A GATHERING STORM: THE NEW FALSE CLAIMS ACT AMENDMENTS AND THEIR IMPACT ON HEALTHCARE FRAUD ENFORCEMENT

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Introduction

On May 20, 2009, the Fraud Enforcement and Recovery Act of 2009 (“FERA”)1 was signed into law. It includes the most comprehensive and significant amendments to the civil False Claims Act (“FCA” or “Act”)2 – the Government’s chief weapon and enforcement tool against the healthcare industry – in nearly 25 years. While the purported intent of FERA’s sweeping amendments to the FCA is to enhance the federal government’s ability to fight fraud in the financial industry in the wake of the establishment of the Troubled Asset Relief Program (“TARP”) and unprecedented economic stimulus spending, the amendments apply equally to all, including healthcare entities.

FERA’s amendments to the FCA constitute an exponential expansion of the FCA’s liability provisions as well as its qui tam “whistleblower” provisions. These amendments will have a substantial impact on virtually every person, company, or entity that pays money to the government or receives federal funds. Healthcare entities, which have been the primary focus of the government’s FCA enforcement efforts for over a decade, are no exception and are likely to be the hardest hit.

In tandem with these expanded liability and qui tam provisions, the Draconian penalties provided for under the Act – e.g., treble damages, penalties of up to $11,000 per violation, assessment of attorneys’ fees and costs, and suspension and debarment – warrant grave concern and demand the highest attention of healthcare leaders and executives to ensure that compliance programs are in place and effective. FERA contains vague provisions, undefined terms, and inconsistencies and it may be months, if not years, until judicial decisions interpreting and applying its amendments to the FCA provide needed clarity. One thing, however, is likely: the government will not wait to pursue investigation and enforcement in the interim. Healthcare entities must exercise extreme caution to avoid falling prey to investigations due to their unfamiliarity with new legal boundaries – even vague ones. Measures should include the implementation and execution of robust compliance programs and initiatives, including fraud and abuse education and training for managers and employees,3 fraud “hot line” and/or other reporting mechanisms, response and investigation procedures, and constant auditing of compliance programs to ensure they are both current and effective.

FERA’s amendments to the FCA are but one factor in a gathering storm in healthcare fraud enforcement resulting in a perfect confluence that will bring dire consequences for the unwary. The book, The Perfect Storm, by Sebastian Junger, describes in graphic detail the havoc created when three smaller storms gather and combine into one. Not unlike the gathering storms in the book, three metaphorical “storms” have now combined in the health fraud enforcement world, and their force is bearing down to create substantial risk of liability for healthcare entities.

The first storm is the federal government’s current spending spree in federal healthcare programs and economic recovery efforts. Combined with Medicaid and Medicare spending, new TARP and stimulus funds have the government on track to spend trillions of dollars in the coming years. These government funds are being distributed at a staggering rate to a wide array of companies. Under FERA’s amendments, the distribution of these funds will constitute federal funding capable of triggering potential FCA liability. Any entity that either directly or indirectly receives federal funds, including healthcare providers that participate in federal programs such as Medicaid and Medicare, are at risk. These entities, including contractors, subcontractors, and vendors, are also likely to face whistleblower retaliation claims from employees, former employees, and competitors.

The second storm has arisen from FERA’s recent amendments to the FCA. By amending the Act, Congress removed two key provisions, which prevented it from operating as a “boundless” “all-purpose antifraud fraud statute.”4 First, Congress removed the requirement that the allegedly false claim actually be presented to the government for payment. Now liability may attach to claims that are submitted to a “contractor, grantee, or other recipient” of federal funds, regardless of whether a false claim was submitted to the government. Congress also removed the requirement that a subcontractor act with the specific intent “to get” a false claim paid “by the government.”5 As a consequence, there is no longer a requirement that an individual or entity act with the specific intent to defraud the government. Together, these two amendments expose a large number of companies to potential liability under the FCA, including companies that are not traditionally thought of as – and have never considered themselves to be – government contractors, such as subcontractors and vendors who simply work with grantees or recipients of federal funds.

The third storm in play is ignorance. A recent study found that nearly 80 percent of business executives from a broad array of companies, including those in the healthcare industry, were
unfamiliar with the FCA. This means that many companies, which are now unwittingly in the cross-hairs of federal fraud enforcement, are likely unprepared to prevent FCA violations through the implementation and execution of adequate compliance measures. Perhaps more problematic, these entities are also likely ill-equipped to respond if and when potential problems arise.

It is crucial that all entities, including healthcare entities, whether traditional government contractors, government program participants, or merely recipients of federal funding, heed warnings and take measures to avoid disastrous FCA liability. First and foremost, it is necessary to understand the FCA, its recent amendments, and their implications for the healthcare industry. Only then may one assess the compliance challenges that must be met. This article begins with a basic overview of the FCA, followed by a review of its use in healthcare fraud enforcement. The article then examines specific FCA provisions, and then presents an in-depth discussion of the recently enacted amendments to the Act and their practical effects and implications for the healthcare industry. Finally, this article addresses the compliance challenges created for healthcare entities and the measures that must be taken to address them.

**Brief Overview of the FCA**

Congress enacted the federal FCA in 1863 to combat abuse of federally funded programs in the Civil War reconstruction era. In essence, the FCA prohibits the submission of false claims for payment where federal funds are involved. Although its use as an enforcement tool diminished greatly over the century that followed, its use by the federal government re-emerged as a mechanism for addressing abuses in the defense contracting industry in the 1980s. This was due, in part, to the FCA amendments in 1986, which significantly expanded the incentives – i.e., monetary awards, damages, and penalties – and reduced the barriers to bringing actions against entities alleged to have engaged in fraud by lowering the standards for intent and burden of proof required to establish liability. Combined, these amendments ushered in a sharp increase in FCA cases in the decades which followed.

The popularity and strength of the FCA as an enforcement tool is a result of its financial potential and extensive reach. Violations of the FCA are subject to treble damages, penalties of between $5,500 to $11,000 per violation above and beyond the damages subject to the FCA’s trebling provision, and attorneys’ fees and costs to successful whistleblowers if they file suit under the qui tam provisions of the Act. The Act’s qui tam provisions permit private individuals – colloquially referred to as “whistleblowers” and referred to under FCA law as “relators” – to act in place of government enforcement agencies and offer financial incentives to them to investigate and bring to the federal government allegations of abuse of public funds.

Qui tam actions are brought under the FCA “for the person and for the United States government,” in the name of the United States. The FCA requires a relator to file the complaint under seal, and gives the government sixty days to investigate the relator’s allegations and determine whether to intervene in and take over the action. After the government fully investigates the allegations made by the relator in the complaint and written disclosure, it has several options. It may: (1) notify the court that it will intervene in the suit and take over responsibility for the litigation; (2) formally decline intervention, thus allowing the relator to conduct the litigation on his or her own; (3) move to dismiss the litigation, even over the relator’s objection; or (4) seek to settle the case. If the government elects to intervene in the suit, it then takes over control and, importantly for the relator and his or her counsel, the bulk of the work and costs attendant to the litigation. If the government declines intervention, then the FCA allows the relator to continue the litigation without the active participation and financial support of the government. If successful, a relator may receive between 15 percent and 30 percent of any recovery obtained, in addition to attorneys’ fees and costs. Once the government makes its decision and determines whether to intervene in the case, the case is unsealed and the litigation – regardless of the government’s election – proceeds very similarly to any other federal case under the Federal Rules of Civil Procedure.

In the wake of the 1986 amendments to the FCA, which increased damages and penalties, lowered the standards for intent and burden of proof required to establish liability, and enhanced whistleblower incentives, many commentators suggested that the FCA’s character shifted from a true fraud statute into what is, in essence, a “recklessness” statute. Of course, similar criticisms have recently been voiced with the fresh passage of the new amendments to the FCA under FERA, which expand the FCA well beyond the 1986 amendments.

**The Use of the FCA in Healthcare Fraud Enforcement**

Since the early 1990s, the FCA has become the primary enforcement tool used by the federal government to combat fraud, waste, and abuse in federal healthcare programs, including Medicaid and Medicare. FCA cases have been brought against virtually every segment of the healthcare industry, and the large settlements and judgments in those cases make up a substantial portion of the government’s total FCA recoveries.

Since the last major amendments to the FCA in 1986 through and including fiscal year 2008, a total of 10,063 cases were filed under the civil FCA. Thirty-eight percent (3,864) of these cases were non-qui tam cases filed by the government without any qui tam relator (i.e., continued on page 16
cases not initiated under the qui tam provisions of the FCA by a relator or so-called “ whistle blower”), while 6,199 or 62 percent of these cases were initiated and filed by qui tam relators. Through settlements and judgments, the government has recovered nearly $22 billion in FCA cases during this time. Of this amount, approximately $8 billion has come from non-qui tam cases and approximately $14 billion has come from cases brought under the Act’s qui tam provisions. 

Key FCA Liability Provisions Prior to FERA

Under the FCA – prior to its most recent amendment – liability arose primarily under the provisions of 31 U.S.C. §§ 3729(a)(1)-(7). The four most commonly invoked liability provisions of the FCA included:

- Section 3729(a)(1), also known as “direct” false claims to the federal government, which imposed liability for submitting or causing another to submit a false claim;
- Section 3729(a)(2), which imposed liability for the making of false records or false statements to support a false claim;
- Section 3729(a)(3), which imposed liability for participation in a conspiracy to submit a false claim for payment; and
- Section 3729(a)(7), also known as “reverse false claims provision,” which imposed liability for the submission of a false claim or statement to avoid payment of, or to decrease, an obligation to the government.

FERA’s Recent Amendments To The FCA

As a result of FERA’s recent amendments to the FCA, any company or individual doing business in the healthcare marketplace – providers, payors, subcontractors, and vendors – are potentially subject to the FCA. It is incumbent on those in the industry to be aware of the substantive and procedural provisions of the Act as amended in order to ensure that they have effective compliance programs in place as their first line of defense. While the substantive changes are likely to have the greatest impact on how such programs are structured, the procedural changes, which are focused on the investigatory provisions of the Act, will also greatly impact those who may unwittingly find themselves in the government’s enforcement net. Thus, a full understanding of both the substantive and procedural provisions of the Act and the changes brought about by its recent amendment by FERA is essential.

Substantive Changes to the FCA

1. Expansion of the Scope of the FCA

FERA’s amendments to the FCA exponentially expand the FCA’s scope. Not only do these amendments remove statutory language limiting its reach, they also eliminate some historical and commonly used legal defenses to alleged FCA violations. In broad terms, FERA extends the FCA’s reach to any false or fraudulent claim for government money or property regardless of whether the claim is presented to a government official or employee; the government holds title or has physical custody of the money; or the defendant specifically intended to defraud the government.

The purported intent of the Act is to “correct” and/or “clarify” statutory language as well as erroneous interpretations of the law by the federal judiciary, including the U.S. Supreme Court in Allison Engine Co. v. United States ex rel. Sanders, which limited the scope of the law, allowed subcontractors and non-governmental entities to assert defenses against allegations of fraud, and arguably limited the FCA’s application to Medicaid claims.

FERA re-defines a “claim” under the FCA to mean “any request or demand, whether under a contract or
otherwise, for money or property and whether or not the United States has title to the money or property” that is 1) presented directly to the United States, or 2) “to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest” and the government provides or reimburses any portion of the requested funds. As made clear by this new definition, FCA liability can now attach to knowingly false requests paid with federal funds, regardless of whether the government has title to the money requested, and regardless of whether it is requested directly from the government or from a recipient of federal funds, so long as that money is used to “advance a Government program or interest.” Consistent with the elimination of the presentment language as described above, the change clarifies that requests for payment submitted to Medicaid contractors and managed care organizations are “claims” subject to liability under the FCA.

b. Elimination of the FCA’s “Presentment” Requirements

Before enactment of the FERA amendments, proof of “presentment” – i.e., that a false claim was presented to “an officer or employee of the Government, or to a member of the Armed Forces” was required to establish liability for a false claim under the FCA. As explained in the Senate Judiciary Committee report accompanying the legislation, the FERA amendments clarify and confirm that FCA liability “attaches whenever a person knowingly makes a false claim to obtain money or property, any part of which is provided by the Government without regard to whether the wrongdoing deals directly with the Federal Government; with an agent acting on the Government’s behalf; or with a third-party contractor, grantee, or other recipient of such money or property.” Furthermore, the Senate Judiciary Committee report specifically notes that removal of the presentment clause clarifies that the FCA “reaches all false claims submitted to State administered Medicaid programs.” This means that FCA liability may attach not only to any claims submitted to the government, but also to those submitted to intermediaries such as Medicaid Managed Care, Medicare Advantage, and Medicare Part D plans as well.

c. Elimination of the FCA’s Intent Requirement

Prior to being amended by FERA, liability under the FCA would attach if a person “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” The FERA amendments delete the language requiring that a person use a false statement “to get” a false claim “paid or approved by the Government.” Now all that is required is that the false statement be “material to” a false claim. Thus, it is no longer required for the government or a relator to establish a direct connection between the allegedly false statement and the government’s payment of the claim. Now all that is required for liability to attach is the establishment that such a statement has a “natural tendency to influence, or is capable of influencing” the payment of government funds.

The Senate Judiciary Committee report justifies these changes by characterizing them simply as changes that “clarify and correct erroneous interpretations of the law” stemming from the Supreme Court’s decision in Allison Engine Co. v. United States ex rel. Sanders. In Allison Engine, former employees of a Navy subcontractor alleged their employer submitted fraudulent certificates of compliance to the prime contractor, but could not prove that the fraudulent certificates were issued for the purposes of obtaining payment by the government. The Supreme Court held that, to impose liability under the FCA, it was not enough merely to show that a false statement resulted in payment with government funds. Rather, the Supreme Court made it clear that to establish liability under Section 3729(a)(2) of the FCA, it must be shown that a defendant using a false record or statement to get a false claim paid or approved by the government intended for the government itself to pay the claim.

Allison Engine essentially stood for the proposition that, in order to establish liability under the FCA, there must be a clear link between a false claim and payment or approval by the government. As the Allison Engine Court cautioned, without this, the FCA would be “boundless” and tantamount to an “all-purpose antifraud statute.” FERA has legislatively overruled the Supreme Court’s Allison Engine decision, which had cleared up varying interpretations in the lower courts, by eliminating this intent requirement. As amended by FERA, both the “to get” and “by the Government” language have been removed from the Act. The FCA now requires only that a false record or statement be “material to a false or fraudulent claim.” The government need no longer prove that the relator intended to get the government to pay any allegedly false claim.

Healthcare providers submitting claims for payment that are construed to be false may now be liable under FCA even if they do not present or intend to defraud the government. In essence, FERA has done precisely what the Supreme Court cautioned against: it has turned the FCA into a “boundless” “all-purpose antifraud statute.”

2. Expanded Conspiracy Provisions

The amendments also expand conspiracy liability under the FCA to include conspiracies to commit a violation of any other substantive section of the FCA. Previously under the FCA, the conspiracy section covered only a conspiracy “to get a false claim paid or approved” and most courts had construed this to limit the conspiracy section to apply only to violations of Section 3729(a)(1).
3. Explicit “Materiality” Requirement

The amendments also establish an express materiality requirement, which explicitly pertains where one “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.”48 “Material” is now statutorily defined as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”49 Previously, the FCA did not expressly have a materiality requirement; however, many courts required such a finding as an implied standard within the Act, and some imposed a heightened materiality standard.49

In FCA cases before courts utilizing the heightened materiality standard, the government or relator was required to show that the government agency would have acted differently had it known of the alleged falsity.50 Put another way, to show that the government agency to make a decision that it would not have made if the statement had not been false. While FERA amends the FCA to confirm a materiality requirement, the amendment describes a reverse false claims provisions of the FCA51 to expand liability to “knowingly and improperly avoid[ing] or decrease[ing] an obligation to pay or transmit money or property to the Government.”52 Under this provision, there is now no longer a need for a person to have taken an affirmative act — a false statement or record — in order to conceal, avoid, or decrease the obligation to the government, and the Senate Judiciary Committee report on FERA states that the revised provision is aimed at imposing liability “without notice [by the provider] to the Government about the overpayment.”53 While it is clear that this change constitutes a vast expansion to the FCA’s reach, the new metes and bounds of its scope are anything but clear, since courts will soon just begin to interpret these provisions. Compounding this is the confusion that has arisen over the use of the terms “obligation” and “knowingly.”

Under the amendment to the FCA’s false claims provisions, it is now sufficient for liability purposes that the defendant be found to have merely retained an overpayment where there was an “obligation” to repay the government. “Obligation” is confusingly defined as “an established duty, whether or not fixed” that arises from “a contractual, grantee, licensure or fee based relationship, from a statute or regulation, or from the retention of any overpayment.”54 Therefore, while there is no new “obligation” to repay an overpayment, the amendment describes a derivative “obligation” by referencing other possible legal situations where that obligation may be found.

Healthcare entities and their counsel know all too well that identifying such potential “obligations” to repay an overpayment within the complex healthcare regulatory scheme is not a simple endeavor. In the context of health insurers and payors, there is an existing “obligation” for disclosure of “Federal Employee Health Benefit Plan (“FEHBP”) overpayments. The Federal Acquisition Regulation (“FAR”), which governs federal government contracting law, provides that a contractor may be debarred for “knowing failure . . . until 3 years after final payment on any Government contract . . . to timely disclose to the Government, in connection with the award, performance, or closeout of the contract . . . credible evidence of . . . [significant overpayment].”55 Additionally, there is an existing “obligation” for disclosure of Medicare and Medicaid overpayments.56 In order to meet the new FCA “obligation” to repay money to the government, counsel and healthcare entities must navigate these and numerous other statutory and regulatory provisions in order to identify areas in which repayment obligations might exist. This is no easy task. As one court has remarked:

There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.57

Furthermore, the amendment’s use of the “knowingly” scienter standard also adds confusion. Under the FCA, “knowingly” is defined not only to comprise “actual knowledge” of a falsity, but also includes “deliberate ignorance” or “reckless disregard” of the “truth or falsity” of a claim or statement.58 So, assuming the same usage of the term in application to FERA’s “reverse false claims” language, a question is raised with regard to what responsibility is placed on the potential “possessor” of an overpayment to identify the existence of that overpayment. If an
entity's internal accounting or compliance systems are not state-of-the-art and able to detect immediately each and every potential overpayment, does that constitute “deliberate ignorance” or “reckless disregard”?

Regarding current potential overpayments, equally difficult questions arise. For example, how often must an entity check for overpayments to avoid being “reckless” or “deliberately ignorant”? How quickly must overpayments be returned to avoid liability? Once an overpayment is identified, and even when the entity’s motivations are pure, the unanswered questions do not end: to whom and how should the repayment be made (since this information is not frequently included in statutory or regulatory provisions)? Perhaps most importantly, will the repayment itself resolve the FCA problem, or could repayment trigger the risk of further investigation or even a whistleblower action? These are merely some of the many difficult questions with which lawyers and their clients must grapple in the wake of the FERA amendments to the FCA.

Without sufficient statutory guidance, it may be some time before it will become clear how the language will be applied to overpayments retained by healthcare entities that participate in federal healthcare programs, particularly those programs that employ a periodic reconciliation process, such as under the Medicare cost reporting scheme. The only “guidance” offered by the government at this time comes from the Senate Judiciary Committee report, which states that the new definition “will be useful to prevent Government contractors and others who receive money from the Government incrementally based upon cost estimates from retaining any Government money that is overpaid during the estimate process.” While at the same time, it attempts to offer some comfort by noting that the language is directed at the “willful” retention of overpayment, and is not intended to create liability for a “simple retention of an overpayment . . . permitted by a statutory or regulatory process for reconciliation.” Until, however, key terms such as “obligations” and “knowingly” are interpreted and clarified, through court decisions or otherwise, no comfort should be found in these words alone.

5. New Whistleblower Protections

FERA has also added new and expanded whistleblower protections to the FCA. FERA expands the class of persons who are entitled to protection for retaliation. The class now includes not just employees, but also contractors and agents. The whistleblower is entitled to receive “all relief necessary” that will make the individual “whole.” The relief, according to the statute, shall include reinstatement at the same level of seniority, two times the amount of back pay, interest on the back pay, and compensation for any special damages, including litigation and attorneys’ fees.

The amendments also extend whistleblower protections to ensure that whistleblowers are protected when taking lawful actions “in furtherance of other efforts to stop 1 or more violations” of the FCA. Previously, protection applied only when the purported whistleblower was engaged in conduct (e.g., investigation) directly in furtherance of an actual action under the FCA, the employer had knowledge of such investigation, and then retaliated against the employee/whistleblower as a result. Extending the prior standard to include undefined “other efforts,” as FERA has done, promises to expand the class of those who may seek protection — and a bounty — under the Act.

Procedural Changes to the FCA

1. The Government’s Complaint

Previous case law, perhaps unsettled due to varying Circuit Court interpretations, stood for the proposition that the statute of limitations for the filing of the government’s complaint began to run at the time of the relator’s qui tam filing, and that the government’s complaint-in-intervention did not relate back to the relator’s complaint. Congress again legislatively overruled the courts and concluded that the government’s complaint should in fact relate back to the relator’s filing. Specifically, the Act’s liberal relation-back standard now reads: “any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.” This change permits the government more leeway in terms of meeting its original statute of limitations obligations, but the new provision also may permit the government additional room for discovery in various cases.

2. Service On State and Local Government Co-Plaintiffs

Numerous states have false claims laws analogous to the federal FCA and it is not uncommon for federal and state investigations to proceed in tandem. Because cases under the federal FCA are filed under seal and remain under seal during the government’s initial investigation, a procedural question would arise as to whether a qui tam relator had the right to share the federal FCA complaint with state authorities without breaking the seal. The FERA amendments have clarified that, whenever a state or local government is named as a co-plaintiff in an action, the government or the relator “shall not [be] preclude[d] . . . from serving the complaint, any other pleadings, or the written disclosure of substantially all material evidence.”

3. Civil Investigative Demands

Civil Investigative Demands (“CIDs”) are a powerful tool used by the government to conduct investigative discovery. CIDs are used prior to the time that the government makes an intervention decision, and they may take the form of typical discovery, including depositions and interrogatories. continued on page 20
This tool, however, has been used infrequently in the past due to the fact that only the Attorney General had the authority to issue CIDs. The FERA amendments, however, have provided the authority for the Attorney General to delegate the power to issue CIDs to a designee. The Justice Department is expected to issue regulations regarding this delegation of authority and it is probable that the frequency with which the government issues CIDs may be on the increase.

With the increased ability to delegate and manage this form of pre-intervention investigation, defendants may find themselves subjected to the various forms of investigation permitted, including oral questioning. In addition, where a qui tam relator is involved, the notion of information moving in one direction – from relator to the government – could be a vestige of the past and dilute defense opportunities. If the government uses its new CID authority to share information with relators, it may actually allow relators to cure a fatally deficient complaint by using information obtained through such sharing to shore up allegations that might otherwise be deemed infirm under Rule 9(b)’s strict pleading requirements.

Effective Date of Amendments

The FCA Amendments generally relate prospectively, affecting conduct that occurs on or after May 20, 2009, which is the enactment date of FERA. One significant exception to this prospective application, however, relates to FERA’s elimination of the “intent” requirement to have a false claim paid by the government. As amended, the new FCA materiality provision – requiring a false record or statement to be just “material to a false or fraudulent claim” – applies retroactively to all “claims” pending as of June 7, 2008.

Potential Compliance Challenges For Healthcare Entities

Standing alone, the new reverse false claims and “overpayments” provisions pose significant compliance challenges for healthcare entities. As mentioned, it is difficult in many contexts to determine when one has an existing “obligation” to repay the government. In terms of contractual relationships, various forms, including the Centers for Medicare and Medicaid Services (“CMS”) enrollment form and the electronic claim submission form, may give rise to certain obligations. Furthermore, elements of Corporate Integrity Agreements and Certification of Compliance Agreements may likely provide obligations to repay the government. The federal physician self-referral law (“Stark”) also has a confusing statutory “refund” requirement, which establishes an “obligation” to refund Stark-tainted payments. Such payments, however, go not to the government, but to the beneficiary. See, e.g., 42 U.S.C. § 1320a-7b(a)(3), where the statutory language elliptically describes the potential disclosure (not repayment) obligation of an “individual.”

In order to meet the new FCA “obligation” to repay money to the government, counsel and healthcare entities must navigate these and numerous other statutory and regulatory provisions in order to identify areas in which repayment obligations might exist to avoid potentially making any “reverse false claims.” The Medicare regulatory framework, for example, may pose myriad other circumstances in which repayment “obligations” may arise. Therefore, healthcare entities in particular must remain vigilant in all facets of their operation — from enrollment or initial contracting to day-to-day operations and claims submission — to ensure that they do not inadvertently expose themselves to liability. Furthermore, individuals and companies will likely require guidance, counseling, and legal support in assessing new areas that did not traditionally pose FCA risks.

Importantly, providers are not the only healthcare entities that should be concerned. Risk areas now exist for health insurers, payors, and managed care organizations not traditionally thought of as FCA targets. For example, there are enhanced risks for health plans sitting on overpayments, under Medicare, FAR, and FEHBP laws. Other key risk areas include inaccurately reporting or certifying data in bids and rate proposals, using inaccurate data to support reported claims experience and loss ratios, failing to correctly report rating or discounts for “similarly sized subscriber groups” under the FEHBP, recklessly relying on faulty data extraction tools in rate setting, falsely certifying compliance with marketing or other program requirements, inaccurately reporting enrollment or failing to correct inaccurate enrollment or other demographics, and manipulating provider or vendor dealings to distort reported claims expenses under governmental programs.

While the amendments to the FCA certainly create new compliance challenges for all those in the healthcare industry, disastrous results can be avoided by heeding warnings and taking advantage of the opportunities that exist for compliance auditing, implementation, and execution. At the very least, the ability to demonstrate a significant and substantive internal compliance program — with evidence that it has been adhered to in good faith — may help allay the government’s suspicion or help ward off an investigation. Even if an investigation proceeds and litigation is commenced, however, what a defendant has done — or not done — to comply with the FCA will assuredly come into play and likely affect the disposition of the action. Although some FCA
Conclusion

The new amendments to the FCA, however well-intentioned, will be significantly challenging for anyone or any entity that comes into contact with federal funds, and healthcare entities are no exception. They constitute the most sweeping expansion of the FCA’s liability and qui tam provisions in nearly 25 years and will most certainly result in increased FCA enforcement by both the government and whistleblowers — including whistleblowers who may be disgruntled former employees, competitors, or simply “bounty hunters” motivated by greed. Moreover, the amendments enable both the government and whistleblowers to pursue FCA cases in situations that have not, in the past, been subject to liability or sanctions provided for by the Act.

The gathering storm, triggered by these amendments to the FCA, presages a new era in fraud and abuse enforcement — and compliance — for healthcare entities. The amendments stand to impact not only those traditionally susceptible to FCA enforcement, such as federal healthcare program participants, but also subcontractors, vendors, and others who are the indirect recipients of government funds. While traditional targets such as healthcare entities may be best equipped to prepare for this storm as compared to those unwittingly caught in its path, the fact remains that all who fail to heed its warnings are destined to become its victims.

Although much concern has arisen over the new amendments and their lack of clarity, one thing is clear: the new amendments constitute warnings and present compliance opportunities – and the time to take advantage of these opportunities is now. Healthcare entities must ensure that they maintain comprehensive and effective compliance programs, which will require careful and thoughtful legal counsel. All healthcare entities should reassess their potential FCA liability, evaluate their current compliance policies and programs, and implement new measures and modifications to gird themselves for increased scrutiny and enforcement activity.

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Endnotes
1 P.L. 111-21.
2 31 U.S.C. § 3729 et seq.
7 31 U.S.C. §§ 3729 et seq.
8 See, e.g., John T. Boese, Civil False Claims and Qui Tam Actions, §§ 1.01-1.04 (3d ed. 2006).
9 False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. §§ 3729-33 (2000)), which, inter alia, provided for the establishment of defendant liability for “deliberate ignorance” and “reckless disregard” of the truth; restoration of the “preponderance of the evidence” standard for all elements of the claim, including damages; imposition of treble damages and civil fines of $5,000 to $10,000 per false claim; increased rewards for qui tam plaintiffs of between 15-30 percent of the funds recovered from the defendant; and payment of attorney’s fees and, employment protection for whistleblowers. See also, John T. Boese, Civil False Claims and Qui Tam Actions, § 1.04 (3d ed. 2006).
less than $5,000 and not more than $10,000 for each false claim.” 31 U.S.C. § 3729(a).

This penalty range was adjusted for inflation under the Federal Civil Monetary Penalties Inflation Act of 1990, Pub. L. No. 101-410, Title III, § 31001, and the Debt Collection Improvement Act of 1996, Pub. L. No. 104-134, to between $5,500 and $11,000 for conduct occurring after September 29, 1999, 28 U.S.C.A. § 2461 note (2002); 28 C.F.R. § 85.319 (2000). The next inflationary increase that could have been implemented under the Inflation Adjustment Act was due, according to the analysis of a General Accounting Office report, on August 30, 2003, Gen. Acct. Off., GAO-030409, Agencies Unable to Fully Adjust Penalties for Inflation Under Current Law, at 13 (Mar. 2003), but no additional penalty increase was announced by the Department of Justice by that date.

12 See 31 U.S.C. § 3730(d)(1). The FCA also provides, on a very limited basis, for the possibility for the recovery of fees and expenses by defendants who prevail. 31 U.S.C. § 3730(d)(4) (permitting prevailing defendants to recover fees and expenses if the Government does not intervene, and if the court finds that the relator’s claim was “clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.”).

31 U.S.C. § 3730(b)(1). The term “qui tam” is derived from a Latin phrase, “qui tam pro domino rege quam pro se ipso,” or “who pursues this action on our Lord the King’s behalf as well as his own.” Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 769 n.1 (2000).

14 Id. at § 3730(b)(2). In addition to serving the federal government with a copy of the complaint, a relator is required to file with the federal government before filing suit a “written disclosure of substantially all material evidence and information the [relator] possesses.” Id.

15 Id. at § 3730(b)(4)(A).

16 Id. at § 3730(b)(4)(B).

17 Id. at § 3730(c)(2)(A). See also United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F. 3d 1139 (9th Cir. 1998).

18 Id. at § 3730(c)(2)(B).

19 Id. at § 3730(d). The maximum share is increased from 25 percent to 30 percent if the Government declines to intervene and the relator succeeds in the litigation. Id.


21 United States Department of Justice, Civil Division, “Fraud Statistics — Overview: October 1, 1986 - September 30, 2008” (November 5, 2008).

22 See United States v. Medshares Mgmt. Group Inc., 400 F.3d 428, 440-445 (6th Cir. 2005) (false statements or conduct must be material to the false or fraudulent claim to hold a person civilly liable under the FCA); United States ex rel. Siwick v. Jameson Sci. and Eng’g, Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000) (requiring showing that payment would have been withheld had the government known of the defendant’s statutory violation and that “payment [was] conditioned on that certification” of compliance with the statute); United States ex rel. Ortega v. Columbia Healthcare, Inc., 240 F. Supp. 2d 8, 19 (D.D.C. 2003) (requiring showing that “if the government had known of the violation when presented with the claim for payment, it would not have paid the claim”). See also United States ex rel. Mercy v. Rowan Co., 520 F.3d 384 (5th Cir. 2008) (rejecting “capable of influencing” test in favor of more stringent materiality test).


52 Id. at § 3729(a)(1)(C).


71 Id. Moreover, the use of the term “claims” in this provision may also raise uncertainty as to whether the legislators intended retroactive application to actual cases filed as of June 7, 2008, or, as read literally, whether perhaps the drafters meant to apply this retroactive application to pending and viable FCA “claims.” The difference pertains to how far along in the process a relator or the government must have been in June of 2008 in order to get this more favorable treatment under the Act.

72 42 U.S.C. § 1395nn(g)(2).