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Fraud and Compliance

The Supreme Court Issues Significant Ruling Substantially Narrowing Application of False Claims Act

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On June 16, Justice Thomas, writing for a unanimous Supreme Court, in *Universal Health Services v. United States ex rel. Escobar* examined the circumstances under which an “implied false certification” can trigger liability under the False Claims Act (FCA) and clarified how the FCA materiality requirement should be enforced.

Since the Court’s opinion, a number of questions have been asked regarding whether the decision will help or hurt businesses operating in the health care industry; whether it will result in more viable FCA qui tam actions or fewer; and whether the opinion will foster more expansive or narrower theories of FCA liability.

The answers are that ultimately the Court’s decision will substantially curtail the number of viable qui tam actions and significantly narrow current theories of FCA liability.

FCA Legal Landscape Leading to *Escobar*

Rules, regulations, and statutes governing the provision of Medicare and Medicaid services literally occupy several volumes in the Code of Federal Regulations and the United States Code. Additionally, the Centers for Medicare & Medicaid Services, states, and their agents promulgate volumes of interpretative guidance in Medicare and Medicaid manuals, handbooks, and bulletins.

In light of this vast array of rules and regulations, courts have frequently confronted the question of when does a violation of any of these rules and regulations potentially result in an FCA violation under which the plaintiff may receive treble damages and the imposition of substantial civil penalties. The FCA, after all, as its title indicates —the False **Claims** Act—is concerned with claims, which are statutorily defined as requests or demands for payment, and the FCA’s purpose is to protect the federal fisc and not to operate as some super enforcement statute to enforce all laws on the books.[\[1\]](#)

Thus, in answering this question regarding whether a violation of any rule or regulation potentially triggers an FCA violation, courts have frequently distinguished between violations of law or contract that concern “conditions of payment” and those that are “conditions of participation.” Conditions of payment “are those which, if the government knew they were not being followed, might cause it to actually refuse payment.”[\[2\]](#) Conditions of participation are those where violations may trigger administrative sanctions (like the imposition of a corrective action plan), but will not necessarily result in the government’s denial of payment.[\[3\]](#)

Because the health care industry is heavily regulated with substantial oversight and a vast array of administrative remedies, the distinction between conditions of payment and participation became important in FCA jurisprudence. In several cases, and in multiple contexts, health care entities obtained dismissal by asserting that the purported legal violation was nothing more than a condition of participation. Indeed, applying this principle, courts rejected FCA plaintiffs' actions when they alleged nothing more than:

- a hospital violates Medicare conditions of participation (such as not having an adequate number of nurses to provide nursing care);[\[4\]](#)
- a skilled nursing facility fails to provide “quality of care” (as opposed to worthless services);[\[5\]](#)
- a drug company fails to report an “adverse event” under the FDA’s reporting procedures;[\[6\]](#)
- an end-stage renal disease facility violates conditions of coverage;[\[7\]](#)
- a managed care entity violates marketing regulations;[\[8\]](#)
- an independent diagnostic testing facility breaches regulations regarding physician supervision;[\[9\]](#)
- a health care company violates the Health Insurance Portability and Accountability Act;[\[10\]](#)
- a drug company knowingly violates the FDA’s Current Good Manufacturing Practice regulations; and[\[11\]](#)
- health care entities violate state licensing rules.[\[12\]](#)

Additionally, in determining whether violations of rules or regulations resulted in FCA violations, courts distinguished between “express” false certifications and “implied” false certifications. An express false certification occurs when on the face of the claim form the company represents that the claim complies with specific laws (such as the Medicare Anti-Kickback law). An implied false certification is when the claim itself is factually accurate but the government would not have paid had it known that the defendant was acting in violation of some rule or regulation when it submitted the claim. Theories of implied false certification are disfavored because its application is potentially unfair in that the defendants submit a factually accurate claim but may not have had fair notice that any regulatory violation could result in an FCA violation when there is no express certification stating that compliance with a particular law was a condition of payment.

Government Reaction to FCA Trends

To counter these legal trends which were resulting in a narrower construction of the FCA, the government embarked upon a three-prong counterattack to argue for a more expansive construction of the FCA. First, the government filed, in various courts that had applied the distinction between conditions of participation and conditions of payment or had distinguished between implied and express false certifications and factually false claims, Amicus Curiae briefs to persuade courts that they should not use these distinctions because they are not specifically

referenced in the FCA itself.^[13] Second, the government would expressly draft in laws and enrollment applications that compliance with law is a condition of payment so that courts would not find that the violation was merely a condition of participation.^[14] Third, the government would require those who do business with the government to execute exceedingly broad certifications averring that they would comply with all provisions of the U.S. Code and the Code of Federal Regulations that applied to the government's program.

Given the government's counterattack, the government was well-positioned to ultimately win this FCA interpretative battle. This is because, to avoid any doubt, the government would simply require all claims to have broad certifications asserting that the provider agrees to comply with all laws (no matter how unrelated to the services actually provided) and that such compliance was an express "condition of payment." Agency officials would draft regulations and Manual provisions to state that compliance is a condition of payment. Thus, if courts were to credit blindly the labels the government affixed to certifications and rules (that is, that compliance is a "condition of payment"), then the government would prevail in each case in proving that compliance with law is a material precondition to payment.

The Supreme Court's Decision

Against this legal backdrop, the Supreme Court issued its decision in *Escobar*. The narrow question before the Court was whether an implied false certification theory could create FCA liability and, if so, the scope of the theory. As noted in more detail below, in resolving this issue, the Court ultimately applied a very narrow theory of implied false certification. However, more significantly, the Court went beyond that issue to explore the government's contentions that the government's statement that compliance with law is an express condition of payment, by itself, can establish FCA materiality and whether the defendant's certification that it has complied with the entire U.S. Code and Code of Federal Regulations, by itself, can establish FCA liability. In what will have monumental consequences in FCA jurisprudence, the Court expressly rejected both of the government's contentions.

The Factual Background

In *Escobar*, the relators' daughter was a Medicaid recipient who, once she began to experience behavioral problems, began receiving services at Arbour Counseling Services, a satellite mental health facility in Massachusetts.^[15] Five medical professionals treated her. Eventually the daughter had an adverse reaction to a medication that a purported Arbour doctor prescribed and ultimately died.

Thereafter relators learned that few Arbour employees were actually licensed to provide mental health counseling and that supervision of them was minimal. The practitioner who prescribed medicine to the daughter and who was held out as a psychiatrist, was in fact a nurse who lacked authority to prescribe medications absent supervision. The practitioner who diagnosed the daughter as bipolar identified herself as a psychologist with a Ph. D. (based upon a degree obtained from an unaccredited Internet college) but Massachusetts had rejected her application to be licensed as a psychologist.

In its reimbursement claims, there were two types of potential falsity. First, the defendant used payment codes corresponding to different services that its staff provided to relators' daughter, such as "Individual Therapy" and "family therapy." Second, staff members misrepresented their qualifications and licensing status to the federal government to obtain individual National Provider Identification numbers, which were submitted in connection with Medicaid reimbursement claims and correspond to specific job titles. For example, one Arbour staff member who treated relators' daughter registered for a number associated with "Social Worker, Clinical," despite lacking the credentials and licensing required for social workers engaged in mental health counseling.

The Court's Ruling Regarding False Implied Certification

The relator's complaint asserted an implied false certification theory that Arbour submitted reimbursement claims contending that specific services were provided by specific types of professionals but failed to disclose the serious violations of regulations pertaining to staff qualifications and licensing requirements for these services.

In addressing this theory, the Court noted that appellate courts had split three ways on this issue: (1) one circuit rejected this theory, finding that only an express falsehood on a claim form can render a claim "false or fraudulent"; (2) other circuits permitted the theory but only if the relevant statute, regulation, or contract expressly stated that compliance with the rule was a condition of payment; and (3) other courts applied the theory regardless of whether the relevant statute, regulation, or contract specifically designated compliance with the relevant provision to be an express condition of payment as long as compliance with the relevant provision was in fact a condition of payment.

The Court rejected all three of these approaches. Specifically, it found that the precise label that the government affixes to the relevant law or contract—such as, compliance is a "condition of payment"—is not determinative of whether the claim is "false or fraudulent."^[16] Instead, it ruled that an implied certification theory can be a basis for FCA liability only if two conditions are satisfied: (1) "the claim does not merely request payment, *but also makes specific representations about the goods and services provided*"; **and** (2) the defendant must fail to disclose its noncompliance with a provision that is "material" to the government's decision to pay.^[17]

Applying this rule, the Court held that submitting claims for payment using payment codes that corresponded to specific counseling services is equivalent to a representation that these services had been provided in accordance with applicable law.^[18] The Court also held that submitting Medicaid reimbursement claims using National Provider Identification numbers is equivalent to a representation that the services were provided by properly trained and licensed employees.^[19] "By using payment and other codes that conveyed this information without disclosing Arbour's many violations of basic staff and licensing requirements for mental health facilities, [the] claims constituted misrepresentations."^[20]

But, by specifically linking the relevant law breached (basic staff and licensing requirements) to specific codes used on the claim form, the Court seemingly adopted the narrowest interpretation

of an implied false certification theory by essentially asserting that the claim form itself must be expressly false (not impliedly false) because the code used did not accurately correspond to law (for example, a social worker's service is billed when the person is not a licensed social worker under law). Thus, in this sense, the Court's ruling is very narrow and in essence stating nothing more than that the claim form was factually false, which is a paradigmatic FCA violation when the falsity is knowing and material. The Court did not consider, because it was not presented in the facts of the case, the extent to which non-compliance with rules and regulations that are not directly linked to specific codes and factual representations on the claim form may result in FCA liability based upon an implied false certification theory.

The Court's Ruling Regarding Materiality

After addressing the viability of implied false certification theories, the Court turned to the FCA's materiality element. The FCA contains a definition of materiality, but the Court did not merely apply the definition.^[21] Instead, it cited to a number of common law tests describing when materiality can be satisfied, such as a misrepresentation is material if it "went to the very essence of the bargain."^[22]

The Court ruled that the FCA's materiality requirement is "rigorous" and "demanding."^[23] The Court identified a couple of factors that may be relevant to materiality: (1) the provision is labeled a condition of payment, although, as noted below, this is not "dispositive"; and (2) there exists "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement."^[24]

However, the Court also identified a number of limiting factors regarding materiality: (1) "A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment"; (2) "Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance"; (3) "Materiality . . . cannot be found where noncompliance is minor or insubstantial"; (4) "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that these requirements are not material"; (5) and "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material."^[25] Additionally, the Court noted that it disagreed with the government's view of materiality "that any statutory, regulatory, or contractual violation is material so long as the defendant knows the Government would be entitled to refuse payment were it aware of the violation."^[26]

Analytically, the "demanding" and "rigorous" nature of these materiality tests reveal that each of the cases described above (at notes 4-12) would be decided the same way under the Supreme Court's materiality test that they were decided under a condition of participation analysis because under each of the situations described – e.g., a hospital or skilled nursing facility breaches conditions of participation; a managed care business violates marketing regulations; a drug company breaches the Food and Drug Administration's Current Good Manufacturing

Practices or fails to report an “adverse event”—the government typically pays the underlying health care claim in full and instead pursues some other administrative remedy which, as the Supreme Court pointed out, is “very strong evidence that these requirements are not material.”[\[27\]](#)

Application of the Supreme Court’s Ruling

The Supreme Court’s decision will have a significant impact on FCA jurisprudence. Although some have deemed the Supreme Court’s ruling a victory for the government because the Court recognized the implied false certification theory, that viewpoint appears incomplete and mistaken. While recognizing the potential application of an implied false certification theory, the Court’s application of the theory was extraordinarily narrow—applying it under the facts to only a situation where the specific legal backdrop governing licensing and supervision would render specific codes and numbers used on the claim form to be false. Few would doubt that the FCA should apply under those circumstances if the defendant knew the codes and numbers were false and the falsity was material to the government’s decision to pay.

Overall, the Supreme Court’s decision appears much more favorable to those operating in the health care industry. This is true for at least three reasons.

First, the Court’s decision reset the legal landscape from one where the government was positioned to win the interpretative battle regarding how to prove materiality because it could establish materiality in every case by a mere stroke of a pen (*i.e.*, by drafting broad certifications and laws stating that every rule and regulation are “conditions of payment”) to one where instead a “rigorous” and “demanding” materiality test must be applied. Indeed, the Court was well aware of the interpretative battles giving rise to the action and specifically rejected the government’s position that “any statutory, regulatory, or contractual violation is material so long as the defendant knows that the government would be entitled to refuse payment were it aware of the violation”; rejected the government’s view that labeling the violation as a condition of payment was sufficient to render the violation material; and rejected the view that if the “Government required contractors to aver their compliance with the entire U.S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material” because the “False Claims Act does not adopt such an extraordinarily expansive view of liability.”[\[28\]](#)

Second, the Court underscored the FCA’s narrow scope of application. The Court plays an important role in educating lower courts and the public regarding the scope and application of statutes. As to the FCA, the Court reaffirmed its prior ruling in *Allison Engine Co. v. United States ex rel. Sanders*, that the FCA is not “an all-purpose antifraud statute” or a “vehicle for punishing garden-variety breaches of contract or regulatory violations.”[\[29\]](#) Indeed, the Court took the opportunity to “emphasize” that “the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations.”[\[30\]](#) From this, lower courts, the government, and potential whistleblowers will understand that simple “garden-variety breaches of contract or regulatory violations” are not actionable under the FCA but the violations, at a minimum, must actually relate to instances where the government

consistently refuses to pay claims based upon the particular noncompliance with the specific statutory, regulatory, or contractual requirement.

Third, the Court emphasized that lower courts can dismiss FCA actions on materiality grounds at several stages prior to trial. Specifically, the Court underscored that FCA plaintiffs must “plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)” by “pleading facts to support allegations of materiality” and specifically rejected the notion “that materiality is too fact intensive for courts to dismiss FCA cases on a motion to dismiss or at summary judgment.”^[31] As a result, defendants will be positioned, in FCA actions, to compel FCA plaintiffs to assert plausible and specific materiality claims (to surmount Rule 12(b)(6) and 9(b)) and, if they do, to prevail on summary judgment on the issue of materiality if the undisputed facts show that the noncompliance with a statutory, regulatory, or contractual requirement was insignificant or was otherwise not likely to have caused the government to consistently refuse to pay the claim.

Every action has a reaction. On the last occasion in which the Supreme Court substantively construed the FCA, *Allison Engine Co. v. United States ex rel. Sanders*, the Court also enunciated a narrow construction of the FCA that resulted in Congress, at the Department of Justice’s (DOJ’s) behest, to promptly amend the FCA. It is currently unclear whether DOJ will seek legislative reform to define the FCA “false or fraudulent” or materiality element so that the government’s broad certifications or condition of payment label will carry more weight in determining FCA liability. For those who practice in this area, we will all need to strap in. For the next few years, we should be in for a bumpy ride.

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^[1] See *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 496 (D.C. Cir. 2004) (rejecting FCA construction that would result in “almost boundless” reach); see also *United States ex rel. Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2009) (noting that the FCA is not “an all-purpose antifraud statute”) (quoting *Allison Engine Co., Inc. v. United*

States ex rel. Sanders, 553 U.S. 662, 672 (2008)). See also *United States ex rel. Campie v. Gilead Sci., Inc.*, No. C-11-0941, 2015 U.S. Dist. LEXIS 1635, at *24 (N.D. Cal., Jan. 7, 2015) (“the FCA is not a catchall anti-fraud provision”) (citation omitted).

[2] *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir. 2008) (citation omitted).

[3] See, e.g., *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 799 (8th Cir. 2011) (ruling that the relator “must plead and prove that [the defendant’s] allegedly false Certifications were conditions of payment – ‘those which, if the government knew they were not being followed, might cause it to actually refuse payment’” and noting that, by contrast, “if the regulatory violations were only conditions of . . . participation, they ‘are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program’”).

[4] *United States ex rel. Huey v. Summit Healthcare Ass’n, Inc.*, No. CV-10-8003, 2011 U.S. Dist. LEXIS 26740 at *17 (D. Ariz. Mar. 2, 2011) (rejecting the relator’s allegation that defendant hospital breached FCA because of its nurse supervision practices because in “the Medicare context, . . . conditions of participation, unlike conditions of payment, are insufficiently related to the government’s payment decision to form the basis of an FCA claim”); *United States ex rel. Landers v. Baptist Mem’l Health Care Corp.*, 525 F. Supp. 2d 972, 975, 978-79 (W.D. Tenn. 2007) (finding breaches of conditions of participation for hospitals—such as having an adequate number of nurses and other personnel to provide nursing care, having policies governing surgical care designed to ensure the achievement and maintenance of high standards of medical practice and patient care, and providing a sanitary environment—did not result in FCA liability, because even though “Defendants’ alleged non-compliance with Conditions of Participation may lead to prospective corrective action or even termination, Plaintiff has not presented any evidence that Defendants would have been ineligible to receive payment of its Medicare claims during a potential period of non-compliance,” but the government would, notwithstanding the breach, have continued to reimburse their claims for at least a period of time).

[5] *United States ex rel. Portilla v. Riverview Post Acute Care Ctr.*, No. 12-1842, 2014 U.S. Dist. LEXIS 44002, at *46-47 (D.N.J. Mar. 31, 2014) (noting that where administrative adjudications revealed that the quality of care regulations the relator claimed were breached resulted in administrative sanctions and not denial of payment, the compliance with those regulations “is a classic condition of participation and not payment” and hence not actionable under the FCA); *Sweeney v. ManorCare Health Servs., Inc.*, No. C03-5320RJB, 2005 U.S. Dist. LEXIS 45216 at *4, *11-14 (W.D. Wash. Mar. 4, 2005) (dismissing the relator’s Medicare FCA complaint where the relator alleged the nursing home did not provide prescribed snacks and nutritional supplements to residents because, notwithstanding plaintiff’s contention that defendant failed to adhere to state and federal regulations concerning the quality of care to be provided to nursing home residents, the relator did not state a cause of action, because the relator did not show that regulatory violations were conditions of payment, but were only “conditions of participation in the Medicare and Medicaid programs. Moreover, there are administrative and other remedies for regulatory violations.”) (internal quotations omitted).

[6] *United States ex rel. Ge v. Takeda Pharm. Co.*, No. 10-11043, 2012 U.S. Dist. LEXIS 156752 at *19-20 (D. Mass. Nov. 1, 2012) (ruling that the legal requirement that drug companies report adverse events is a condition of participation, because the “FDA has discretion to take a number of different actions should a drug manufacturer violate the adverse-event

reporting requirements” and thus because the “relator has not adequately established compliance with adverse-event reporting procedures was a material precondition to payment of the claims at issue, the complaints do not state a claim upon which relief can be granted under Rule 12(b)(6)”, aff’d other grounds, 737 F.3d 116 (1st Cir. 2013).

[7] *United States ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 5:09 CV 00710, 2011 U.S. Dist. LEXIS 4862, at *54 (N.D.N.Y. Jan. 19, 2011) (finding that defendant’s alleged violation of “Conditions for Coverage for End-Stage Renal Disease Facilities” constituted conditions of participation and not a condition to payment and, hence, did not result in FCA liability).

[8] *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 308 (3d Cir. 2011) (an allegation that “appellees violated the regulations do[es] not state a plausible claim for relief under the FCA inasmuch as the Government’s payments of appellees’ Medicare claims were not conditioned on their compliance with the marketing regulations”).

[9] *United States ex rel. Hobbs v. MedQuest Assocs. Inc.*, 711 F.3d 707, 712-13 (6th Cir. 2013) (rejecting the government’s contention that the defendant independent diagnostic testing facility’s (IDTF) violation of the regulation requiring that services mandating a physician’s direct or personal supervision must be supervised by a physician designated as a supervising physician on the IDTF’s CMS enrollment form and its failure to properly enroll in the Medicare program and instead submitting claims under a physician’s billing number, did not violate the FCA, because the regulations violated were conditions of participation and not conditions of payment, and, hence “do not mandate the extraordinary remedies of the FCA and are instead addressable by the administrative sanctions available, including suspension and expulsion from the Medicare program”).

[10] *United States ex rel. Chesbrough v. VPA, P.C.*, 655 F.3d 461, 469 (6th Cir. 2011) (rejecting relators’ claim that defendant’s violation of the Health Insurance Portability and Accountability Act (HIPAA) resulted in an FCA violation because relators “do not cite to a statute or regulation that conditions payment of a claim on compliance with HIPAA”).

[11] *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 700-02 (4th Cir. 2014) (finding that where the relator contended that defendant violated the FDA’s Current Good Manufacturing Practice (CGMPs) regulations, causing drugs to be “adulterated,” because penicillin and non-penicillin drugs were not packaged in complete isolation from one another, the relator did not state a cause of action because “compliance with the CGMPs is not required for payment by Medicare and Medicaid” and the “relevant statutes do not provide that when an already-approved drug has been produced or packaged in violation of FDA safety regulations, that particular drug may not be the proper subject of a reimbursement request under Medicare and Medicaid” and thus concluding that “once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, the submission of a reimbursement request for that drug cannot constitute a ‘false’ claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations;” finally the court noted that in “the present case, the FDA pursued numerous regulatory actions against [the defendant], including conducting multiple inspections of the Toledo building and issuing the warning letter. The FDA also threatened seizure of [the facility] products, use of injunctive remedies, and action recommending ‘disapproval of any new applications listing [the facility] as a manufacturer of drugs’. The existence of these significant remedial powers of the FDA buttresses our conclusion that Congress did not intend that the FCA be used as a regulatory-compliance mechanism in the absence of a false statement or fraudulent conduct directed at the federal government”).

[12] *United States ex rel. Ortolano v. Amin Radiology*, No. 5:10-cv-583, 2015 U.S. Dist. LEXIS 9724, at *29-30 (M.D. Fla. Jan. 28, 2015) (vacating jury verdict in relator’s favor and entering Judgment for defendant because violation of Florida law mandating that only a nuclear medicine technologist is authorized to perform the entirety of a PET/CT scan was “at most, a condition of participation, and not a condition of payment” because there was a “complete absence of any statutory, regulatory, decisional, or other viable authority suggesting that a failure to comply with Florida’s licensing laws with respect to radiation and nuclear medicine testing is a condition of payment under Medicare, Medicaid, or Tricare” and noting that the only way to accept the relator’s theory is by “weaving together isolated phrases from several sections in the complex scheme of Medicare regulations as well as portions of Florida statutes” and this “cut-and-paste approach is not supported by the structure of the regulatory scheme, and it is not reasonable to expect Medicare, [Medicaid, or Tricare] providers to attempt such an approach to statutory interpretation in their efforts to comply with the FCA”) (internal quotation and citation omitted).

[13] *See, e.g.*, Br. for United States, *United States ex rel. Hobbs v. MedQuest Assocs.*, No. 11-6520 (6th Cir. May 18, 2012); Br. for United States, *United States ex rel. Steury v. Cardinal Health, Inc.*, No. 12-20314 (5th Cir. Aug. 2, 2012); Br. for United States, *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, Nos. 13-1886, 13-1936 (7th Cir. Sept. 26, 2013).

[14] *See, e.g.*, CMS Enrollment Forms (noting that compliance with conditions of participation are a condition of payment); *see generally* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6407, 124 Stat. 119, 769-70 (2010) (mandating as an express “condition of payment” that the physician certify and document in specified fashion a face-to-face encounter with a patient for the patient to be eligible for home health services).

[15] *Id.*, No. 15-7, 2016 U.S. LEXIS 3920, at *11-12 (U.S. June 16, 2016) (the relators were the patient’s mother and stepfather).

[16] *Id.*, at *24.

[17] *Id.*, at *22 (emphasis supplied).

[18] *Id.*, at *21-22.

[19] *Id.*

[20] *Id.*, at *22.

[21] The FCA defines materiality as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4).

[22] *See Escobar*, 2016 U.S. LEXIS 3920, at *28, n. 5.

[23] *Id.* at *26-28.

[24] *Id.* at *29-30.

[25] *Id.* at *28-30.

[26] *Id.* at *30-31.

[27] One can only imagine the burden this aspect of the ruling will place upon the government as FCA defendants will need to seek, even in FCA cases in which the government does not intervene, information from the government regarding what remedies it typically imposes for specific violations of rules and regulations.

[28] *Id.* at *28-32. *See also id.* at *8-9 (“What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision”).

[29] *Id.*, at *28.

[30] *Id.*, at *32.

[\[31\]](#) *Id.* at *30, n. 6.