THE FEDERAL FALSE CLAIMS ACT & THE ONGOING FIGHT AGAINST HEALTHCARE FRAUD

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The False Claims Act (FCA) is one of the United States government's most powerful weapons to combat the perpetration of fraud against federal programs. While the FCA is applicable to claims submitted for payment by any type of government contractor, it has been widely used in the healthcare industry. Also referred to as the "Lincoln Law," the FCA dates back to the 1800s and was created to address fraud by defense contractors during the Civil War. The law included a provision to reward whistleblowers (called "relators") for disclosing the fraud to the government. This is called a qui tam provision. Qui tam is short for the Latin phrase "*qui tam pro domino rege quam pro se ipso in hac parte sequitur*," which roughly translates to "he who brings an action for the king as well as for himself." As such, while the government can identify fraudulent activity on its own and proceed with an FCA case accordingly, the majority of FCA cases are qui tam actions. This article will educate wound care stakeholders on the qui tam process and discuss how clinicians and program directors can initiate the procedure, if necessary.

QUI TAM DEFINED

In a qui tam action, the relator who has identified fraudulent claims being submitted by a government contractor can file a claim in both his/her name and on behalf of the U.S. government.[1] The relator is often an employee of an organization that is submitting false claims to the government for reimbursement. These individuals, in many cases, have attempted to stop these organizations from engaging in this activity and have become frustrated by the continued fraud. The federal government, through the U.S. Department of Justice (DOJ), is required to investigate all FCA claims and either intervene and proceed with the case or decline action (in which case the relator may proceed with action independently, if desired). The DOJ will investigate the case alongside the Offices of the U.S. Attorneys for the state in which the case is filed.

Beyond the altruistic goal of preventing fraud against the government, the benefit to a relator in filing an FCA case is that he or she is entitled to an award of 15–25% of whatever funds the government recovers from the defendant.[2] (Of the 799 new FCA actions filed in 2017, 674 were qui tam actions.) The relator plays a significant role in the DOJ's investigation, and the DOJ relies initially on the relator to identify and explain the fraudulent scheme. Additionally, the relator gathers and provides any documentary evidence that supports the allegations of any FCA violations. (The DOJ relies on this initial information in deciding how to proceed with its investigation.) While, historically, the majority of FCA cases involved military contractors, energy providers, and technology companies, there has been a shift occurring over the past few decades with healthcare and procurement fraud cases constituting the vast majority of all FCA actions. For example, in 2017 the U.S. government recovered $3.7 billion from FCA actions. Of that amount, $2.4 billion came from the healthcare industry, marking the eighth consecutive year that healthcare fraud recoveries had surpassed $2 billion. The DOJ settled or obtained judgments against defendants in a variety of sectors of the healthcare industry, including pharmaceutical companies, hospitals, physicians and physician practice groups, outpatient clinics, hospice and hospice care systems, and pharmacies. False claims are not claims involving innocent billing mistakes. False claims occur when the individual(s) know the claims are false and they include, for example, services that are not actually provided, upcoded, part of a previously submitted claim, and/or not supported by the medical record. The FCA holds liable any person who "knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; conspires to commit a violation; or knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government."[3] The key terms to remember here are "knowing" and "knowingly." These terms mean that a person has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information.[4] As such, there are two additional ways for a defendant to have "knowingly" violated the FCA without having "actual knowledge" that a submitted claim was false.

FCA CONSEQUENCES & PROCEDURES

Violations of the FCA can result in extraordinary penalties. The most extreme penalty is that the defendant is excluded from the Medicare and/or Medicaid programs. There are not many organizations in the healthcare industry that could financially survive such a result. The statute provides for the recovery of three times the amount of the actual damages incurred by the government due to the submission of false claims. Additionally, there are civil penalties of between $11,181 and $22,363 per claim.[5] Consider cases involving thousands

of claims of a "de minimus" (too trivial or minor to merit consideration) value. While the actual damages may not be substantial, once each claim generates a civil penalty of at least $11,181 the penalties can be massive. While the government is entitled to seek these treble damages and penalties, such penalties are generally reserved for cases that go to trial as opposed to settling. A settled case will most often not involve these severe penalties, but rather a recovery of the actual damages incurred. When a case is filed by a relator, it is placed under seal by the court, so that not even the defendant knows it has been filed. The FCA provides the government a period of time (60 days initially) for the case to remain under seal, in order to investigate the claim. Despite not having been served with a complaint, the defendant can generally conclude that it has been named in an FCA case when the government contacts him/her/them and begins requesting information. (The seal period is extended while the government continues its investigation.) Often, the case will remain under seal for years, giving the government the time it needs to reach a conclusion as to whether or not fraud has occurred.

During this period, the government may seek permission to provide a copy of the complaint to the defendant only, giving the defendant an opportunity to explain why he/she does not think he/she knowingly violated the FCA (without the claim being made known to the public). This is important because that news can be devastating to a company's reputation. With the weight of such serious allegations being considered, government officials do not intend to cause undue repercussions to any person and/or company until it has concluded that the FCA has actually been violated. Once the government has investigated a claim, heard the defendant's reasoning, and still reached the determination that a defendant has knowingly submitted false claims for payment, it will generally engage in settlement discussions. The DOJ does not settle cases until it is satisfied that sufficient evidence of FCA violations exist.

However, as the matter will have settled prior to a jury making a final determination of violations, it is accurate for the DOJ and the defendant to state that the issues settled were "only allegations and no determination of liability has been made." Additionally, defendants can continue to publicly maintain their position that they did not believe their actions violated the FCA. Should the government conclude that insufficient evidence exists to prosecute a case, it will inform the relator and legal counsel that it declines to intervene in the matter. In fact, the government at the conclusion of its investigation only determines that the FCA has been violated and intervenes in approximately 25% of filed cases. At that point, the relator can choose to either dismiss the case or proceed without the government's involvement. As part of a settlement with a defendant, the U.S. Department of Health & Human Services' Office of Inspector General (OIG) will, in virtually all cases, require a corporate integrity agreement (CIA). The defendant negotiates the terms with the OIG and ultimately agrees to the obligations in exchange for the OIG agreeing not to seek its exclusion from participation in federal healthcare programs (including Medicare and Medicaid). CIAs are very burdensome and expensive for the defendant, and typically have a term of five years. There are several requirements that appear in the majority of CIAs, including:

- hiring a compliance officer/appointing a compliance committee;
- developing written standards and policies;
- implementing a comprehensive employee training program;
- retaining an independent review organization to conduct annual reviews;
- establishing a confidential disclosure program;
- restricting employment of ineligible persons;
- reporting overpayments, reportable events, and ongoing investigations/legal proceedings; and
- providing an implementation report and annual report to the OIG on the status of the entity's compliance activities.

Consider the intrusive requirement that a defendant hires a compliance officer: This involves an outsider coming in to review the defendant's daily activities. This compliance officer's goals are often not aligned with what management is trying to accomplish to grow its business. Similarly, there is a requirement that the company retain an independent review organization to conduct periodic reviews. Should the company not be meeting the CIA's requirement to the compliance officer's (or review organization's) satisfaction, a report will be made to the OIG. The CIA will set forth specified monetary penalties that may be imposed on a per-day basis for the provider's failure to comply with the CIA, and the CIA will identify certain violations that are specified as a "material breach." A provider may be subject to exclusion from participation in government healthcare programs based on a material breach of the provider's CIA.

CONCLUSION

FCA settlements and jury verdicts continue to make headlines. As stated, these are not cases of "innocent billing errors." These cases show patterns of practice that the DOJ has concluded involve a defendant "knowingly" presenting or causing to present a false claim for payment. For some companies, the reward is worth the risk. However, for those companies that find themselves subject to a DOJ investigation asserting claims of FCA violations, there is a tough legal battle ahead. ■

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