Quality of Care, Medical Necessity, and Worthless Services under the False Claims Act: Where Are We Headed Now?

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Introduction

Known as "the most powerful tool . . . to deter and redress fraud," the False Claims Act ("FCA")[1] has long been the federal government's key civil remedy to pursue federal money or property, such as Medicare reimbursement, federal subsidies and loans, and payments under contracts for goods and services.[2] The government's use of the FCA in the health care sector has reaped substantial recoveries and it has been used to investigate a diverse range of activity, including the conduct of providers, hospitals, suppliers of durable medical equipment, clinical laboratories, pharmaceutical companies, long-term care facilities, and managed care organizations.

Though the FCA appears on its face to be a static statutory mechanism for combating health care fraud, it has proven to be a quite pliable and effective government tool for addressing two critical areas—substandard care and unnecessary care.

I. The False Claims Act

The FCA was enacted during the Civil War in 1863 in response to government defense contractors defrauding the Union Army. It can be used to impose liability on any person or corporation who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the federal government.[3] Financial recovery under the FCA can be tremendous, with penalties of $5,500 to $11,000 per claim plus three times the government's damages.

[1] 31 U.S.C. §§ 3729–3733.
[2] Press Release, Dep't of Justice, Acting Associate Attorney General Tony West Speaks at Pen and Pad Briefing Announcing Record Civil FY 2012 Recoveries (Dec. 4, 2012).
[3] 31 U.S.C. §§ 3729(a)(1)(A).

A. General Provisions

Although the FCA has been amended several times over the years, in current form, it provides that 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), (D), (E), (F), or (G);
> (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
> (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
> (F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; 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, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.[4]

B. The Fraud Enforcement and Recovery Act of 2009

President Obama signed the Fraud Enforcement and Recovery Act of 2009 ("FERA") into law on May 20, 2009.[5] FERA amended several FCA provisions in an effort "to clarify" the FCA "to reflect the original intent of the law." There were several key amendments. For

[4] 31 U.S.C. § 3729(a). The current adjustment of the statute allows the United States to recover penalties of up to $11,000 per claim and treble damages.
[5] Pub. L. No. 111- 21, 123 Stat. 1617 (2009). The FCA has been amended twice since the passage of FERA in 2009. *See* Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010) (hereinafter "PPACA"); The Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010).

example, FERA expanded liability for "reverse" false claims, to impose liability on a party that fails to make timely repayment of any "obligation to pay or transmit money or property to the government" even in the absence of a false statement.[6] It also made clear that false claims made to the federal government or its agent, contractor, or grantee are all actionable under the FCA (pre-FERA, the FCA's presentment provision was interpreted to require that false claims be presented directly to the government).[7] The FCA core elements discussed below include relevant FERA amendments.

C. The Patient Protection and Affordable Care Act of 2010

President Obama signed the Patient Protection and Affordable Care Act of 2010 ("PPACA") into law on March 23, 2010. The PPACA, which is designed to incrementally overhaul the United States health care system, regulates all aspects of the health care arena, including individuals, employers, and health insurers. Among PPACA's most notorious provisions, each state will be required to offer a health insurance exchange to residents, or a federally-run exchange will be set up in that state.[8] The PPACA makes health insurance exchange payments subject to FCA liability if the payments are "made by, through, or in connection with an Exchange . . . if those payments include any Federal funds."[9] Because providers will be submitting claims for reimbursement to Qualified Health Plans ("QHPs") which may be reimbursed—in whole or in part—with federal funds, this brings providers within the scope of the statute.[10] The damages provision also makes clear that any civil penalties

[6] 31 U.S.C. § 3729(a)(1)(G). Under Section 3729(a)(1)(G) of the FCA, a "reverse false claim" occurs when the payee of a federally-sponsored program discovers receipt of a payment to which it was not entitled and fails to return the overpayment. Prior to FERA, liability under this section had to be predicated on the payee's affirmative use of false statements or records to retain or conceal the government payments. As amended, a payee's mere passive retention of a known overpayment constitutes a violation.
[7] 31 U.S.C. § 3729(b)(2)(A)(ii).
[8] PPACA § 1321.
[9] PPACA § 1313(a)(6)(A).
[10] *See* PPACA § 1301 (articulating the parameters of QHPs).

assessed under the FCA shall be "not less than 3 times and not more than 6 times the amount of damages" sustained by the government.[11]

D. Core Elements of a False Claims Action

There are five core elements of an action brought under the False Claims Act: (1) knowingly; (2) present or cause to be presented; (3) materiality; (4) falsity/fraudulence; and (5) claim against the government. Knowledge, or scienter, is defined under the FCA to "mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information . . . ."[12] No proof of specific intent to defraud is required.[13]

The FCA does not prohibit the provision of worthless or substandard quality services. A violation of the FCA occurs only if there was a claim presented to the federal government—directly or indirectly—for payment of federal funds. Specifically, Section 3729(a)(1) imposes liability on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval."[14] This provision has the ability to ensnare downstream subcontractors furnishing false claims.

There are two types of actionable false claims under the FCA—factually false statements and legally false statements. Factually false statements include billing for goods or services that were never performed or misrepresenting services that were performed—such as altering CPT or ICD-9 codes, or improperly unbundling billed services. Legally false statements occur when goods or services are provided in violation of a particular statute, regulation, or contractual term.

[11] PPACA § 1313(a)(6)(B).
[12] 31 U.S.C. § 3729(b)(1).
[13] *Id.*
[14] 31 U.S.C. § 3729(a)(1)(A).

II. False Certifications: Express and Implied

There are two subcategories of legally false statements, those made by express false certification and those made by implied false certification. An express false certification occurs when a provider falsely certifies compliance with a particular statute, regulation, or contractual term that is a prerequisite to government payment. Express false certification is the most common theory relied upon by the government and relators in FCA cases. These cases are conceptually more straightforward than implied certification cases and circuit courts of appeals tend to regard these cases similarly. In every federal circuit that has considered the issue, a claimant who expressly certifies compliance with a specific legal obligation as a condition of payment, knowing that the certification is false, may be subject to FCA liability.

An implied false certification claim is premised on the theory that the act of submitting a claim for reimbursement itself implies compliance with all overarching federal rules that are prerequisites to payment—including compliance with certain statutes or regulations not identified in the claim itself.[15] Not all federal circuits recognize implied false certification, and the elements of such claims vary among circuits, and even within circuits. The First Circuit has jettisoned the "certification" framework altogether—holding that FCA liability can be based upon a failure to comply with a contractual, statutory, or regulatory obligation whenever the government could theoretically reject the claim for non-compliance.[16] The Second, Third, Sixth, Eighth, Ninth, and Tenth Circuits tend to limit the application of the implied certification theory to where there is a statute or regulation that is a prerequisite to government payment.[17] The

[15] The crux of implied false certification can be gleaned from four key health care decisions: United States *ex rel.* Pogue v. Diabetes Treatment Ctrs. of Am., 238 F. Supp. 2d 258 (D.D.C. 2002); United States *ex rel.* Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001); United States v. NHC Health Care Corp., 163 F. Supp. 2d 1051 (W.D. Mo. 2001); and United States *ex rel.* Aranda v. Cmty. Psychiatric Ctr. of Okla., 945 F. Supp. 1485 (W.D. Okla. 1996).
[16] *See, e.g.*, United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011).
[17] *See, e.g.*, United States *ex rel.* Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001); United States *ex rel.* Wilkins v. United Health Grp., Inc., 659 F.3d 295 (3d Cir. 2011); United States *ex rel.* Augustine v. Century Health Servs.,

Fourth, Fifth, and Seventh Circuits have expressly declined to adopt, or have taken positions incompatible with, the theory of implied certification of compliance.[18] The Eleventh Circuit has held that implied certification can be based on either a condition of payment or a condition of participation in a federal program.[19] Finally, the D.C. Circuit has held that a violation of a contractual obligation that was "material" to the government's obligation to pay a claim can result in FCA liability—regardless of whether that requirement was an express precondition to payment.[20]

III. Level of Care & Worthless Services under the False Claims Act

Worthless services and level of care cases are often conflated by courts and litigants. A worthless services claim is derivative from a factually false claim and asserts that the knowing request of federal reimbursement for services with no medical value violates the FCA irrespective of any express or implied certification. In other words, worthless services cases allege that the service performed was so deficient that it was tantamount to no service at all.[21] On the other hand, level of care cases do not contend that the services rendered were entirely worthless, but rather that they failed to conform to various regulations, statutes, or program requirements. Under the worthless services theory, when a provider bills the federal government for a service that the provider knows, or should know, has no value, the provider is essentially billing for something that was not provided—a factually false claim. Under the level of care theory, valued services were provided, but it is typically alleged that they were rendered in an

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Inc., 289 F.3d 409 (6th Cir. 2002); United States *ex rel.* Vigil v. Nelnet, Inc., 639 F.3d 791 (8th Cir. 2011); Ebeid *ex rel.* United States v. Lungwitz, 616 F.3d 993 (9th Cir. 2010); United States *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211 (10th Cir. 2008) ("[T]he analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment.").

[18] *See, e.g.*, United States *ex rel.* Herrera v. Danka Office Imaging Co., 91 F. App'x 862 (4th Cir. 2004); United States *ex rel.* Steury v. Cardinal Health, Inc., 625 F.3d 262 (5th Cir. 2010); United States *ex rel.* Yannacopoulos v. Gen. Dynamics, 652 F.3d 818 (7th Cir. 2011).

[19] *See, e.g.*, McNutt *ex rel.* United States v. Haleyville Med. Supplies, Inc., 423 F.3d 1256 (11th Cir. 2005).

[20] *See, e.g.*, United States v. Sci. Applications Int'l Corp., 626 F.3d 1257 (D.C. Cir. 2010).

[21] These cases equally apply to products; however, "service" is used throughout for consistency and brevity.

untimely manner or of insufficient quality or quantity—below what was required by applicable regulations, statutes, or program requirements.

The legal theory of liability for level of care cases is murkier than worthless services cases, and quality of care theories are not universally recognized among federal circuit courts. Though not all circuits have considered the issue, most courts would apply an implied certification theory to cases challenging the level of care provided. As mentioned above, implied certification liability is premised on the theory that the act of submitting a claim for reimbursement itself implies compliance with all overarching federal rules that are prerequisites to payment (including all applicable regulations, statutes, and program requirements). An additional level of complexity arises regarding what is required for an implied certification case—whether the "overarching federal rules" aspect can be based on various documents, or whether a specific regulatory or statutory directive is required. Courts have struggled to expound upon the point at which deficiencies in the quality of service or noncompliance with regulations, statutes, or program requirements will trigger FCA liability.

The worthless services theory emerged in 1996 when the United States Attorney's Office for the Eastern District of Pennsylvania filed a FCA action against the Tucker House, a Pennsylvania nursing facility.[22] The government alleged that the Tucker House submitted "false, fictitious or fraudulent" claims to the government for services that "were not adequately rendered." The allegations were resolved with a $600,000 settlement and consent orders that imposed rigorous ongoing quality of care standards on the Tucker House.

The Ninth Circuit, in *United States ex rel. Lee v. SmithKline Beecham, Inc.*, was the first circuit court to use the term "worthless services."[23] *Lee* was a laboratory services quality of care

[22] United States v. GMS Management-Tucker, Inc., Civil Action No. 96-1271 (E.D. Pa. 1996).
[23] 245 F.3d 1048 (9th Cir. 2001).

case where the realtor alleged that the defendant laboratory operator falsified medical test results and billed Medicare for the worthless tests.[24] Formulated as an express false certification case—due to noncompliance with federal testing regulations—the district court dismissed the case, holding that regulatory violations could not support a FCA action.[25] The Ninth Circuit Court of Appeals reversed and remanded, finding that the district court overlooked the possibility that the defendant violated the FCA by seeking federal reimbursement for medically worthless tests.[26]

The Second Circuit, in *United States ex rel. Mikes v. Straus*, was the first court to substantively weigh in on the worthless services theory.[27] Though the case was not initially brought as a worthless services case, the court nonetheless found that worthless services was a distinct claim under the FCA and articulated a definition that has been universally adopted by federal courts deliberating the issue.[28] In *Mikes*, the relator's theory was that the defendant physicians submitted claims to Medicare for "worthless" spirometry[29] tests. The relator alleged that because the spirometers were not properly calibrated in accordance with certain standards, they produced unreliable data. Because the data was unreliable, the tests were essentially worthless, and billing Medicare for worthless tests violated the FCA. The Second Circuit found that defendants' certification in submitting claims to Medicare pertained only to medical necessity and did not "impart a qualitative element mandating a particular standard of medical

[24] *Id.* at 1050–51.
[25] *Id.* at 1051–53.
[26] *Id.* at 1053 ("Neither false certification nor a showing of government reliance on false certification for payment need be proven if the fraud claim asserts fraud in the provision of goods and services").
[27] 274 F.3d 687 (2d Cir. 2001). The Ninth Circuit was actually the first circuit to acknowledge the FCA's worthless services theory in the health care context. *See* United States *ex rel.* Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001) ("knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under [the FCA] regardless of any false certification conduct.").
[28] 274 F.3d 687, 703 (2d Cir. 2001).
[29] According to the Mayo Clinic, a spirometer is a "diagnostic device that measures the amount of air you're able to breathe in and out and the time it takes you to exhale completely after you take a deep breath." *Spirometer*, Mayo Clinic, 2013, *available at* http://www.mayoclinic.com/health/medical/IM01608.

care."[30] Moreover, the court concluded that the defendants' certification only certified that the procedure—the spirometry test—was performed and that it was medically necessary. Because the relator only challenged the quality of care and not the decision to administer the care, she failed to prove that the tests were not medically necessary and therefore violated the FCA. It is clear that post-*Mikes*, in order to sustain a worthless services theory, the service performed must be so deficient as to be equivalent to no performance at all.[31]

In addition to the Ninth and Second Circuits, the Third,[32] Fifth,[33] Sixth,[34] and Eighth[35] Circuits have also broached the worthless services issue to varying degrees.

In a district court quality of care case, the court in *United States v. NHC Health Care Corp.* refused to dismiss, based on an implied false certification theory, the plaintiff's FCA claims emanating from allegations of substandard medical care.[36] The federal government alleged that a Missouri long-term care facility violated the FCA by submitting claims to Medicare and Medicaid for services that were "so insufficient and negligent that the claims for reimbursement amounted to fraud."[37] Because NHC was submitting claims for grossly deficient services, the government contended that NHC was furnishing false claims. Drawing a distinction between allegations of care being administered poorly and not administered at all

[30] 274 F.3d 687, 698 (2d Cir. 2001).
[31] *Id.* at 703.
[32] *See, e.g.*, *In re* Genesis Health Ventures, Inc., 112 Fed. Appx. 140, 143 (3d Cir. 2004) ("Case law in the area of 'worthless services' under the FCA addresses instances in which either services literally are not provided or the service is so substandard as to be tantamount to no service at all.").
[33] *See, e.g.*, Steury v. Cardinal Health, Inc., 625 F.3d 262, 270 (5th Cir. 2010) ("Other courts have suggested that the knowing provision of 'worthless' goods or services to the Government may violate the FCA. . . . Steury has not yet pursued or briefed these theories, however, so we need not address them here.") (internal citation omitted).
[34] *See, e.g.*, Chesbrough v. VPA, P.C., 655 F.3d 461, 468 (6th Cir. 2011) ("A test known to be of 'no medical value,' that is billed to the government would constitute a claim for 'worthless services,' because the test is 'so deficient that for all practical purposes it is the equivalent of no performance at all.'") (internal citation omitted).
[35] *See, e.g.*, United States *ex rel.* Roop v. Hypoguard USA, Inc., 559 F.3d 818, 824 (8th Cir. 2009) ("'In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.' That was not alleged, only that Hypoguard's products, when misused, have resulted in serious adverse consequences.") (internal citation omitted).
[36] 115 F. Supp. 2d 1149 (W.D. Mo. 2000).
[37] *Id.* at 1053.

(this case alleging the latter), the court noted that an implied certification theory may be appropriate in "some" cases, such as when "the standard of care is at the 'heart' of the parties' agreement."[38] Because the allegation in this case was not a violation of the standard of care, but rather a failure to provide a billed service entirely, the court held that the implied certification theory was inapplicable.[39]

Relying upon the worthless services endorsement in *NHC Health Care Corp.*, the district court in *United States v. Villaspring Health Care Center, Inc.* refused to dismiss the case based on allegations that a long-term care facility billed Medicare and Medicaid for worthless services.[40] According to the court, when alleging claims for worthless services, "[i]t is not necessary to show that the services were completely lacking; rather, it is also sufficient to show that 'patients were not provided the quality of care' which meets the statutory standard."[41] The concern generated by *Villaspring* is the possibility that relators, surviving a motion to dismiss, will be able to impose substantial pressure and financial burden on defendants through pre-trial discovery to ascertain, among other things, the standard of care and whether any quality assurance programs exist.

A recent and notable case from the Sixth Circuit, *United States ex rel. Williams v. Renal Care Group, Inc.* alleged that the defendant was not in substantial compliance with certain technical standards for home care medical devices, and as a result, submitted false claims to the government.[42] The appellate court reversed, finding that the allegedly contravened regulations were merely Medicare conditions of participation and such conditions were not expressly or

[38] *Id.* at 1055.
[39] *Id.*
[40] 2011 WL 6337455 (E.D. Ky. Dec. 19, 2011).
[41] *Id.* at *5.
[42] 696 F.3d 518 (6th Cir. 2012).

impliedly material to the government's payment decision.[43]

The government has recently decided to intervene in two *qui tam* actions against a national skilled nursing facility company, Life Care Centers, Inc.[44] In a case under seal since 2008, the government alleges that Life Care Centers of America billed federal programs for unnecessary and unprovided care, as well as deliberately upcoded various procedures to maximize reimbursement. This complaint suggests the government's continued interest not only with regard to skilled nursing facilities, but also with enforcing standards of care for federally-funded health care programs.

IV. Medical Necessity and the False Claims Act

In addition to the government using the FCA to ensure more and higher quality care, the FCA may also be used to combat claimed overtreatment—seeking to have less care provided.

Federal health programs only reimburse for products and services that are medically necessary.[45] Since all health care providers certify to Medicare or Medicaid that the billed service is medically necessary, billing for a medically unnecessary claim is a false certification of compliance and constitutes a false claim under the FCA. Although CMS requires that physicians certify that services provided are "medically indicated and necessary for the health of the patient," CMS has not delineated precisely what constitutes medical necessity and what documentation is required to support a showing of medical necessity. This tends to complicate

[43] *See id.* at 532 ("The regulations set forth in the United States's complaint are conditions of participation, the violation of which do not lead to False Claims Act liability.").

[44] United States *ex rel.* Martin v. Life Care Ctrs. of Am. 08-CV-251 (E.D. Tenn., Nov. 28, 2012); United States *ex rel.* Taylor v. Life Care Ctrs. of Am. 12-CV-64 (E.D. Tenn., Nov. 28, 2012).

[45] The source of the certification language for Medicare reimbursement claims may vary based on service provided. Health care providers submit claims to Medicare and Medicaid on the CMS-1500 form (chiefly for physicians' services). As part of the CMS-1500 form, the provider must certify that the services shown on the form were "medically indicated and necessary to the health of the patient." *See* NAT'L UNIFORM CLAIM COMM., 1500 CLAIM FORM, *available at* http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//CMS1500805.pdf. Other forms that claimants may file include the UB-04 (for certain hospital services), and/or a CMS-2552 form (the annual hospital cost report).

the analysis of whether a physician's provision of care was in fact "medically necessary."

With the advent of data mining for Medicare claims data, it has become much easier for government enforcers to target providers and hospitals reporting greater utilization of certain procedures as compared to peers. Though there have been substantial government investigations into dozens of medical service lines, this section introduces some of the most prominent of the FCA medical necessity investigations.

A. Operation LabScam

Dating back to 1992, clinical laboratories were among the first health care entities to come within regulatory crosshairs of the Office of Inspector General ("OIG"). Dubbed "Operation LabScam," the OIG began to investigate clinical laboratories' billing practices. The first significant settlement occurred in 1992, and was the $111 million FCA settlement with National Health Laboratories—one of the nation's then-largest providers of clinical diagnostic testing. The government contended that National Health Laboratories induced physicians into ordering unnecessary blood tests. This case made clear that laboratories could be held liable for billing for unnecessary services when the lack of medical necessity was known.

Another notable settlement involving claims of unnecessary laboratory tests occurred in 1996 and involved Laboratory Corporation of America ("LabCorp").[46] LabCorp agreed to pay $182 million to resolve allegations that it submitted false claims for medically unnecessary laboratory tests to federal and state health care programs. In this case, a doctor brought the case to the attention of federal enforcement officials after noticing that his customary blood laboratory routinely ran tests that he neither ordered nor needed for his patients. In effect, the laboratory was forcing multiple tests to be ordered and then billing Medicare separately for each unbundled test.

[46] Press Release, Dep't of Justice, DOJ Health Care Fraud Report, Fiscal Year 1997 (1997).

In 1996, Damon Clinical Laboratories, Inc. ("Damon") entered into a settlement agreement with the Department of Justice ("DOJ") for $119 million to resolve allegations of submitting false claims to Medicare and Medicaid between 1988 and 1993.[47] Damon operated thirteen regional laboratories across the country, and was alleged to have submitted false claims for laboratory tests that were not ordered and were not medically necessary. Damon agreed to pay a criminal fine of $35.3 million and $83.7 million to settle the two whistleblower lawsuits.

In 1997, then one of the largest FCA settlements ever reached, SmithKline Beecham Clinical Laboratories ("SmithKline") paid $325 million to resolve federal and state fraud claims alleging overcharges to the Medicare, Medicaid, Federal Employees Health Benefits, Railroad Retirement, and the Department of Defense Tricare (formerly known as CHAMPUS) health care programs.[48] In this case, federal investigators contended that SmithKline billed the government for millions of laboratory tests that were medically unnecessary, were not ordered by a physician, or were not performed. Tolling over $800 million in aggregated clinical laboratory settlements between 1992 and 1997, Operation LabScam was quite successful in combating false claims within the health care sector.

B. Implantable Cardioverter Defibrillators ("ICDs")

The DOJ has been conducting a multi-state investigation into providers billing Medicare for implantable cardioverter defibrillator ("ICD") procedures that allegedly did not satisfy CMS criteria.[49] ICDs are small devices implanted in the chest or abdomen and used to treat arrhythmias by sending electrical pulses or shocks to the heart to restore normal rhythm. In this investigation, the government claims that in certain instances implanting an ICD was not

[47] *Id.*
[48] *Id.*
[49] Joe Carlson, *Cardiac Arrests*, MODERN HEALTHCARE, July 21, 2012, *available at* http://www.modernhealthcare.com/article/20120721/MAGAZINE/307219994.

medically necessary. The investigation is examining a seven-year period (between 2003 and 2010) and is chiefly focused on whether providers violated the CMS timing guidelines for ICD device implantation as reflected in the Medicare National Coverage Determination ("NCD"). Pursuant to the NCD, Medicare does not cover ICDs implanted within forty days of a patient having a heart attack, or within ninety days of a patient having angioplasty to widen obstructed arteries or bypass surgery to divert blood flow around an obstructed artery.[50] A study published in early 2011 found that of 111,707 patients who received ICD implants, 25,145 (22.5%) did not meet the CMS coverage criteria reflected in the NCD.[51] However, because it is difficult to practice medicine in accordance with evolving medical evidence while complying with literal—and often less modernized—government claims regulations like the NCD, this study's conclusion has been the subject of significant controversy.[52]

C. Stents

Similar to ICD implants, stents comprise another federal FCA investigative arena. Two of the primary investigations include a settlement with Lafayette General Hospital and the investigation of various Hospital Corporation of America ("HCA") hospitals.

Lafayette General Medical Center in Lafayette, Louisiana ("Lafayette General"), paid $1.9 million to resolve allegations of unnecessary stenting by a local cardiologist.[53] Federal authorities contended that between 1999 and 2004, Lafayette General knowingly made claims for payment to federal health plans in connection with medically unnecessary elective stenting,

[50] *Id. See also Medicare Coverage Determination Process*, CMS, Mar. 5, 2012, *available at* http://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html?redirect=/DeterminationProcess.
[51] S.M. Al-Khatib et al., *Non-Evidence-Based ICD Implantations in the United States*, 305 J. AM. MED. ASS'N, 43–49, Jan. 5, 2011.
[52] *See, e.g.*, Jonathan S. Steinberg & Suneet Mittal, *The Federal Audit of Implantable Cardioverter-Defibrillator Implants*, 59 J. AM. COLL. CARDIOLOGY, 1270–74, Apr. 3, 2012; Jeanne E. Poole & George H. Crossley, *Letter to the Editor*, 305 J. AM. MED. ASS'N, 1537, Apr. 20, 2011.
[53] Press release, Dep't of Justice, Lafayette General Medical Center to Pay $1.9 Million to Settle Fraud Allegations in Connection with Medically Unnecessary Cardiology Procedures (Jan. 11, 2008).

angiogram, and angioplasty procedures performed at its facilities.[54] Moreover, the government contended that Lafayette General had knowledge of the unnecessary procedures—based on internal reviews and employee reports—but deliberately failed to address the problem.[55]

In July of 2012, the civil division of the United States Attorney's Office in Miami, Florida requested information from HCA, the nation's largest hospital operator, regarding reviews assessing medical necessity of various interventional cardiology services (including stents) provided at ten HCA hospitals. It is believed that the impetus for the federal investigation was a HCA internal audit that purportedly revealed numerous cases of doctors conducting unnecessary surgeries in its facilities, and never contacted patients, medical authorities, or insurers (including Medicare and state Medicaid agencies) regarding the findings of those probes. The *New York Times* then published a detailed article and made very public the allegation that medically unnecessary procedures were not isolated incidents at HCA.[56]

D. Proper Patient Status: Short Stay & Observation Cases

Billing for medically unnecessary observation or inpatient stays can also trigger FCA liability. The federal government has been bringing FCA cases under the theory that hospitals are unlawfully increasing Medicare reimbursements by admitting patients who should have received care in less expensive outpatient settings. For example, in June 2012 Atlantic Health System Inc., and Overlook Hospital, located in New Jersey, agreed to pay almost $9 million to resolve allegations that they violated the FCA by overbilling Medicare for patients who were treated on an inpatient basis, when they should have been treated on either an outpatient or

[54] *Id.*
[55] *Id.*
[56] *See Hospital Chain Inquiry Cited Unnecessary Cardiac Work*, N.Y. TIMES, Aug. 6, 2012, *available at* http://www.nytimes.com/2012/08/07/business/hospital-chain-internal-reports-found-dubious-cardiac-work.html?pagewanted=all.

observation basis.[57] Similarly, in December 2007 Saint Joseph's Hospital of Atlanta, Inc. and Saint Joseph's Health System, Inc. agreed to pay $26 million to settle FCA allegations of improperly billing for inpatient admissions and other services.[58] The settlement resolved an investigation primarily focusing on Saint Joseph's Hospital's submission of Medicare claims between 2000 and 2005, where services that should have been billed as outpatient visits were allegedly billed under the higher rate as inpatient admissions.[59]

Another ongoing example of the federal government using the FCA to enforce patient status is the national investigation into the spinal reconstruction procedure known as the kyphoplasty.[60] Known as the "kyphoplasty initiative," the investigation has resulted in over $39 million in settlements from forty hospitals nationwide, and another $75 million FCA settlement with medical device manufacturer Medtronic Spine LLC, formerly known as Kyphon, Inc.[61] Kyphon sold costly equipment and medical devices for use in kyphoplasties, and allegedly devised a seven-year marketing scheme to encourage hospitals to keep patients overnight and bill Medicare for an inpatient kyphoplasty. Relators alleged that this is typically an outpatient treatment, but that one-night hospital inpatient stays were "in the vast majority of cases, medically unnecessary" for kyphoplasty patients.[62]

V. Potential Challenges to Medical Necessity Cases

[57] Press Release, Dep't of Justice, New Jersey Hospital Pays U.S. $8,999,999 to Settle False Claims Act Allegations (June 21, 2012).
[58] Press Release, Dep't of Justice, Saint Joseph's Hospital of Atlanta to Pay U.S. $26 Million to Settle False Claims Allegations (Dec. 21, 2007). More specifically, the settlement covers claims submitted by Saint Joseph's Hospital for short inpatient admissions, usually of one day or less, where the services were such that they would be properly billed as on an outpatient observation basis or as an emergency room visit. In addition, the settlement also includes certain claims submitted by the hospital for inpatient admissions relating to implantation of carotid artery stents, which Medicaid did not cover.
[59] *Id.*
[60] According to the Mayo Clinic, a kyphoplasty is a procedure used on patients with compression fractures in the spine, and offers the potential to reverse spinal deformity and restore bone height in the vertebra. *Vertebroplasty*, Mayo Clinic, 2013, *available at* http://www.mayoclinic.org/vertebroplasty/kyphoplasty.html.
[61] United States *ex rel.* Bates v. Kyphon, Inc., Amended Complaint, 2005 WL 6180590 (W.D.N.Y. 2005).
[62] *Id.* at ¶ 102.

There are a number of potential theories that providers might pursue which are specific to the defense of FCA medical necessity cases, two of which are discussed below.

A. Clear & Binding Medical Necessity Standard

CMS has not delineated what constitutes medical necessity and what documentation is required to support a showing of medical necessity. When confronted with allegations of failing to meet a threshold of medical necessity, it may behoove defendants to inquire into whether CMS has promulgated a standard for determining when a specific service is reasonable and necessary. According to Section 1395hh(a)(2):

> "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation . . . ."[63]

Even if the government has promulgated a statement of policy, any profound ambiguity in the guidance may favor the defendant since the defendant cannot "knowingly" furnish a false claim when the conduct is consistent with a reasonable interpretation of ambiguous governmental regulatory guidance.[64] Moreover, if medical necessity is unclear, the government may have difficulty proving that the submitted claim was "false" under the FCA—since claims are not false when reasonable persons can disagree as to whether the service was properly billed.[65] Similarly, because claims that are the product of an honest mistake lack the "knowing"

[63] 42 U.S.C. § 1395hh.
[64] *See* United States v. Prabhu, 442 F. Supp. 2d 1008, 1029 (D. Nev. 2006).
[65] *See id.* at 1027 ("claims are not 'false' under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government.").

element required by the FCA, the FCA cannot condemn honest professional or logistical shortcomings; there must be lies or at least conscious disregard for the truth.[66]

B. Deference to the Treating Physician

Ambiguity surrounding the medical necessity issue can carry considerable weight for the defendant in a FCA case. If the issue of medical necessity is unclear and open to reasonable debate, courts may defer to the medical judgments of the treating physician—employing what is known as the "treating physician" rule. According to the "treating physician" rule, the court will afford "extra weight" to the judgment of the treating physician with respect to whether the intervention was medically necessary.[67]

CONCLUSION

Government concern with health care quality is certainly not a new phenomenon; however after more than a decade of litigation related to medical necessity and worthless services, the law is still transforming among and within the various federal circuits. Recent DOJ enforcement activity, coupled with a renewed emphasis on quality and an expanded reach of the FCA, as demonstrated by key provisions within the PPACA,[68] suggest that this will be a key focus area in 2013 and beyond.

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[66] *Id.* at 1033–34.

[67] *See* State of N.Y. v. Sullivan, 927 F.2d 57, 60 (2d Cir.1991) ("[W]e would expect the Secretary to place significant reliance on the informed opinion of a treating physician and either to apply the treating physician rule, with its component of 'some extra weight' to be accorded to that opinion . . . or to supply a reasoned basis . . . for declining to do so.").

[68] The PPACA is structured to employ a multi-faceted approach to incrementally improve and monitor the quality of health care delivery and payment in America. Specific provisions on quality improvement include: PPACA §§ 2701–2707 (Medicaid quality measures and demonstration projects); PPACA §§ 3001–3008 (Medicare value-based purchasing, quality reporting, and payment adjustment for nosocomial conditions); PPACA §§ 3011–3015 ("National Strategy to Improve Health Care Quality"); PPACA §§ 3501–3512 (variety of health care improvement initiatives and demonstrations).