

Client Alert

Latham & Watkins
Corporate Department

Newly Amended False Claims Act Expands Liability for Inadvertent Stark Law Violations

On May 20, 2009, President Obama signed into law the Fraud Enforcement and Recovery Act of 2009 (FERA). FERA greatly expanded the liability provisions of the False Claims Act¹ (FCA), the US government's primary tool to recover damages for fraud involving government funds. While Congress's primary motive in passing FERA appears to have been the potential for fraud by financial institutions and other entities participating in the Troubled Asset Relief Program (TARP), other entities, including healthcare providers, face increased exposure under the revised FCA. Many of the changes address and expand the types of entities and conduct subject to the FCA's reach. One change in particular—relating to the so-called "reverse false claims" provision—significantly increases the risk that a healthcare provider's failure to identify and refund overpayments resulting from inadvertent Stark Law violations will result in a liability under the FCA, creating new incentives for providers who discover such violations to repay and/or self-disclose. At the same time, the options for voluntary disclosure appear to be narrowing, creating somewhat of a dilemma for providers seeking to limit their Stark Law exposure.

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Major FERA Amendments Expanding FCA Liability

The key liability sections of the FCA include the provisions addressing false claims, false statements supporting false claims, conspiracy, and the reverse false claims and obligations provisions. Under FERA, liability provisions of the FCA remain categorically the same, but are renumbered and expanded to cover additional conduct. The new sections 3729(a)(1)(A)-(C) and (G) extend liability to any person who:

- A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- B) knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false or fraudulent claim;
- C) conspires to commit a violation of subparagraph (A), (B), (C), (D), (E), (F), or (G);
or
- G) 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.*²
[emphasis added]

Congress admittedly crafted these and other amendments to overturn several recent judicial decisions which had set limits on the scope of the FCA.³ Most notably, in the 2008 case *Allison Engine Co. v. United States ex rel. Sanders (Allison Engine)*, the Supreme Court unanimously concluded that without a clear link between a false claim and payment or approval by the government, the FCA would be “boundless” and become an “all-purpose antifraud statute.”⁴ Therefore, the Court held that FCA liability was limited to fraudulent statements that were designed to get false claims paid for or approved by the government.

To combat the Court’s limitation on the FCA’s scope, FERA includes amendments to the FCA’s requirement that false statements or records created in support of false claims must be used “to get” a false claim paid by “the Government.” The new law removes the requirement of proving that false records and statements be supplied with the “intent” of having false claims paid, as the Supreme Court required in *Allison Engine*. The amendments provide that FCA liability will now depend on whether the false record or statement was “material” to getting a false claim paid or approved. Moreover, the term “material” is newly defined as “having a tendency to influence, or be capable of influencing, the payment or receipt of money or property”⁵—a broader definition of “materiality” than had been applied in many prior FCA cases.⁶

In addition to changing the “intent” and “materiality” concepts, FERA expands the types of claims submitted to the government that can trigger FCA liability. The amendments redefine the term “claim” to include demands for money and property even if the government does not have title to the money or property. Simply stated, this means that whether the funds received from an alleged false claim are obtained directly from the United States government is not controlling.

Rather, if the funds are “spent or used on the Government’s behalf or to advance a Government program or interest,”⁷ a recipient will now be exposed to FCA liability. This would likely include payments received from Medicare administrative contractors and may expand FCA liability to claims submitted to Medicaid Advantage plans and Medicaid HMOs. Indeed, the new revisions were intended, at least in part, to dispel the notion that past court decisions can be read to restrict FCA liability from attaching to Medicaid claims.⁸ Moreover, the legislation does not define the phrase “used on the Government’s behalf or to advance a Government program or interest,” an omission which will presumably require courts to decide the meaning on a case-by-case basis.

Reverse False Claims

The FCA revisions that may have the most significant impact on the healthcare industry are the revisions to strengthen the so-called “reverse false claims” provisions. By redefining the term “obligation” to specifically include the retention of overpayments, FERA adds a new level of complexity and concern for healthcare providers.

The pre-amendment FCA established liability for a person who knowingly uses a false record or statement to conceal or avoid paying or returning government funds that it is otherwise obligated to return. Prior to the enactment of the FERA, this so-called “reverse false claim” provision required a person to take an affirmative act (using the false record or statement) toward avoiding or decreasing the obligation to the government in order to be liable. Moreover, the term “obligation” was not defined, opening the door for argument that repayment of certain overpayments was not an “obligation” for the purposes of a reverse false claim.

The amended reverse false claims liability provision in section 3729(a)

(1)(G) (quoted earlier in this *Alert*) extends liability for “knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government.” There are two important aspects of the new law embedded in the amended language: (1) there is no longer a requirement that an affirmative action be taken to conceal, avoid or decrease the obligation to the government in order to find liability; and (2) the key term “obligation” is now specifically defined to include the retention of an overpayment from the government as within the scope of FCA liability.⁹

Providers may be unintentionally overpaid by government programs in a number of different situations. Examples of such unintentional overpayments include: (1) minor clerical errors such as the transposition of billing code numbers; (2) systematic (but unintentional) billing errors such as the repeated use of an incorrect billing code or improper application of insurance coverage prerequisites; (3) amounts paid in error by fiscal intermediaries or carriers; (4) routine interim payments under a Prospective Payment System (PPS) that are reconciled through a cost report; or (5) payments made on beneficiaries referred in violation of the Stark Law where the violation is inadvertent and not known at the time the claim is submitted. Historically, these types of overpayments did not trigger FCA liability and stood in contrast to the types of fraudulent overpayments that resulted in FCA liability (*e.g.* intentional upcoding, knowingly submitting claims for services not provided, claims submitted with knowledge of underlying Stark Law violations). Post-FERA, it is possible that the retention of routine unintentional overpayments may also lead to FCA liability.

The practical effect of the amended reverse false claims provision is to impose FCA liability for any alleged failure to pay or re-pay the government based on any statutory, regulatory,

contractual or other requirements, even when the party submitting the claim did so with no fraudulent intent or there has been no prior determination that the repayment is owed to the government. Questions will necessarily arise as to the application of this expanded liability in the healthcare field. For example, certain entities, such as hospitals that receive PPS funding, routinely retain interim overpayments subject to a reconciliation process—does this knowing retention of an overpayment subject them to potential FCA liability?

The Senate Judiciary Committee report on the FERA suggests that the Senate bill’s revision was not intended to interfere with the process of routine accounting reconciliation and does not “create liability for a simple retention of an overpayment that is permitted by a statutory or regulatory process for reconciliation.”¹⁰ In accord with the Senate’s stated intention, the term “improperly” in the language of section 3729(a)(1)(G) is presumably designed to limit liability in situations such as PPS and cost report reconciliations in which an interim overpayment is issued to the provider that is later subject to year-end reconciliation through the provider’s cost report. Based on this legislative history, providers can hope that courts will apply the FERA so that overpayments repaid at the time a cost report is reconciled will not constitute improperly retained government funds. This interpretation does not, however, lessen the enhanced care and scrutiny that will now be required to determine whether an “overpayment” has been received and retained “improperly.”

Another liability trap for healthcare providers lies in the potential application of the new standard to overpayments that were received prior to the effective date of FERA. While the amendment itself does not operate retroactively, the government almost certainly will argue that the character of an overpayment is not changed merely because it was received before May 20, 2009. Thus,

the new amendments may be found to apply to overpayments made before the effective date of the amendments, so long as they are improperly retained after that date.

Increased Risk of FCA Liability for Inadvertent Stark Law Violations

The Stark Law¹¹ is a wide-ranging federal statute that prohibits physicians from making referrals for certain designated health services (DHS) payable by Medicare, to any entity with which the physicians have a non-expected financial relationship. A financial relationship is defined as either an ownership interest or a compensation arrangement and includes both direct and indirect arrangements. Unless an exception applies, a physician cannot refer, and an entity receiving a prohibited referral is prohibited from billing Medicare for the services. Because compliance with the Stark Law is a prerequisite to payment of Medicare claims, the government takes the position that amounts paid on claims submitted on prohibited referrals are overpayments. Courts have agreed.¹²

The revisions to the “reverse false claims” provisions could have a significant impact on the applicability of the FCA to violations of the Stark Law. Prior to FERA, if a healthcare provider discovered that it had a financial relationship not in compliance with the Stark Law, it would likely be exposed to statutory penalties under Stark, but the FCA would not have been implicated unless the claims were filed with knowledge of the Stark violation. After the recent revisions to the FCA, if the provider does not immediately repay the overpayment amount upon discovery of the Stark violation, it could be exposed to FCA liability under the theory that it knowingly avoided an obligation to repay an overpayment to the government.

The implications of FCA liability for Stark Law violations arises from the significant differences in the penalty structure of each law. An inadvertent violation of the Stark Law generally could lead to denial of payment for the prohibited referral and/or require refunding of any payments made.¹³ Stark itself contains penalties for the failure to refund identified overpayments, but the civil monetary penalties authorized by the Stark Law and regulation are “up to \$15,000” per claim, thus giving the government the ability to resolve the violation for something less than the maximum penalty.¹⁴ In contrast, under the new amendments, if a Stark Law overpayment were improperly retained after discovery, a finding that the conduct violates the FCA results in *mandatory* civil penalties of not less than \$5,500 and not more than \$11,000 for *each* false claim, plus *three times* the amount of the overpayment.¹⁵

FERA has fundamentally changed the landscape of repayment of funds obtained through Stark Law violations. The explicit liability created for knowing and improper retention of overpayments regardless of an affirmative false claim or statement in order to retain the payment places an inadvertent Stark Law violator squarely within the ambit of the FCA's liability structure. Thus, the interplay between FCA liability and Stark Law violations has become fraught with uncertainties that will likely remain unclear until court decisions define the scope of the new amendments.

Reducing FCA Exposure by Self-Reporting of Stark Law Violations

Another potential consequence of the increased risk of Stark Law non-compliance triggering FCA liability is the effect it will have on the decisions of hospitals and other DHS entities to self-report Stark Law violations. As a general rule, there is no statute or regulation that explicitly requires the

disclosure of a violation of the Stark Law to the government. There is, however, an explicit provision in the Stark law regulations that requires a provider to refund “on a timely basis” any amounts paid for services performed under a referral prohibited by Stark.¹⁶ Prior to FERA, because the penalty for retaining an inadvertent overpayment arguably was no greater than the amount of the overpayment itself, providers may have perceived little downside to not disclosing the incident to the government, hoping that the overpayment would never be brought to the attention of enforcement authorities. The increased FCA exposure for overpayments received as a result of inadvertent Stark Law violations has significantly complicated the decision of whether and how to self-report.

Historically, providers who discovered overpayments resulting from Stark Law violations had four options: (1) repay the overpayment to the fiscal intermediary or carrier, without necessarily disclosing the underlying violation itself; (2) self-report the violation to CMS, knowing that such a report will require full payment of the overpayment amount and may also involve civil monetary penalties; (3) self-report to the HHS Office of the Inspector General (OIG) through the OIG’s formal Self-Disclosure Protocol, which could result in a settlement for an amount less than the total overpayment amount so long as the conduct also implicated the federal Anti-kickback Statute;¹⁷ or (4) self-report to the Department of Justice or the local United States Attorney’s Office, which have the authority and ability to resolve the matter as a potential violation of the FCA.¹⁸ These options were narrowed on

March 24, 2009, when the OIG issued an Open Letter indicating that the Self-Disclosure Protocol would no longer be available to providers wishing to disclose physician arrangement matters implicating only the Stark Law (and not both Stark and the Anti-kickback Statute).¹⁹ This significantly limits the likelihood that a provider can limit its liability to something less than the amount of the overpayment.

The uncertainties regarding meaningful relief from self-disclosure need to be weighed against the risks. Under any alternative, self-disclosure necessarily provides the government with a road-map of the wrongdoing, and may result in the opening of investigations by agencies other than the one to which the disclosure is made. Self-disclosure also generally provides no meaningful protection against *qui tam* relators, as disclosure to the OIG or CMS will not bar a relator’s FCA action. And if the conduct that implicates the Stark Law also implicates the Anti-kickback Statute, there is always the worst case scenario of the Department of Justice initiating a criminal investigation.

Conclusion

The scope of FERA’s expansion of liability under the FCA may be unclear, but its theoretical impacts on Stark Law overpayments, and the uncertainty surrounding the risks and rewards of self-disclosure as a means to limit liability, suggest that each provider should familiarize itself with the new rules and consult experienced counsel before making any repayment or disclosure decisions.

Endnotes

- ¹ 31 U.S.C. §§ 3729-3733.
- ² FERA, Publ. L. No. 111-21, § 4 (May 20, 2009) [emphasis added].
- ³ See Senate Judiciary Committee (March 23, 2009) "Senate Report 111-10, part III" ("This section amends the FCA to clarify and correct erroneous interpretations of the law that were decided in *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008), and *United States ex. rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004).").
- ⁴ 128 S. Ct. 2123, 2130 (2008).
- ⁵ 31 U.S.C. § 3729(b).
- ⁶ See John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.04 (Aspen Publishers)(3d ed. & Supp. 2009-2); see also *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, 543 F.3d 1211 (10th Cir. 2008).
- ⁷ 31 U.S.C. § 3729(b).
- ⁸ See Senate Judiciary Committee Report, *supra* at 11 (The revisions in § 3729(a)(2) were intended to clarify that FCA liability extends to "all false claims submitted to State administered Medicaid programs").
- ⁹ The new law defines an "obligation" to pay or repay government funds as a situation when there is an "established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, form a fee-based or similar relationship, from statute or regulation, or from the retention of *any overpayment.*" U.S.C. § 3729(b) [emphasis added].
- ¹⁰ Senate Judiciary Committee Report 111-10, "Fraud Enforcement and Recovery Act of 2009," p. 15 (Mar. 23, 2009)
- ¹¹ 42 U.S.C. §1395nn.
- ¹² See, e.g., *United States ex. rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 238 F. Supp. 2d 258, 266 (D.D.C. 2002) (indicating that the Stark Law explicitly states "that compliance is required in order to receive Medicare reimbursement").
- ¹³ See 42 U.S.C. §§ 1395nn(g)(1)-(2); 42 C.F.R. §411.353(d).
- ¹⁴ See 42 U.S.C. §1395nn(g)(3); 42 C.F.R. §1003.102(b)(9).
- ¹⁵ See 31 U.S.C. § 3729(a).
- ¹⁶ See 42 CFR §411.353(d).
- ¹⁷ See Department of Health and Human Services, *An Open Letter to Health Care Providers* (Apr. 24, 2006).
- ¹⁸ Note that the DOJ is likely to take the position at least initially that it will resolve the matter for no less than double damages. The FCA contains a voluntary disclosure provision which provides that penalties will be limited to double the government's damages stemming from the violation, rather than the treble damages otherwise available, if the disclosure is made to the DOJ within 30 days after discovery of the violation. 32 U.S.C. §3729(a).
- ¹⁹ Department of Health and Human Services, *An Open Letter to Health Care Providers* (Mar. 24, 2009).

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