



A LONG WAY FROM “GUNS THAT DON’T SHOOT”

18 PROACTIVE, SELF-DEFENSE TACTICS AGAINST THE EVER-EXPANDING APPLICATION OF THE FALSE CLAIMS ACT

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The False Claims Act (FCA) was passed by Congress in 1863 to provide a remedy against dishonest contractors who were supplying the Union Army with guns that didn’t shoot, rancid food, ammunition filled with sawdust, and uniforms that dissolved in the rain. The FCA, which has been better-preserved than the spoiled food that led to its creation, today targets charitable healthcare providers who bear no resemblance to the Civil War-era profiteers defrauding the government.

Healthcare systems find themselves on the wrong end of FCA claims because they innocently misinterpret the complex provisions of the Ethics in Patient Referrals Act (Stark Law) or the Anti-Kickback Statute (AKBS), fail to report and repay “obligations” to the government they don’t know they owe, or submit claims based on the often-concealed misconduct of non-employed physicians who operate at their facilities.

The U.S. Department of Justice (DOJ) reports that the total recovery under the federal FCA was \$3.7 billion in 2017, with \$2.5 billion recovered from the healthcare industry alone.

The FCA authorizes private individuals to bring suit on behalf of the government. Such representative plaintiffs are called *qui tam* relators, popularly referred to as “whistleblowers,” and they are entitled, under the FCA, to receive a portion of the recovery. In 2017 the total *qui tam* settlements and judgments for all industries was \$272 million, of which the relators received \$49.7 million.

The annual DOJ report is statistical, sterile, and clinical. A sense of the human toll and the real-life personal consequences are lost. Those with the stomach for it should read the accounts of *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, No. 3:05-CV-02858 (D.S.C.). A \$237 million FCA judgment against Tuomey resulted from a Stark Law violation. The case was settled for \$72.4 million. Dr. Drakeford, the *qui tam* relator, was paid \$18.1 million. The Tuomey CEO paid \$1 million personally to settle claims against him. A judge on the reviewing appellate court referred to the Stark Law as a booby trap for well-intentioned healthcare providers, especially when coupled with the FCA.

Just prior to the announced settlement of *Tuomey*, DOJ released the Yates Memo, which requires corporations seeking settlements to cooperate with DOJ in assigning individual responsibility.

There is no magic formula to prevent FCA claims. All healthcare providers are obligated to comply with the law. The self-defense strategies discussed in this article are not intended to help providers evade the law, but to protect those acting in good faith from becoming a statistic.

1. Don’t document the value of anticipated referrals. Don’t keep return-on-investment-type calculations for financial relationships with physicians. Such information suggests that the health system has unlawfully “taken into account” the volume or value of a physician’s referrals. Aggregated information about increased use of hospital

services may be considered by appropriate committees, such as planning committees.

- 2. Be careful about promotional PowerPoint presentations.** These are often referenced in FCA complaints. They are likely not privileged documents, even if a lawyer is in the room. Assume all such presentations will be seen by others.
- 3. Minimize and explain losses from employed physician practices.** Most hospitals lose money on their employed physicians when measured on a profit-and-loss basis. A health system should document a reasonable explanation for why it makes economic sense to lose money on contracts with employed physicians. The practice of employing physicians at compensation levels that guarantee losses suggests that anticipated referrals were unlawfully considered.
- 4. Don’t permit internal audit (IA) or corporate compliance to create non-privileged documents concerning sensitive compliance topics.** Cover sensitive IA and compliance work with the attorney-client privilege and the attorney-work-product doctrine to avoid creating a discoverable roadmap for an FCA claim.
- 5. Engage fair-market-value and commercial-reasonableness experts through counsel, and don’t allow experts to send unsolicited draft reports.** Draft re-

ports that contradict or substantially vary from the conclusions contained in the final document are trouble. Worse is the appearance that expert reports have been coached by, if not written by, hospital executives.

Experts should be engaged by counsel and instructed that they will take direction only from counsel, do nothing until requested to do so by counsel, and won't send anything in writing until requested by counsel.

6. **Valuation reports must be clear and persuasive.** Almost all FCA defendants rely on a favorable valuation report. The existence of such a report is not determinative of anything. The report must make sense and be based upon accepted analytical methods and reasonable, factual assumptions.
7. **Don't circulate written legal opinions or reports on compliance-sensitive matters.** Don't prepare and distribute to compliance committees, audit committees, directors, or other stakeholders written legal opinions or reports on sensitive compliance matters. Reports should be made orally by counsel.
8. **Be smart and thoughtful about self-disclosures to the government.** Self-disclosures always present important advantages and disadvantages. Consider them carefully. Use the disclosure in a manner that cuts off relators under the public disclosure bar.
9. **Understand, correctly apply, and protect the attorney-client privilege and the attorney-work-product doctrine.** Statements are not privileged just because a lawyer is present. Maintaining the privileged character of information has two helpful purposes: (1) it denies access to privileged communications; and (2) the theft and misuse of privileged material by a *qui tam* relator may be grounds for dismissal or disqualification of plaintiff's counsel.
10. **Limit access to sensitive information.** Whistleblowers sometimes gain access to information that is outside the requirements of their day-to-day responsibilities. Access to such information should be denied.
11. **Create a "culture of compliance."** The board must hold management accountable for compliance. IA and compliance departments should prepare and execute an integrated annual work plan that addresses areas of greatest foreseeable exposure.

Compliance personnel should have a direct line of reporting to the board and not report to in-house counsel or the chief financial officer.

Health systems should maintain a hotline as a process to receive anonymous reports of suspected compliance problems.

12. **Seek insurance coverage.** Corporate directors have a fiduciary responsibility to obtain adequate insurance coverage to protect corporate property and to file timely claims for losses. Many believe that no part of an FCA defense or judgment is covered by insurance. That is not true. Many policies will cover some FCA expenses.
13. **Recognize the difference between Fair Market Value (FMV) and Commercial Reasonableness (CR).** A physician may receive compensation consistent with FMV but without meeting the separate element of CR. The question is whether a transaction makes commercial sense absent any expectation of referrals. And, does the amount being paid advance an identified and legitimate institutional objective?
14. **Be aware that almost anyone can be a *qui tam* relator.** Here are some real-world relators, from personal experience:
 - Compliance officers, when their employer fails to correct a compliance problem;
 - Vendors who believe their competitors are getting an unfair advantage through impermissible financial arrangements;
 - Potential physician partners;
 - Nurses and surgical assistants who work in the operating room; and
 - Consultants who are engaged to fix a problem or determine whether a problem exists.
15. **Pay careful attention to what goes on in the operating room and with the operating room budget.** Certifying Part A claims (the hospital portion of the bill) for procedures performed by non-employed physicians creates a risk. Watch out for medical-necessity issues. Medical necessity is a condition of payment under the Medicare program, and seeking reimbursement for procedures not permitted under Coverage Determination Letters may result in liability.
16. **Petition the U.S. Attorney to dismiss cases in which the U.S. Attorney declines to intervene.** When healthcare

systems become aware of an unsealed *qui tam* relator action in which the U.S. Attorney has declined to intervene, they should use the Granston Memo to request the U.S. Attorney to move to dismiss.

17. **Adopt reasonable personnel policies aimed at the threat of whistleblowers.** Current law makes non-disclosure agreements and pre-filing releases unenforceable against whistleblowers as a violation of public policy. But employers should still consider protective contract provisions and personnel policies:
 - A broad prohibition against employees, vendors, and contract partners providing confidential or proprietary information outside the organization;
 - Use of only the employer's IT system and a prohibition against downloading any information on any device not owned by the employer;
 - A permissible-use policy that prohibits the employee from accessing restricted information;
 - The return of all property upon termination of employment;
 - Required reporting of any contact with any outside regulatory or law enforcement agency; and
 - Severance payments conditioned on the signing of a separation agreement in which the employee affirms compliance with the foregoing and provides a general release.
18. **Treat whistleblowers with respect and do not retaliate against them.** Federal and state law contains extensive protections for whistleblowers, and case law is developing rapidly. Consult counsel in this tricky area.

This article is a summary of a more in-depth series on the topic. If you would like to receive updates, please email info@rivkin.com.



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