication in 2025.

All individuals and entities participating in federal healthcare programs should actively monitor the release of relevant guidance documents and continue to prioritize compliance (through

internal and external audits, repayments, and self-disclosures) to minimize potential FCA exposure.

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