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DOJ'S DATA-DRIVEN FCA ENFORCEMENT INITIATIVE RAISES STAKES FOR HEALTH CARE PROVIDERS

Health care enforcement is entering a data-driven era in which artificial intelligence ("AI") and large-scale analytics increasingly shape how fraud is identified and pursued, as reflected in the U.S. Department of Justice's ("DOJ") launch of the Fraud Oversight through Careful Use of Statistics ("FOCUS") initiative.

OVERVIEW OF THE FOCUS INITIATIVE

On April 7, 2026, DOJ launched the FOCUS initiative, a first-of-its-kind program formalizing the Civil Division's engagement with data miners who file *qui tam* complaints under the False Claims Act ("FCA"). The initiative coincides with DOJ's creation of the National Fraud Enforcement Division ("NFED") and signals a broader commitment to data-driven fraud enforcement across federal programs.

FOCUS responds to a sharp increase in *qui tam* filings driven by data miners rather than traditional whistleblowers. The Civil Division received 980 *qui tam* complaints in FY2024, followed by nearly 1,300 in FY2025. As of early FY2026, filings have already exceeded 780, placing DOJ on pace for another record year, with data miners now accounting for more than 45% of all filings since FY2024. DOJ attributes this trend in part to the rapid adoption of AI and machine-learning tools, which have made it easier to analyze large public datasets—including Medicare billing data, Small Business Administration loan records and federal procurement data—for potential fraud signals.

FOCUS invites data miners, including entities and individuals who analyze publicly available government data for fraud indicators, to engage with the Civil Fraud Section before filing *qui tam* complaints. In evaluating participants, DOJ will consider: 1) whether their methodologies use reliable analytics that meaningfully correlate with fraud rather than isolated anomalies; 2) whether any resulting allegations satisfy Rule 9(b)'s requirement of particularity; 3) whether alternative lawful explanations are meaningfully addressed in assessing falsity and scienter; 4) whether participants demonstrate regulatory fluency in applicable program requirements; and 5) whether they conduct and disclose robust pre-filing diligence.

FCA LITIGATION: DATA MINERS, PUBLIC DISCLOSURES AND EARLY THRESHOLD BATTLES

FOCUS underscores a recurring FCA tension between data-driven *qui tam* filings and the statute's "original source" requirement. The public disclosure bar generally precludes *qui tam* suits based on publicly available information unless the government intervenes, or the relator can show independent, material knowledge beyond those disclosures—an issue likely to be sharply contested in data miner cases.

Several courts have addressed the question of whether a *qui tam* case relying on publicly available statistics triggers the public disclosure bar, with mixed results. For example, the Third Circuit requires whistleblowers to contribute significant, non-duplicative details beyond information already publicly disclosed, whereas the D.C. Circuit permits a relator to proceed where one element of the alleged fraudulent transaction is publicly available and the relator supplies either the additional elements necessary to complete the fraud allegation or the fraud allegation itself. For health care defendants, this creates meaningful early motion opportunities, including challenges under the public disclosure bar and disputes over relator standing. DOJ's continued focus on evaluating data mining methodologies may also influence intervention decisions and increase the value of early engagement with the government.[1]

More broadly, these cases are likely to feature earlier, more technical litigation. Defendants will press Rule 9(b) challenges to statistical, inference-based pleadings lacking particularized allegations of falsity, presentment and scienter. The result is an FCA landscape increasingly defined by disputes over data validity and legal sufficiency, rather than traditional whistleblower narratives.

IMPLICATIONS FOR HEALTH CARE ENTITIES

The FOCUS initiative marks a shift toward more systematic, AI-enabled FCA enforcement and increases exposure for health care entities that participate in federal programs. Given the breadth and accessibility of Medicare and Medicaid data, providers are a primary focus of data miner *qui tam* activity, a trend likely to accelerate as AI tools improve the scale and speed of analysis. Health care entities should assume that billing patterns, claims submissions and enrollment data are already being actively screened for potential FCA theories.

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This environment underscores the need for proactive, data-driven compliance programs and early legal assessment of emerging risk signals, including vulnerabilities tied to publicly available data, relator knowledge and data miner-driven theories of liability.

PRACTICAL TAKEAWAYS

- **Know your data footprint**: Assume all public data is mined. Understand what information is publicly available through CMS databases and Freedom of Information Act requests, and use that information in your risk assessment process to identify and investigate outliers before relators do.
- **Strengthen compliance programs**: Regularly update policies, training and auditing to prevent issues before they trigger FCA risk, and incorporate publicly available databases into compliance reviews.
- **Use AI for compliance**: Invest in and deploy analytics to identify, analyze and correct anomalies early, reducing FCA risk.
- **Exploit data-mining weaknesses**: Emphasize lawful explanations and challenge scienter based on statistics alone.
- **Track FOCUS trends**: Monitor enforcement to identify high-risk data signals and adjust compliance priorities.

For more information or assistance in evaluating your compliance program in light of the FOCUS initiative and related liability risks, please contact:

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[references][1] *See, e.g., United States v. Omnicare*, 903 F.3d 78, 92 (3d Cir. 2018); *United States ex rel. Moore v. Majestic Blue Fisheries*, LLC, 812 F.3d 294, 306 (3d Cir. 2016); *see also U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 655 (D.C. Cir. 1994).[/references]

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