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Feature Article

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The Rise of the "Reverse" False Claim And Proposed Rules from CMS on Reporting and Returning Overpayments

While providers enrolled in federal government healthcare programs have long reconciled and returned overpayments through various ongoing and post-payment audit and self-disclosure mechanisms, Congress has enacted laws and the Centers for Medicare and Medicaid Services (CMS) has proposed a set of rules that have *incredible* and *immediate* implications with respect to a provider's obligation to expeditiously identify and return government overpayments in order to avoid *significant* liability under the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733. This article details the evolution of the FCA to encompass a provider's retention of government overpayments, Congress's new 60-day deadline to report and return government overpayments, and proposed rules from CMS that could forever change the manner in which hospitals investigate and report government overpayments.

False Claims Act Background

The FCA has long been recognized by its supporters as the single most effective tool the United States has to combat fraud being perpetrated against the government. The United States Supreme Court has noted that the FCA is "the primary vehicle [used] by the Government for recouping losses suffered through fraud." *Vt. Agency of Natural Res. v. U.S.* ex rel. *Stevens*, 529 U.S. 765, 792 (2000) (quoting H.R. Rep. No. 99-660, at 18 (1986)). The FCA was enacted by Congress in 1863 at the behest of President Abraham Lincoln to redress fraud being perpetrated against the Union Army during the Civil War. S. Rep. No. 99-345, at 8-10 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5273-75. The FCA, sometimes referred to as "Lincoln's Law," was enacted so the government could "recover monies from unscrupulous contractors who sold the Union Army decrepit horses and mules in ill health, faulty rifles and ammunition, and rancid rations and provisions." Press Release, U.S. Dep't of Justice, Justice Department Celebrates 25th Anniversary of the False Claims Act Amendments of 1986 (Jan. 31, 2012), *available at* http://www.justice.gov/opa/pr/2012/January/12-ag-142.html (last visited October 21, 2013).

Between 1986 and 2012, civil lawsuits filed pursuant to the FCA have allowed the federal government to recoup more than $33 billion from fraud perpetrators. U.S. Dep't of Justice, Civil Div., Fraud Statistics – Overview, October 1, 1987 - September 30, 2012 (Oct. 24, 2012), *available at*

http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf (last visited Oct. 21, 2013). Between 2008 and 2012 alone, the United States Department of Justice (DOJ) reported an increase of 268 FCA lawsuits and $2.3 billion in FCA recovery. *Id*. The influx of FCA lawsuits and recovery has come by way of recent congressional amendments that have strengthened FCA enforcement actions and by the formation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT). A combination of Medicare Fraud Strike Force teams spread throughout the United States, HEAT was created in 2009 by United States Attorney General Eric Holder and Health and Human Services Secretary Kathleen Sebelius for purposes of improving coordination of FCA enforcement. Since the formation of HEAT, DOJ has utilized the FCA to collect more than $9.5 billion in federal health care funds. Press Release, U.S. Dep't of Justice, Justice Department Recovers Nearly $5 Billion in False Claims Act Cases in Fiscal Year 2012 (Dec. 4, 2012), *available at* http://www.justice.gov/opa/pr/2012/December/12-ag-1439.html (last visited Oct. 21, 2013).

The FCA provides for both civil and criminal penalties assessed against those who are found to have submitted a false claim to the government knowingly. The FCA, also referred to as a "whistleblower" statute, permits a private individual called a "Relator" to file a lawsuit in the name of and on behalf of the United States government against an entity or individual whom the Relator believes is perpetrating fraud against the United States government. If the Relator's lawsuit, characterized as a "*qui tam*"[1] lawsuit, is successful, the Relator is entitled to an award of up to 30 percent of the judgment or settlement,[2] plus costs and attorneys' fees. See 31 U.S.C. § 3730(d)(2).

Congress's 1986 Amendments

The FCA has been the subject of significant congressional amendments since its enactment in 1863, the most significant of which came by way of Congress's 1986 amendments. Among the significant changes the 1986 amendments made to the FCA were the increased financial incentive for whistleblowers to file *qui tam* lawsuits from 15 percent to 30 percent and the added whistleblower protections to prevent retaliation by the whistleblower's employer. The 1986 amendments also clarified that the FCA extends liability to false claims designed to decrease an obligation to pay or to transmit money or property to the government. H.R. Rep. 99-660, at 29 (1986). Classified as a "reverse" false claim theory of liability, the Senate Judiciary's Committee's Report on the 1986 Amendments stated the following:

[T]he subcommittee added a clarification that an individual who makes a material misrepresentation to avoid paying money owed the Government should be equally liable under the Act as if he had submitted a false claim. The Justice Department testified that recent court rulings have produced an ambiguity as to whether such "reverse false claims" were covered by the False Claims Act, and the subcommittee agreed that such matters should be addressable under the Act.

S. Rep. No. 99-345, at 14 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5280.

As a result of the 1986 amendments, the FCA extended liability to any person or entity that "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an *obligation* to pay or transmit money or property to the Government." Pub. L. No. 99-562, § 2, 100 Stat. 3153 (1986) (codified at 31 U.S.C. § 3729(a)(7)) (emphasis added). Since its inception, this theory of FCA liability has been characterized as a "reverse" false claim "because it is designed to [re]cover Government money or property that is knowingly retained by a person even though they have no right to it." S. Rep. No. 111-10, at 13-14 (2009), *reprinted in* 2009 U.S.C.C.A.N. 430, 441.

After the 1986 amendments, plaintiffs relying on the "reverse" false claim theory of FCA liability were stifled with inconsistent and unpredictable rulings due, in large part, to the fact that the FCA did

not define the term "obligation." In a commonly cited case addressing this issue, the United States Court of Appeals for the Sixth Circuit in *U.S.* ex rel. *American Textile Manufacturers Institute, Inc. v. The Limited, Inc.*, 190 F.3d 729, 736 (6th Cir. 1999), concluded that "a reverse false claim action cannot proceed without proof that the defendant made a false record or statement at the time the defendant owed to the Government an obligation sufficiently certain to give rise to an action of debt at common law." According to the *American Textile* court, FCA liability did not extend to "[c]ontingent obligations—those that will arise only after the exercise of discretion of government actors." *U.S.* ex rel. *Am. Textile Mfrs. Inst., Inc.*, 190 F.3d at 738. The Sixth Circuit's opinion in *American Textile* was consistent with similar holdings out of the United States Courts of Appeal for the Eighth, Tenth, and Eleventh Circuits that interpreted "obligation" to mean "a fixed sum" or "independent legal duty" to pay an amount that is "immediately due." See, *e.g., U.S.* ex rel. *Bahrani v. Conagra, Inc.*, 465 F.3d 1189 (10th Cir. 2006) (holding that, for there to be FCA liability, the defendant must have an *independent legal duty* to pay the government at the time the false statement is made); *United States v. Q Int'l Courier, Inc.*, 131 F.3d 770, (8th Cir. 1997) (holding that, for there to be FCA liability, the obligation "must be for a fixed sum that is immediately due"); *United States* ex rel. *Bain v. Georgia Gulf Corp.*, 386 F.3d 648, 657 (11th Cir. 1997) ("[T]he reverse false claims act does *not* extend to the potential or contingent obligations to pay the government fines or penalties which have not been levied or assessed . . . and which do not arise out of an economic relationship between the government and the defendant . . . under which the government provides some benefit to the defendant wholly or partially *in exchange* for an agreed or expected payment . . . to . . . the government." (emphasis in original)).

Despite Congress's attempt to broaden the "reverse" false claims theory to encompass instances where an individual "makes a material misrepresentation to avoid paying money owed the Government," S. Rep. No. 99-345, at 15, 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5280, 5283, the theory was significantly weakened by courts instituting a narrow interpretation of "obligation." As a result, DOJ lobbied Congress for an amendment to define "obligation" in such a way "that would correct those cases that unduly narrowed the reverse false claim provision by holding or suggesting that the term "obligation" encompasses only a duty to pay that is fixed in all particulars, including the specific amount owed." Letter from M. Faith Burton, Acting Assistant Attorney General, U.S. Dep't of Justice, to Sen. Patrick Leahy, Chairman, Senate Comm. on the Judiciary, Appendix (April 1, 2009) (copy on file with author). DOJ further sought to clarify that reverse false claim liability exists "without any additional requirement of a false statement or record." *Id.* That is, an individual or entity can be held liable for the act of knowingly retaining government funds to which the individual or entity is not entitled without having to actually present a claim for government reimbursement.

FERA: Congress Attempts to Resolve the "Obligation" Paradox

On May 20, 2009, Congress enacted the Fraud Enforcement Recovery Act of 2009 (FERA). Pub. L. No. 111-21, 123 Stat. 1617 (2009). Among other things, FERA significantly amended the FCA by defining "obligation" to mean "an established duty, *whether or not fixed*, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." Pub. L. No. 111-21, § 4, 123 Stat. 1617 (2009) (codified at 31 U.S.C. § 3729(b)(3)) (emphasis added). According to the Senate Judiciary Committee, the term "obligation" is meant to encompass "the fixed amount debt obligation where all particulars are defined to the instance where there is a relationship between the Government and a person that 'results in a duty to pay the Government money, whether or not the amount owed is yet fixed.'" S. Rep. No. 111-10, at 14 (2009) (quoting Brief for United States at 24, *United States v. Bourseau*, No. 06–56741, 06–56743 (9th Cir. July 14, 2008)), *reprinted in* 2009

U.S.C.C.A.N. 430, 441. In plain terms, regardless of whether a government overpayment has been quantified, a provider's knowledge of the overpayment gives rise to FCA liability under a "reverse" false claims theory approach. That is, a provider knowingly retaining a government overpayment, by itself, gives rise to FCA liability.

According to the Senate Judiciary Committee's Report (the Report), the inclusion of "retention of an overpayment" into the definition of "obligation" was supported by DOJ. *Id.* at 15. In fact, DOJ took an active role during the drafting stages of FERA when it strongly encouraged Congress to include "overpayment" in the definition of "obligation." Letter from Brian Benczkowski, Principal Deputy Assistant Attorney General, U.S. Dep't of Justice, to Sen. Patrick Leahy, Chairman, Senate Committee on the Judiciary, Appendix 3 (Feb. 21, 2008), cited in S. Rep. No. 111-10, at 15. According to the Report, a "reverse" false claim violation is committed "once an overpayment is knowingly and improperly retained, without notice to the Government about the overpayment." S. Rep. No. 111-10, at 15 (2009), *reprinted in* 2009 U.S.C.C.A.N. 430, 442. The Report noted, however, that FCA liability is not designed to encompass cases where there exists statutory or regulatory processes for reconciliation, "provided the receipt of the overpayment is not based upon any willful act of a receipt to increase the payments from the Government" to which the recipient was not entitled. *Id.*

PPACA: Congress Injects a 60-Day Timeline to Report and Refund Overpayments

Not even a year after it passed FERA, Congress enacted the Patient Protection and Affordable Care Act of 2010 (PPACA), Pub. L. 111-148, 124 Stat. 119 (2010), and Health Care and Education Affordability Reconciliation Act, Pub. L. 111-152, 124 Stat. 1029 (2011) (collectively referred to as "PPACA"). Specifically, on March 23, 2010, Congress injected a 60-day timeline upon which providers and suppliers (hereinafter "providers") receiving government funds, such as Medicare and Medicaid reimbursements, must report and refund government "overpayments" they have received. According to Section 6402 of PPACA:

An overpayment must be reported and returned . . . by the later of --

(A) the date which is 60 days after the date on which the overpayment was identified; or

(B) the date any corresponding cost report is due, if applicable.

42 U.S.C. § 1320a-7k(d)(2).

PPACA was clear that an overpayment retained after the deadline for reporting and returning an overpayment is considered an obligation, 31 U.S.C. § 3729(b)(3), for purposes of "reverse" false claims liability under the FCA. To avoid inconsistent, narrow interpretations of the term "overpayment," Congress broadly defined "overpayment" to mean "any funds that a person receives or retains under" Medicare or Medicaid to which the person, "after applicable reconciliation, is not entitled." 42 U.S.C. § 1320a-7k(d)(4)(B). Interestingly, Congress did not define or clarify the phrase, "after applicable reconciliation." Presumably, Congress was accounting for the sophisticated cost report and multifaceted reconciliation processes associated with Medicare that can take months, if not years, to elicit a fixed or final amount in what CMS owes to the provider or what the provider owes to CMS for a benefit year.

Nevertheless, after the enactment of PPACA, all health care providers receiving Medicare or Medicaid funds are required to "report" and "refund" any overpayments within 60-days from the date the overpayment is "identified" or within 60-days after the due date of any applicable cost report. Uncharacteristically, it took CMS almost two years to develop its much-anticipated proposed

regulations interpreting PPACA. Having failed to finalize two previous sets of proposed rules relating to CMS's ability to recover overpayments in 1998, 63 Fed. Reg. 14506 (Mar. 25, 1998), and 2002, 67 Fed. Reg. 3662 (Jan. 25, 2002), PPACA reinvigorated CMS's strive to reduce fraud, waste, and abuse in the Medicare and Medicaid programs.

Proposed Regulations from CMS: More Questions than Answers

On February 16, 2012, CMS published in the Federal Register a set of proposed rules, establishing a new Subpart D in Part 401 of Title 42 of the regulations and interpreting PPACA's requirement that providers timely report and return Medicare and Medicaid overpayments. 77 Fed. Reg. 9179-02 (Feb. 16, 2012). Among other things, CMS sought to clarify and define PPACA's key terms, such as when an overpayment is "identified" and the 60-day "reporting and returning" timeline. Although CMS limited the scope of its proposed rules to those providers and suppliers that participate in Medicare Part A and Part B, CMS stated that it intended to address other stakeholders, such as Medicare Advantage organizations (MAO), Medicare prescription drug plans (PDP), and Medicaid managed care organizations (MCO), at a later date. 77 Fed. Reg. 9179-02, 9180 (Feb. 16, 2012). Notwithstanding the limited scope of it proposed rules, CMS cautioned that all providers are obliged to comply with the overpayment procedures set forth in PPACA. *Id.* at 9181.

"Identified"

With respect to when an overpayment is "identified," CMS proposed that "a person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard to deliberate ignorance of the overpayment." *Id*. at 9182. CMS sought to mirror the FCA's definition of the terms "knowing" and "knowingly," explaining that the term "identified" should be interpreted in such a way as to give providers "an incentive to exercise reasonable diligence to determine whether an overpayment exists." *Id.* Without such an incentive, the fear was that providers would "avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research." *Id.*

Unfortunately, CMS was silent on the issue of whether there is a monetary threshold upon which an overpayment has been "identified" and, thus, must be reported and returned. CMS has focused on the *existence* of the overpayment, not on the *amount* of the overpayment. This point is key in that, presumably, the 60-day clock starts upon the awareness or deliberate indifference of the *existence* of an overpayment—even if the provider has not had the ability to quantify the *amount* of the overpayment. This glaring omission from CMS begs the question as to what providers are to do when they have identified the *existence*, but not the *amount*, of an overpayment. Until the provider can quantify the amount of the overpayment, providers should contact the entity to which they will inevitably submit their report and refund and describe their efforts to identify the amount of overpayment.

Reporting and Returning Deadlines

In cases where an overpayment is "identified," CMS proposed a regulation identical to that which was set forth in PPACA, wherein an overpayment must be reported and returned by the later of: "(A) the date which is 60 days after the date on which the overpayment was identified; or (B) the date any corresponding cost report is due, if applicable." 42 U.S.C. § 1320a-7k(d)(2)(A)-(B). CMS explained that if the overpayment is "claims-related," the provider is required to report and return the overpayment within 60 days of identification. If the claims-related overpayment is one that is typically reconciled on the provider's cost report, on the other hand, CMS stated that the provider is permitted

to report and return the overpayment by the later of: (A) 60 days from the identification of the overpayment, or (B) 60 days from the date the cost report is due. 77 Fed. Reg. 9179-02, 9182 (Feb. 16, 2012). CMS cautioned that providers should not attempt to delay their reporting and returning claims-related overpayments by waiting until their cost reports are due.

In further explanation of a provider's obligations under PPACA, CMS theorized that there might be instances where a provider receives information that it has potentially received an overpayment. In such cases, CMS stated that providers have an obligation to undertake a "reasonable inquiry" with "deliberate speed" to determine whether the overpayment exists. *Id.* If, after receiving a notification of a potential overpayment, the provider fails to undertake a "reasonable inquiry," such a failure "could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment." *Id.* CMS provided an example for further illustration, wherein a provider received an anonymous compliance hotline telephone complaint about a potential overpayment that the provider received. According to CMS, so long as the provider "diligently conducts the investigation" and "reports and returns any resulting overpayments" within 60 days, the provider would satisfy its obligations under the rules proposed by CMS. *Id.* If the provider failed to investigate the complaint, the provider "may be found to have acted in reckless disregard or deliberate indifference of any overpayment" in violation of the FCA. *Id.*

To further illustrate, CMS provided a series of examples of when a provider has an affirmative duty to investigate and return overpayments, including the following:

- A provider . . . reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement.

. . . .

- A provider of services . . . performs an internal audit and discovers that overpayments exist.

- A provider . . . is informed by a government agency of an audit that discovered a potential overpayment, and the provider . . . fails to make a reasonable inquiry.

Id.

According to the rules proposed by CMS, once an overpayment is identified, the provider is expected to send a written report to the Department of Health and Human Services, or an intermediary, carrier, or contractor, and provide an explanation of why it has received an overpayment. 77 Fed. Reg. 9179-02, 9181 (Feb. 16, 2012). CMS proposed adopting the "self-reported overpayment refund process" currently in place for reporting Medicare overpayments. CMS instructed providers to obtain forms available on each Medicare Administrative Contractor's website and to provide sufficient information to allow the contractor to identify the affected claims. *Id.* Among other things a provider must report, the provider must summarize the following information: (1) the way in which the error was discovered; (2) a description of the corrective action plan that was implemented to ensure that the error does not occur again; (3) a refund in the same amount as the overpayment; and (4) if the overpayment amount was determined using a statistical sample, a description of the statistically valid methodology used in the determination of the overpayment. *Id.*

In connection with its proposed rules, CMS anticipated that there most certainly will be intersections between the 60-day deadline to report and return overpayments and the existing procedures for providers to self-disclose actual or potential violations to CMS through a Medicare Self-Referral Disclosure Protocol (SRDP) mechanism.[3] CMS proposes that a providers' obligation to *return* overpayments would be suspended when CMS acknowledges receipt of a disclosure made pursuant to a SRDP mechanism. *Id*. at 9182-83. To be clear, the proposed rule from CMS does not suspend a provider's obligation to *report* overpayments within the 60-day deadline. CMS proposed a similar suspension of a provider's obligation to *return* overpayments when the Office of Inspector

General (OIG) acknowledges receipt of a submission pursuant to the OIG Self-Disclosure Protocol (SDP), which is a procedure that providers currently utilize to report self-discovered evidence of potential fraud. Unlike SRDP, however, CMS proposed that once the provider notifies OIG through the use of a SDP, such notice satisfies the "report" for purposes of the 60-day deadline. *Id*. at 9183.

10-Year Look-Back Period

As a final note, CMS proposed that overpayments must be reported and returned if a person identifies the overpayment within 10 years of the date the overpayment was received. *Id*. at 9184. CMS chose 10 years "because this is the outer limit of the False Claims Act statute of limitations." 77 Fed. Reg. 9179-02, 9184 (Feb. 16, 2012); see also 31 U.S.C. §3731(b) (providing that a civil action arising under the FCA may not be filed under Section 3730 more than six years after a Section 3729 violation occurred, or no more than three years after the responsible U.S. official knew or should have known of the facts material to the cause of action, but in any event may not be brought more than 10 years after the date of the violation giving rise to the claim, whichever is later). The rule proposed by CMS would amend 42 C.F.R. §405.980(b), wherein there exists a one-year claims reopening period for "any reason" and a four-year reopening period for "good cause." Under the existing regulations, Medicare claims can be reopened only after four years "if there exists reliable evidence . . . that the initial determination was procured by fraud or similar fault." *Id.* § 405.980(b)(3). Under the rule proposed by CMS, overpayments may be reopened for a period of 10 years after their submission. 77 Fed. Reg. 9179-02, 9184 (Feb. 16, 2012).

A critical issue that remains unclear is whether rules proposed by CMS will encompass overpayments identified *before* March 23, 2010–PPACA's effective date. That is, CMS was silent as to whether providers are obligated to undertake reasonable inquiries to identify potential overpayments for the last 10 years of government reimbursement or whether the 10-year period began on March 23, 2010. If courts follow the holding set forth in *U.S.* ex rel. *Stone v. Omnicare, Inc.*, No. 09 C 4319, 2011 WL 2669659 (N.D. Ill. July 7, 2011), providers will *not* be held liable for overpayments identified before the enactment of FERA and PPACA. As of this writing, the *Stone* court is the *only* court to address whether providers have an ongoing obligation to report and return Government overpayments identified *before* the enactment of FERA and PPACA.

Significant Exposure: Penalties for Failure to Report and Return Overpayments

If a provider fails to report and return a government overpayment within the 60-day timeframe contemplated by PPACA, the provider could face liability under the FCA and under the Civil Monetary Penalties Law (CMPL) statute. With respect to the FCA, the theory of liability associated with the provider's knowing retention of a government overpayment resides in 31 U.S.C. § 3729(a)(1)(G). If a provider is found to have violated the FCA, the provider could face damages up to three times the amount of single damages (the *actual* amount of damages suffered by the government), between $5,500 and $11,000 for *each* false claim, and reasonable attorney's fees and costs associated with instituting and litigating the FCA enforcement action. *Id.* § 3729(a)(1).

PPACA also amended the CMPL to extend liability to instances where a provider "knows of an overpayment . . . and does not report and return the overpayment" as required by PPACA's 60-day rule. 42 U.S.C. §1320a-7a(a)(10). If a provider is found to have violated the CMPL, the CMPL provides for a civil monetary penalty of three times the total amount of reimbursement the provider received without regard to whether the provider was lawfully entitled to a portion of the proceeds. *Id.* In addition, the CMPL provides for varying administrative civil penalties for *each* false claim and possible exclusion from Medicare. *Id.*

Conclusion

While the rules proposed by CMS are not yet final, PPACA's 60-day deadline for reporting and returning government overpayments has been the law since March 23, 2010. In light of the significant exposure providers will encounter if found liable under the FCA or CMPL, providers should *immediately* institute policies and procedures to field any potential complaints with respect to potential Medicare overpayments, including the manner in which the complaints are to be handled and who is responsible for conducting the investigation. To substantiate that the provider undertook a "reasonable inquiry" as contemplated by CMS, providers should record the identities of the employees undertaking the investigation and the information they gather.

Finally, as the number of healthcare *qui tam* lawsuits and whistleblower rewards rise with each passing year, providers should familiarize themselves with the latest Medicare statutes, regulations, and CMS publications and bulletins relating to billing requirements and consider integrating their legal team with their internal audit or accounting team to routinely perform statistically valid reviews to ensure compliance with these billing requirements. As a result of CMS indicating in its proposal that it expects 8.5% of the total number of Medicare providers to report three to five overpayments per year, providers should be wary of failing to report *any* overpayments in a benefit year.

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[1] The term "*qui tam*" is short for the Latin phrase "*qui tam pro domino rege quam pro se ipso in hac parte sequitur*," which means "who pursues this action on our Lord the King's behalf as well as his own." *Vt. Agency of Natural Res. v. U.S.* ex rel. *Stevens*, 529 U.S. 765, 769 n.1 (2000).

[2] If the United States government intervenes and proceeds with the lawsuit brought by a Relator, the Relator is entitled to at least 15 percent but not more than 25 percent of the judgment or settlement. 31 U.S.C. § 3730(d)(1). If the United States government does *not* intervene, the Relator is entitled to at least 25 percent but not more than 30 percent. 31 U.S.C. § 3730(d)(2).

[3] The Stark Law, codified at 42 U.S.C. § 1395nn, is a strict liability statute that prohibits a physician from referring Medicare patients to an entity for the furnishing of "designated health services" if the physician or an immediate family member of the physician has a "financial relationship" with the entity, unless an exception applies. If a claim in violation of the Stark Law is submitted to and paid by the government, the submitting provider could be subject to, among other sanctions, liability in the amount of any payment collected and civil penalties in the amount of $15,000 per service. 42 U.S.C. § 1395nn(g)(2). The Self-Referral Disclosure Protocol (SRDP) allows providers to self-disclose to CMS or the Office of the Inspector General actual or potential violations of the Stark Law in order to have any chance of seizing the possibility of reducing the amount of liability exposure. See 42 C.F.R. § 411.361. Once a provider makes a SRDP disclosure and CMS acknowledges receipt of the same, CMS suspends the provider's obligation, pursuant to 42 U.S.C. § 1320a-7k(d)(2)(A), to return the overpayment within 60 days until a settlement agreement is entered, the provider of services or supplier withdraws from the SRDP, or CMS removes the provider of services or supplier from the SRDP. CMS Voluntary Self-Disclosure Protocol, OMB Control Number: 0938-1106, *available at* http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf (last visited Oct. 29, 2013).

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