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HEALTH LAW ANALYSIS
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Modern False Claims Act Liability: Cradle to Grave Liability?—Part I

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I. INTRODUCTION

As corporations are increasingly discovering, there are myriad federal and state statutes and regulations governing corporate activities across a multitude of industries, not the least of which is healthcare. When corporations receive federal funds, those corporations may well have absorbed additional exposure. Specifically, the reach of the modern federal False Claims Act (FCA), the federal government's primary civil tool for purported fraud involving government-funded programs, has expanded to result in potential liability not only for virtually any alleged violation of a federal or state statute or regulation, but also for allegations of improper awards of contracts (in the first instance) as well as deficient contract performance during the duration of the contract.[1] Accordingly, there is potential "cradle to grave liability" under the modern FCA, namely, from the very inception of the receipt of federal funds until termination of participation in a federally funded program. Parties in FCA actions, as well as virtually every company involved in government-funded programs (such as hospitals, healthcare providers, pharmaceutical manufacturers, and prescription benefit managers), must understand the expanding theories of liability under the FCA.

Given the breadth of this subject, this article will be presented as a two-part series. After a brief overview of FCA liability principles, the first part of this discussion will offer an in-depth survey of FCA theories of liability based on fraudulent inducement of a contract and on false certification of compliance with federal or state law. The second part in this series, which will appear in next month's issue, will conclude the discussion by examining the other major FCA theories of liability including for providing "worthless services," for inadequate quality of care, for off-label uses of prescription drugs, and for failure to comply with contract requirements.

II. GENERAL PRINCIPLES OF FCA LIABILITY

The FCA simply states that there is liability for anyone who:

- knowingly presents, or causes to be presented . . . a false or fraudulent claim for payment or approval;
- knowingly makes, uses, or causes to be made or used, a record or statement to get a false or fraudulent claim paid or approved by the Government; or
- 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.

31 U.S.C. § 3729(a)(1), (2), (7) (2006).[2] The critical question, however, is which theories of liability may be used in FCA cases to impose liability. The answer to that question is not merely an academic exercise. If liability is established under the FCA, a person may be liable for a civil penalty of not less than $5,500 and not more than $11,000, *in addition* to "3 times the amount of damages that the Government sustains because of the act of that person[.]" 31 U.S.C. § 3729(a) (emphasis added), *amended by*, 28 C.F.R. § 85.3(a)(9) (2006).

In the past, FCA litigation primarily centered on the submission of individual claims or invoices for payment for particular products or services provided to the government. Recently, the government's focus has shifted to an analysis of the entire relationship with a government

program, including the circumstances under which a contract was awarded (including any misrepresentations as to quality or capabilities). In addition, a detailed examination often will be undertaken as to a potential defendant's express or implied certifications of compliance with a contract.

As a result, unbeknownst to many practitioners, providers, and healthcare corporations, the potential theories of liability under the FCA have expanded well beyond what one typically would expect from phrases such as "false or fraudulent claim." The Supreme Court has construed broadly what constitutes a claim under the Act, noting that "[t]his remedial statute reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money." *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968). Accordingly, the Supreme Court has found that the FCA was "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Id.* at 232; *see also Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 124 (2003). As a result, theories of liability have arisen that encompass every aspect of performance under a government-funded program.

III. FCA THEORIES OF LIABILITY

While courts have addressed a variety of liability theories under the FCA, there are certain major theories of liability to be considered in connection with almost any modern FCA case. Each of these will be discussed in turn below and in the second part of this article appearing next month.

A. FCA Liability Based on Fraudulent Inducement of a Contract

The very inception of a contractual relationship involving a government-funded program may ultimately form the basis of a claim under the FCA. Specifically, FCA liability may be premised on conduct that occurred prior to the beginning of the contractual relationship because liability has been extended under the FCA to contracts allegedly induced by fraud. In *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 542 (1943), the United States held that contractors were liable for claims submitted under government contracts that were obtained via collusive bidding. In *Marcus*, the Supreme Court held that each claim submitted under the contract was a false or fraudulent claim:

> This fraud did not spend itself with the execution of the contract. Its taint entered into every swollen estimate which was the basic cause for payment of every dollar paid by the [government] . . . . The initial fraudulent action and every step thereafter taken, pressed ever to the ultimate goal—payment of government money to persons who had caused it to be defrauded.

Id. at 543-44. Following the *Marcus* decision, courts have recognized a claim for "fraud in the inducement" of a contract. As stated by the U.S. Court of Appeals for the Fourth Circuit: "[C]ourts, including the Supreme Court, [have] found False Claims Act liability for each claim submitted to the government under a contract, when the contract or extension of government benefit was obtained originally through false statements or fraudulent conduct." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787 (4th Cir. 1999).

Accordingly, FCA liability exists "when a contract was originally obtained based on false information or fraudulent pricing." *Id.* at 787-88 (describing past cases); *see also United States ex rel. Bettis v. Odebrecht Contractors of Cal. Inc.*, 393 F.3d 1321, 1326 (D.C. Cir. 2005) ("[C]ourts have employed a 'fraud-in-the-inducement' theory to establish liability under the Act for each claim submitted to the Government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves."); *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 384 (5th Cir. 2003) ("FCA liability has in certain cases been imposed when the contract under which payment is made was procured by fraud."); *United States ex rel. Schweedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) (noting possibility of claim for fraud in the inducement based on "an initial misrepresentation about [the defendant's] capability to perform the contract . . . and that this original misrepresentation tainted every subsequent claim made in relation to the contract . . ."); *United States ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 439 (E.D. Pa. 2004) ("Medco was required to submit certifications of its performance which were used to assess contractual penalties and to determine whether its contract with Blue Cross would be renewed. To the extent that these certifications were false, they could have fraudulently induced Blue Cross to renew its contract with Medco."); *United States ex rel. Wilkins v. North American Constr. Corp.*, 173 F. Supp. 2d 601, 624 (S.D. Tex. 2001) ("A claim may be 'false' even if it is literally true, if the claimant previously made misrepresentations or omissions or committed misconduct in order to induce the government to enter into the contract in the first place."). FCA liability, therefore, may be imposed based on a claim of fraudulent inducement of a government-funded contract.

Potential liability for a fraudulent inducement claim can be staggering. Courts have enunciated a simple and straightforward measure of damages—every claim submitted by a defendant in connection with a fraudulently

induced contract is false or fraudulent. *See, e.g., Oddbrecht*, 393 F.3d at 1326 ("'[F]raud-in-the-inducement' theory [of liability] establish[es] liability under the Act for each claim submitted to the Government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves."); *Harrison*, 176 F.3d at 787 ("[C]ourts, including the Supreme Court, found False Claims Act liability for each claim submitted to the government under a contract, when the contract or extension of government benefit was obtained originally through false statements or fraudulent conduct."); *see also North American Constr. Corp.*, 173 F. Supp. 2d at 631-62 ("The false statements or fraudulent conduct originally used to obtain the contract render the ensuing claims for payment false or fraudulent, even if those claims contain no false statements."); *United States ex rel. Atkinson v. Pennsylvania Shipbuilding Co.*, No. Civ. A. 94-7316, 2000 WL 1207162, at *8 (ED. Pa. Aug. 24, 2000) ("[U]nder the FCA, a government contractor is liable for every claim submitted under a contract if the contract was fraudulently obtained, even if the work is performed to government specifications and at the agreed price."). In FCA cases, therefore, parties must analyze in detail the circumstances underlying the award of a contract in the first instance to determine whether a claim based on fraud in the inducement might be pursued as an FCA theory of liability.

Any analysis of a fraud in the inducement theory of liability will involve a detailed review of the response to a request for proposal (or similar documentation) submitted to a government-funded program where an entity typically represents its qualifications and capabilities as well as its past performance. The accuracy of those representations (as well as whether those particular representations were critical in the award of any contract) may well determine potential FCA liability. Therefore, the theory of fraud in the inducement may be explored as a claim that strikes at the core of any contractual relationship with the government.[3]

B. FCA Liability Based on False Certification of Compliance with Federal or State Law

The most recent developing theory of FCA liability is the "false certification" theory. Although this theory arises in innumerable contexts, at its core, it is based on an assertion that FCA liability should exist because a party provided a "false certification" of compliance with federal law, state law, or contractual requirements.

In general, the "false certification" theory of liability has two separate aspects—the "factually false" theory and the "legally false theory." The "factually false" theory is more straightforward because it "involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001). The "factually false" theory, by its plain meaning, applies where a defendant falsely claims to have provided the product or service at issue.

In contrast, the "legally false" certification theory "is predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term." *Id.* at 696. The "legally false" certification theory is further divided into two additional types of certifications, namely, "express false certification" and "implied false certification." As stated by the U.S. Court of Appeals for the Second Circuit: "An expressly false claim is, as the term suggests, a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Id.* at 698. In contrast: "An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id.* at 699; *see also United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 414 (6th Cir. 2002) (recognizing implied false certification theory); *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 433-34 (Fed. Cl. 1994) (same), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995).

A false certification of charges under a federally funded contract, therefore, may give rise to liability under the FCA. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004) ("[A] false certification of compliance [with applicable law] creates liability [under the FCA] when certification is a prerequisite to obtaining a government benefit.") (modification in original) (citation omitted). As stated by the U.S. Court of Appeals for the Fourth Circuit in *Harrison*:

> A number of courts in a variety of contexts have found violations of the False Claims Act when a government contract or program required compliance with certain conditions as a prerequisite to a government benefit, payment, or program; the defendant failed to comply with those conditions; and the defendant falsely certified that it had complied with the conditions in order to induce the government benefit.

Harrison, 176 F.3d at 786; *see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1998) ("Thus, where the government has conditioned payment of a claim upon a claimant's certifi-

cation of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation.").

Regardless of whether the theory of "express certification" or "implied certification" is pursued, it may well be a distinction without a difference. Certification liability may only prove to be a viable theory if the Government can establish by a preponderance of the evidence that payment was conditioned on compliance with the statute or regulation that was the subject of the allegedly false certification. *See, e.g., United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 441 (3d Cir. 2004) ("The 'certification theory' of FCA liability is based on a false representation of compliance with a contract term, statute or regulation—when payment is conditioned on compliance with that requirement."); *see also Mikes*, 274 F.3d at 697 ("[A] claim under the [FCA] is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment."); *United States ex rel. Siewick v. Jamieson Sci. and Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) ("[A] false certification of compliance with a statute or regulation cannot serve as the basis for a *qui tam* action under the FCA unless payment is conditioned on that certification."). Simply stated,

> a defendant's false certification of adherence to a statute or regulation, standing alone, cannot form the basis of an FCA claim. Rather, such certification of statutory/regulatory compliance must be a prerequisite to governmental payment. In other words, where a defendant's 'alleged noncompliance would not have influenced the government's decision to pay,' the failure to comport with the regulations cannot serve as the basis for an FCA claim.

United States ex rel. Taylor v. Gabelli, 345 F. Supp. 2d 313, 335 (S.D.N.Y. 2004) (footnote omitted). The following are the major areas where "certification litigation" likely will arise.

1. Kickbacks, Referrals, and Cost Reports: Potential Areas of Certification Liability for Medical Providers

Three major areas of FCA "certification litigation" have involved: (1) claims that certain provider arrangements violated the federal anti-kickback laws; (2) claims that certain provider arrangements violated the federal anti-referral laws (the so-called "Stark Law"); and (3) the submission of cost reports under the federal Medicare Program. In each area, courts have held that providers may face potential FCA liability for alleged "false certification" of compliance.

First, the certification theory of liability specifically has been applied to alleged violations of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (2006), where courts have found that violation of the statute may create FCA liability. *See, e.g., McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005) (recognizing claim based on false certification of Anti-Kickback Statute because "compliance with the [s]tatute is necessary for reimbursement under the Medicare program"); *Zimmer*, 386 F.3d at 241-44 (holding that complaint alleging false certification under Anti-Kickback Act sufficiently stated violation of FCA); *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 126 (W.D. Pa. 2006) ("Specific claims for reimbursement under Medicare . . . which the Government does not owe because of the claimant's non-compliance with the Anti-kickback statute, can establish liability under the FCA."); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003) (denying summary judgment and allowing implied certification claim based on violation of Anti-Kickback Statute to proceed).[4]

Second, courts also have allowed FCA claims to be based upon violations of the federal anti-referral laws (known as the "Stark Law"), 42 U.S.C. § 1395nn (2006).[5] *See, e.g., Zimmer*, 386 F.3d at 241, 243-44 (holding that complaint alleging false certification with the Stark Law sufficiently stated violation of FCA); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of America, Inc.*, 238 F. Supp. 2d 258, 266 (D.D.C. 2002) ("[T]he developing law has supported [the] finding that violations of Anti-Kickback and Stark laws can support a claim under the False Claim Act . . . ."); *Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347, 355 (D. Mass. 1999) (denying motion to dismiss stating that, "[a] number of courts, however, have recognized that the submission of a false certification of compliance with the Stark Law in order to qualify for Medicare reimbursement can constitute a false claim under the FCA"); *Thompson*, 20 F. Supp. 2d at 1047 ("Relator has stated a claim under the FCA for violation of the express terms of § 1395nn of the Stark law. . . .").

Finally, courts have recognized FCA claims based on Medicare cost reports. For example, in *In re Cardiac Devices Qui Tam Litigation*, the court held:

> [W]e find that the submission of the annual Cost Report forms with their accompanying certifications that the reports were true, correct, and complete and prepared in accordance with applicable instructions, constituted the submission of a claim.

* * *

> Although the Cost Reports were not requests for payment with respect to the specific services provided to the Medicare beneficiaries, those charges were included in the Cost Reports and were subject to the certification that they were true and correct. Given the Second Circuit's expansive interpretation of the term "claim," we find that the annual Cost Reports constituted "claims" within the meaning of the FCA.

In re Cardiac Devices Qui Tam Litigation, 221 F.R.D. 312, 344 (D. Conn. 2004); *see also Thompson*, 125 F.3d at 902 ("[Plaintiff] fairly alleged that the government's payment of Medicare claims is conditioned upon certification of compliance with the laws and regulations regarding the provision of healthcare services, including the anti-kickback statute and the Stark laws, and that defendants submitted false claims by falsely certifying that the services identified in their annual cost reports were rendered in compliance with such laws and regulations.").

In *Thompson*, the U.S. District Court for the Southern District of Texas held that a plaintiff had sufficiently alleged three separate and distinct FCA claims for:

> the allegedly false certifications of compliance with all applicable Medicare statutes and regulations on which the government conditioned payments, the submission of Medicare claims in violation of the Stark laws' express prohibition, and the submission of claims for services rendered in violation of the Medicare Anti-Fraud and Abuse Act [the anti-kickback statute].

Thompson, 20 F. Supp. 2d at 1021. As stated by the court, the cost reports required for the Medicare Program[6] could form the basis of an FCA claim: "[T]he court concludes that Plaintiffs have stated a claim for violation of the FCA by Defendants' alleged false certification that the Medicare services identified in the annual hospital cost reports complied with the laws and regulations dealing with the provision of healthcare services." *Thompson*, 20 F. Supp. 2d at 1046.

A medical provider, therefore, should undertake a detailed analysis to ensure that: (1) any financial arrangements do not constitute prohibited referrals or kickbacks; and (2) any services or products rendered are in compliance with Medicare laws and regulations. Absent complete compliance, an FCA "certification claim" likely will be pursued.

2. Certification Liability for Prescription Benefit Providers

The U.S. Government's most recent, and now one of its more substantial healthcare expenditures, is the new federal prescription drug benefit under the Medicare Part D Program. An approved sponsor under Medicare Part D, however, must understand that, unlike most federal statutes, the federal regulations implementing the Medicare Part D Program have effectively codified the FCA certification theory of liability. Regulations for the Medicare Part D Program require, as a condition of payment, full compliance with all federal *and* state laws, including specifically the federal Anti-Kickback laws. This is a significant provision.

An "endorsed sponsor" under the Medicare Part D Program is subject to the following:

> Compliance with applicable law. An endorsed sponsor must comply with all applicable Federal and State laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).
>
> * * *
>
> An endorsed sponsor must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

42 C.F.R. § 403.806(c), (i)(3) (2006). Similarly, a *required* contractual provision for any contract with a Part D plan sponsor is the following:

> Comply with State law and preemption by Federal law requirements described in subpart I of this part.
>
> * * *
>
> Requirements of other laws and regulations. The Part D plan sponsor agrees to comply with—(1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. §§ 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act).

42 C.F.R. § 423.505(b)(15), (h)(1) (2006). Finally, the federal regulations specifically require a detailed certification *as a condition for payment*:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual

delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(1)-(2) (2006). The certification requirement also extends to any related entity, contractor, or subcontractor of the Plan D sponsor:

(3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(3) (2006). Thus, pharmacy benefit providers under the Medicare Part D Program (and all related entities, contractors, and subcontractors) will likely find themselves the subject of future FCA litigation in the context of "certification litigation."

3. False Certification of Eligibility to Participate in Federal Program

One last major area where "false certification" liability may arise involves the theory that a putative defendant violated the FCA by falsely certifying its eligibility to participate in a government-funded program. Courts have recognized that a false assertion of eligibility may constitute a violation of the FCA. For example, in *Gabelli*, the court held that an FCA action could proceed against the successful bidders for wireless telecommunication licenses in connection with the public bidding procedures of the Communication Commission:

> Accepting the factual allegations contained in the Complaint as true, defendants *deliberately* violated FCC regulations by concealing relevant financial relationships and falsely certifying that they were eligible for federal monies. The FCC regulations mandate that auction participants make detailed disclosures relating to their eligibility to both (1) participate in auctions in which licenses reserved for small businesses will be awarded and (2) receive federal discounts because of their status as small businesses. Taylor asserts that defendants purposefully sidestepped these regulations in an effort to induce the Government to give them money. At this early stage in the proceedings, these allegations are sufficient to satisfy the "false or fraudulent statement" element of FCA claims.

Gabelli, 345 F. Supp. 2d at 336-37 (footnotes omitted) (emphasis in original); *see also Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (stating that false certification as to eligibility constituted a false claim).

Recently, in *McNutt*, the U.S. Court of Appeals for the Eleventh Circuit held that: "when a violator of government regulations is ineligible to participate in a government program and that violator persists in presenting claims for payment that the violator knows the government does not owe, that violator is liable, under the Act, for its submission of those false claims . . . . " *McNutt*, 423 F.3d at 1259.

The concept that a false certification of eligibility may constitute an FCA violation is supported by the legislative history of the modern FCA, which states: "[a] false claim for reimbursement under the Medicare, Medicaid or similar program is actionable under the act . . . and such claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program . . . . " S. Rep. No. 99-345 at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274.

4. Likely Increase of False Certification Claims Under the Medicare Program

Finally, "false certification" claims based on an alleged lack of eligibility may become more frequent with the adoption of new regulations for participation in the Medicare Program. Specifically, 42 C.F.R. § 424.510 (effective June 20, 2006) requires the submission of detailed information for participation in the Medicare Program

for all providers and suppliers currently participating in the Medicare Program. *See* 42 C.F.R. §§ 424.510, 424.515 (2006). In submitting the enrollment application, the provider or supplier must complete a comprehensive certification as to eligibility and compliance with all applicable statutes, regulations, and program requirements:

> (3) Signature(s) required on the enrollment application. The certification statement found on the enrollment application must be signed by an individual who has the authority to bind the provider or supplier, both legally and financially, to the requirements set forth in this chapter. This person must also have an ownership or control interest in the provider or supplier, as that term is defined in section 1124(a)(3) of the Act, such as, the general partner, chairman of the board, chief financial officer, chief executive officer, president, or hold a position of similar status and authority within the provider or supplier organization. The signature attests that the information submitted is accurate and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions.
>
> (i) Requirements. The signature requirements specified in paragraphs (d)(3)(i)(A) through (C) of this section outline who must sign the enrollment application for an enrolling provider or supplier. In the case of
>
> > (A) An individual practitioner, the applying practitioner.
> >
> > (B) A sole proprietorship, the applying sole proprietor.
> >
> > (C) A corporation, partnership, group, limited liability company, or other organization (hereafter referred to collectively in this section as an organization), an authorized official, as defined in § 424.502. When an authorized official signs the certification statement on behalf of an organization, the signed statement is considered legally binding upon the organization.

42 C.F.R. § 424.510(d)(3)(i) (2006).[7]

A "false certification" claim, therefore, may be based on the assertion that an individual or entity was ineligible to participate in the government-funded program in the first instance and, therefore, all requests for payment constitute "false claims" under the FCA. Given the increasing number of federal regulations mandating the execution of certifications for eligibility and the propriety of charges submitted, more "false certification" claims will arise in FCA litigation.

Simply stated, the government may be able to assert a "false certification" in any FCA action. The critical inquiries that will need to be made are:

- whether there is any contract, statute, or regulation expressly requiring a provider, contractor, or entity to certify the quality of its performance or product and/or the propriety of all amounts charged;
- whether, in the absence of an express certification requirement, the statutory and regulatory schemes at issue support an argument that, to receive any payment, a provider, contractor, or entity "implicitly" has certified compliance with applicable laws;
- whether any statute or regulation could result in a conclusion that a provider, contractor, or entity was ineligible to participate in a government-funded program; and
- whether the particular law or regulation that the provider, contractor, or entity allegedly violated is critical to the ultimate payment decision by the Government.

We will conclude our discussion of "cradle to grave" liability under the modern FCA in the second part of this series appearing in next month's issue.

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END NOTES

1 *See, e.g., Avco Corp. v. U.S. Dep't of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989) ("The False Claims Act is the government's primary litigative tool for the recovery of losses sustained as the result of fraud against the government.") (*citing* S. Rep. No. 99-345, at 2 (1986), reprinted in U.S.C.C.A.N., 5266); *See generally* James F. Barger, Jr., Pamela H. Bucy, Melinda M. Eubanks, and Marc S. Raspanti, "States, Statutes, and Fraud: An Empirical Study of Emerging State False Claims Acts," 80 TUL. L. REV. 465 (2005).

2 The FCA also imposes liability for other types of conduct, such as a conspiracy to defraud. *See* 31 U.S.C. § 3729(a)(3)-(a)(6). The majority of FCA cases, however, address liability under what is known as "(a)(1)," "(a)(2)," and "(a)(7)" claims.

3 Courts have held that the government may seek statutory penalties even in the absence of any actual damage. *See generally United States ex rel. Bettis v. Odebrecht Contractors of Cali.*, 297 F. Supp.2d 272, 278 (D.D.C. 2004) ("[S]tatutory penalties may lie simply for submitting a false or fraudulent claim to the government, even if the government has suffered no loss as a result of the claim."). *Id.* at 278 n.10 ("While the lack of harm would preclude plaintiff from recovering damages, he could still recover statutory penalties if he could prove liability.").

4 *See also United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 32-33 (D.D.C. 2003); *United States ex rel. Kneppkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1046-49 (S.D. Tex. 1998). *But see United States ex rel. Barmak v. Sutter Corp.*, No. 95 Civ. 7637 KTD RLE, 2002 WL 987109, at *5 (S.D.N.Y. May 14, 2002) (holding that "[the court] is not convinced that a qui tam Plaintiff can use the FCA as a vehicle for pursuing a violation of the anti-kickback statute in this Circuit"). *See generally* Lisa Michelle Phelps, Note, "Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations To Support Civil False Claims Actions," 51 VAND. L. REV. 1003 (1998).

5 In general, the Stark Law prohibits certain referrals by physicians to entities. 42 U.S.C. § 1395nn(a)(1). Under the Stark Law, an entity may not seek Medicare reimbursement for any service which constitutes a prohibited referral and, in fact, expressly prohibits payment. 42 U.S.C. § 1395nn(a)(1), (g)(1).

6 As noted by the *Thompson* court, the Medicare cost report is required by law. *Thompson*, 20 F. Supp. 2d at 1035 n.21 (*citing* 42 U.S.C. § 1395g (1992); 42 C.F.R. § 413.20(b) (1998)). *See also* 42 C.F.R. § 413.24 (2006).

7 Under the new regulations, a provider or supplier will have to "resubmit and recertify the accuracy of its enrollment information every 5 years." 42 C.F.R. § 424.515 (2006). This may lead to some interesting future FCA cases.