Proskauer

False Claims Act Roundup Series: Q1 2026 – Increased Government Enforcement Efforts and Circuit Court Developments

Health Care Law Brief on **May 11, 2026**

2026 has opened with unmistakable signals that False Claims Act ("FCA") enforcement in the health care sector is accelerating. On January 16, 2026, the Department of Justice ("DOJ") announced a record-breaking $6.8 billion in FCA settlements and judgments for fiscal year ("FY") 2025—the largest annual total in the statute's history and roughly a 120% increase since 2024. Health care once again dominated. Approximately $5.7 billion (84% of recoveries) related to health care. The DOJ's Civil Division reported nearly 500 new FCA cases initiated in just the second half of FY 2025, and whistleblower-initiated *qui tam* filings reached their highest level since the statute was enacted.

Against this backdrop, several Q1 developments stand out for their potential to reshape the compliance landscape for health care providers, payors, investors, and their counsel.

Medicare Advantage Under the Microscope

Medicare Advantage ("MA") remains squarely in the government's crosshairs. In March 2026, Aetna Inc. agreed to pay $117.7 million to resolve FCA allegations that it submitted or failed to correct inaccurate diagnosis codes for its MA Plan enrollees to increase risk-adjustment payments from the Centers for Medicare & Medicaid Services ("CMS"). The settlement stemmed in part from a *qui tam* filed by a former Aetna risk-adjustment coding auditor. Notably, although they resolved these allegations under the FCA, Aetna refused to enter into a corporate integrity agreement ("CIA") with the Office of Inspector General ("OIG") for the Department of Health and Human Services ("HHS")—meaning that OIG reserved its right to exclude Aetna for the alleged conduct and placed Aetna on its heightened scrutiny list.

The Aetna settlement follows closely on the heels of the $556 million settlement between DOJ and a state-based integrated plan ("the Plan") resolving FCA allegations against the Plan tied to its own MA billing practices—a record amount for alleged MA risk-adjustment fraud. Together with Aetna, this resolution underscores the scale of Federal government recoveries being pursued.

Simultaneously, OIG issued its first major update to MA compliance program guidance since 1999. The updated Industry-Specific Compliance Program Guidance addresses several areas of heightened risk, including:

- Risk adjustment practices (including use of artificial intelligence ("AI"));
- Agent and broker payment structures; and
- In-home health risk assessment programs that generate diagnoses not reflected in the MA enrollee's actual care.

In its guidance, OIG noted that it was increasing oversight over potential AI risks related to physician queries, provider diagnosis code reporting, as well as claims and prior authorization decisions. OIG specifically cautioned against agent and broker payment arrangements that create incentives to steer enrollment, noting that such schemes could mislead Medicare beneficiaries and potentially violate the Federal anti-kickback statute and FCA (with the requisite intent).

OIG's update follows the reestablishment of the DOJ-HHS False Claims Act Working Group , which has identified MA as a priority enforcement area. Looking ahead, CMS issued its final rule for the MA program in 2027. The final rule dropped the updated risk adjustment formula that the agency had included in its proposed rule in January. But the agency excluded diagnoses that are not linked to a face-to-face encounter or those arising from audio-only encounters from risk score consideration. By implication, CMS will no longer consider retroactive diagnoses mined in prior encounters for risk score purposes if the prior diagnoses were not documented at the time of service.

Key Takeaways

- MA participants, including MA health plans, downstream providers, and delegated entities should treat the OIG's updated guidance as an operational compliance checklist.

- Risk adjustment processes warrant particular scrutiny, as do third-party marketing relationships given DOJ, OIG, and CMS continued focus.
- CMS is taking a clear policy and reimbursement position that diagnoses documented in unlinked chart review records cannot be used as risk score support. In other words, services actually have to be rendered and evaluated during a face-to-face encounter in order for a diagnosis to be validated for risk adjustment purposes.
- As AI continues to proliferate across the health care industry, stakeholders should monitor how Federal (and State) government agencies are scrutinizing use of these tools and the tools themselves. For example, while CMS's final rule does not explicitly mention AI, the implications for AI-assisted coding and diagnosis tools are significant given the requirement that physicians evaluate patients and document the supportability of a diagnosis based on a face-to-face encounter. Health care providers deploying AI-assisted coding, clinical documentation, or risk-adjustment tools should implement robust validation and oversight mechanisms, including periodic audits comparing AI-generated codes against underlying clinical documentation, to ensure that AI outputs do not invite scrutiny or become a basis for unsupportable and potentially false claims.

New Enforcement Infrastructure: The National Fraud Enforcement Division and the White House Task Force

Q1 2026 also brought two structural developments that may reshape how FCA cases are pursued and prosecuted in the years ahead.

First, DOJ announced the creation of a new Division for National Fraud Enforcement. In-house counsel should expect the new division to pursue cases that advance the administration's policy priorities, and health care entities billing Federal health care and other programs should assess their exposure to the division's early enforcement actions. The division has already announced actions related to recovering COVID-19 relief funds, Medicare kickbacks, and unnecessary healthcare services rendered.

Second, the White House issued an Executive Order establishing a Task Force to combat fraud in Federal benefits programs, with membership spanning DOJ, HHS, the Department of the Treasury, and other agencies. The Executive Order specifically directs DOJ to expand its enforcement efforts through the FCA. The Task Force will be headed by Vice President JD Vance. HHS Secretary Robert F. Kennedy, Jr. is also a member.

These initiatives build on an already intensified enforcement climate. The reconstituted DOJ-HHS FCA Working Group, the new fraud division, and the White House Task Force collectively represent a layered enforcement architecture that prioritizes health care fraud across both civil and criminal channels.

Notably, this new enforcement infrastructure is also investing in technology. HHS has announced plans to deploy AI tools to detect and prevent Medicare and Medicaid fraud, and CMS has proposed initiatives to significantly expand its fraud prevention, detection, and enforcement capabilities across all major Federal health care programs. The government's investment in AI-driven fraud detection means that patterns of overbilling, upcoding, or aberrant claims data that might previously have gone unnoticed are now far more likely to trigger a potential investigation.

Key Takeaways

- The announcement of DOJ's fraud enforcement division, along with the current administration's initiatives, means health care stakeholders should anticipate more coordinated, policy-driven enforcement actions. Federal health care program participants should proactively identify business lines that may fall within the division's early priorities, and compliance programs should be stress-tested against the specific enforcement areas, including MA conduct, laboratory billing, and kickback arrangements.
- The government's deployment of AI-powered fraud detection tools also means that providers should assume their claims data is being analyzed with increasing sophistication. Robust internal monitoring, self-auditing programs, and whistleblower reporting channels are more important than ever.

Courts Reshaping the FCA Landscape: The 340B Decision and the Constitutionality of *Qui Tam*

While the Federal government's executive branch has been building new enforcement infrastructure, Federal courts have been simultaneously shaping (and reshaping) the contours of FCA liability in ways that could both expand and potentially limit the statute's reach.

The Ninth Circuit's Landmark 340B Ruling

On March 17, the Ninth Circuit issued its decision in *United States ex rel. Adventist Health System of West v. AbbVie Inc.* The decision significantly reshapes the intersection of the FCA and the 340B Drug Pricing Program.

The Ninth Circuit reversed the district court's dismissal of a *qui tam* complaint brought by nonprofit health care provider Adventist Health System. Adventist alleged that certain drug manufacturers violated the FCA by overcharging 340B covered entities, resulting in allegedly higher payments for those drugs by the Medicare and Medicaid programs. Although the 340B statute lacks a private right of action, the Ninth Circuit held that the action as pled was a "prototypical FCA action" aiming to remediate fraud against the government. By allowing the FCA to serve as the enforcement vehicle, the Ninth Circuit's decision potentially opens a new litigation pathway for covered entities to challenge 340B pricing practices. We note, however, that the Ninth Circuit was careful to hold that "Adventist's [FCA] action is not 'in essence' a suit to enforce Section 340B" but rather is "an independent mechanism through which Adventist can assert [their] claims representing the interests of the government." Nonetheless, the Ninth Circuit's reversal means that the case is now back before the district court for further proceedings.

For providers, the ruling is a double-edged sword. On the one hand, covered entities may now be able to use the FCA as a tool to challenge alleged overcharges that have long been difficult to contest if they can link any overcharges they incurred to a financial loss to the government. On the other hand, the decision also highlights the importance of 340B program compliance, including accurate claims and eligibility determinations.

The Constitutionality of *Qui Tam*: *Penelow* and the Third Circuit

The 340B decision was not the only significant judicial development of the quarter. The Third Circuit heard oral argument in *United States ex rel. Penelow v. Janssen Products, LP*. This case resulted in the largest FCA judgment in history, a $1.6 billion award tied to the marketing of HIV drugs. But the case also involves a constitutional challenge to whether the FCA violates Article II's Appointments clause by allowing *qui tam* relators to file suit on behalf of the United States. This issue was first raised in *United States ex rel. Zafirov v. Florida Medical Associates, LLC*, which we previously covered here. With *Penelow* and *Zafirov* now pending in the Third and Eleventh Circuits, respectively, the stage is set for a potential circuit split that could eventually bring this issue to the Supreme Court.

Key Takeaways

- The 340B decision means that hospitals, health systems, Federally qualified health centers, and other 340B-eligible providers should review their program compliance, while drug manufacturers now face a significant new litigation risk. Covered entities considering affirmative action should engage counsel to assess the viability of FCA-based claims while simultaneously ensuring their own 340B purchasing, dispensing, and billing practices can withstand scrutiny.
- The *Penelow* and *Zafirov* cases, meanwhile, warrant close attention from all healthcare stakeholders. The stakes are enormous: as discussed above, whistleblower-initiated *qui tam* filings have reached historic highs, and a ruling that *qui tam* provisions are unconstitutional would curtail the pipeline that generated the bulk of the DOJ's record $6.8 billion in FCA recoveries last year.

The enforcement landscape emerging in Q1 2026 reflects a clear theme: healthcare remains the government's primary FCA target. The tools, infrastructure, and legal theories available to enforcement agencies are expanding. Whether through record-setting settlements, new regulatory guidance, landmark appellate decisions, or the creation of entirely new enforcement bodies, healthcare providers, payors, investors, and their advisors should continue following these developments to manage the risks ahead.

Related Professionals

- **G. Patrick Regan**
  Associate
- **Matthew J. Westbrook**
  Senior Counsel
- **Richard Westling**
  Partner
- **Vinay Kohli**
  Partner