



BNA's Health Care Fraud Report™

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BLOOMBERG LAW INSIGHTS

Escobar One Year Later:

Implied Certification and Materiality Under the False Claims Act



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On June 6, 2016, the Supreme Court issued a decision that wrought a significant change to the way implied certification cases under the Federal False Claims Act (the "FCA") are analyzed. The case, [United States ex rel. Escobar v. Universal Health Servs., Inc.](#), [136 S. Ct. 1989](#), [2016 BL 192168](#) (U.S.2016), resolved a split among the Circuit Courts as to the viability of implied certification cases.

It also articulated the standard for implied certification cases. Prior to Escobar in Circuit Courts that recognized implied certification, the focus was on whether the defendant impliedly certified that it complied with all statutes and regulations setting forth conditions of payment in submitting claims to the United States.

In Escobar, the Supreme Court first established that a false implied certification is a viable means of establishing falsity for purposes of the FCA, thus recognizing implied certification as a base of liability under the FCA.

However, the Court ruled that whether a regulation is a condition of payment is relevant, but not determinative, in the analysis of implied certification. Instead, the critical inquiry is whether the defendant, by act or omission, engaged in conduct material to the government's decision to pay a claim, such that the government would not have been likely to pay the claim had it been aware of the conduct, regardless of whether the involved regulation is labeled a condition of payment.

As stated by the Court in *United States ex rel. Schimelpfenig v. Dr. Reddy's Laboratories, Limited*, BL 96315 (D. Pa. March 27, 2017) (citation omitted), "[s]ince Escobar, the focus of the court's analysis has shifted from whether a particular statute or regulation was a 'condition of payment' to whether compliance was 'material to the payment decision.'"

A year has passed since the Escobar decision, and “materiality” is not self-defining. Therefore, it is timely to review how Courts have elaborated and applied materiality in the context of FCA implied certification.

As shown below, at least for health care providers that bill Medicare or Medicaid, regulatory compliance remains, post-Escobar, of crucial importance in implied certification cases under the FCA. In fact, it may be at least as important as it was pre-Escobar.

Other health care programs also involve claims to the federal government. For ease of reference, this article speaks to Medicare and Medicaid. The legal principles are the same regardless of the federal government program.

The Civil FCA

The FCA provides that one is liable for submitting a false claim to the United States where that is done knowingly or with reckless disregard to the claim's truth or falsity. The penalties for violation of the FCA include treble damages and civil monetary penalties for each claim submitted in violation of the FCA. The FCA states as follows:

any person who –

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

* * *

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 [today, \$21,000 per claim], plus 3 times the amount of damages which the Government sustains because of the act of that person.

[31 U.S.C. § 3729\(a\)\(1\)](#) (internal citations omitted); [81 Fed. Reg. 42,500](#), 42,5011 (June 30, 2016).

Moreover, the FCA can be enforced by whistleblowers, termed “relators,” who act as private attorneys general and enforce the FCA on behalf of the government. The government often intervenes in suits brought by relators, adding its resources to the case against the defendant. Relators are entitled to a percentage of the amount collected in FCA actions, and thus have a financial incentive to bring the actions.

Implied Certification Prior to Escobar

Prior to Escobar, there was a question of whether a claim could be false for FCA purposes if a defendant does not misrepresent facts in making the claim, but instead by submitting the claim arguably impliedly certifies that all conditions for payment of the claim have been satisfied. This is called implied certification.

Many, but not all, Circuit Courts held that implied certification can be a basis to establish the “falsity” element of FCA liability. Some Courts rejected the theory and held that the FCA requires express misrepresentation. Other Courts accepted the theory but limited its scope to violations of expressly designated conditions of payment. Still others held that conditions of payment need not be expressly designated as such to constitute a basis for FCA liability.

Escobar

In Escobar, the Supreme Court held, first, that the implied certification theory can be a basis for liability under the FCA. The Court further held that liability under the theory does not turn on whether the statutory or regulatory requirements involved are express conditions of payment.

The Court stated, “[w]hat 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.” *Id.* at 1996.

The alleged FCA violations in Escobar arose within the Medicaid program. For five years, Tarushka Rivera, a teenage Medicaid beneficiary, received counseling services at defendants' facility, Arbour. After being diagnosed by a purported doctor as having bipolar disorder, the doctor prescribed medication. The beneficiary then suffered a seizure that required hospitalization. Her condition worsened. She suffered another seizure and died.

The Court notes that Rivera was treated by an array of individuals without the licensure or the qualifications and credentials they purported to have. Further, individuals required to be supervised were unsupervised.

The Court further noted that these problems were systemic, and that "[s]ome 23 Arbour employees lacked licenses to provide mental health services, yet—despite regulatory requirements to the contrary—they counseled patients and prescribed drugs without supervision." *Id.* at 1997.

Various counseling and other services were billed using procedure codes requiring the involvement of appropriately licensed and/or supervised personnel where this did not in fact occur. Further, Arbour employees misrepresented their credentials to obtain NPI numbers and bill for services.

Arbour argued that its violations were not violations of express conditions of payment. The Court reasoned that by submitting claims that misrepresented the services provided and the qualifications of the personnel providing the services, the facility submitted claims that were at least misleading in context.

In the Court's view, the government would not have paid the claims had it known the involved services were not provided by appropriately qualified personnel.

Therefore, the Court held that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment but makes specific representations about the goods or services provided; and, second, the defendant's failure to disclose noncompliance with material statutory, regulatory or contractual requirements makes those representations misleading half-truths.

It does not matter whether the requirements are express conditions of payment so long as they are material to the decision to pay. By the same token, express conditions of payment are not necessarily material. The Escobar Court summed up materiality this way:

The Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, 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. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements are violated, that is very strong evidence that those requirements are not material. Or, 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.

Id. at 2003-2004 (footnote omitted).

Materiality After Escobar

Thus, "materiality" is important to the payment determination, whether or not labeled a condition of payment by the government. *Rose v. Stephens Institute*, BL 360745 (N.D. Cal. Sept. 20, 2016), app. docketed, No. 17-15111 (9th Cir. Jan. 20, 2017), is illustrative.

Rose involved Title IV of the Higher Education Act, specifically Title IV's prohibition of paying remuneration based on success in securing college enrollments or financial aid to any person engaged in student recruiting or admission activities.

The relators alleged that the defendant violated this requirement. The defendant's allegedly false claims were applications for student loans. The case addressed defendant's motion for reconsideration of denial of its motion for summary judgment.

In *Rose*, the question was whether the applications impliedly certified compliance with the incentive compensation ban, particularly in view of the defendant's promise to comply with the ban in its Title IV program participation agreements.

The Court determined that the government's corrective reforms, fines and settlement agreements showed that it considered compliance with the incentive compensation ban to be an important part of the Title IV bargain, and that noncompliance was capable of influencing the government's payment decisions. The Court therefore denied the defendant's motion for summary judgment on materiality and ordered the case to proceed to trial.

Similarly, in *United States ex rel. Scutellaro v. Capital Supply, Inc.*, BL 128343 (D.D.C. April 19, 2017), the Court denied motions for summary judgment on materiality. This case involved noncompliance with the Trade Agreements Act and the Buy American Act by a federal government vendor.

In the case, the defendant received mixed signals from the Regional and New York Offices of the GSA as to materiality of compliance and whether compliance was a condition of payment. The Court therefore determined that whether the noncompliance was material for FCA purposes was an issue for trial and not summary judgment.

These two cases show that implied certification for FCA purposes is untethered from the presence or absence of express conditions for payment. But they offer little guidance, beyond "facts and circumstances," regarding the meaning and application of "materiality" in the FCA implied certification context. Below are discussed cases that provide some guidance regarding "materiality," particularly in the health care provider context.

Materiality Found

Worthy

United States ex rel. Worthy v. Eastern Maine Healthcare Systems, BL 13956 (D. Me. Jan. 18, 2017), involved alleged systemic and intentional violations of the Medicare 3 day and 1 day payment rules, as well as the Medicare Secondary Payer ("MSP") provisions.

Under the 3 day rule, if a hospital or facility operated by the hospital provides outpatient services in the 3 days prior to an inpatient hospital stay, the technical component of those services must, in general, be bundled with the claim for the inpatient services and not separately billed. Any diagnostic services within the 3 day window, and any non-diagnostic services that are clinically related to the reason for the hospital admission must be bundled with the claim for the hospital stay.

Similarly, under the 1 day, or "same day," rule, outpatient services furnished to a patient on the same day must, in general, be bundled into the same ambulatory payment classification ("APC") for Medicare payment purposes. Exceptions to both rules exist for services that in principle are unrelated to the inpatient stay or primary APC.

The rules and exceptions are applied through the hospital's submission of claims with prescribed billing codes and modifiers, and the processing and payment of those claims. Medicare program instructions direct hospitals in the use of these codes and modifiers. In *Worthy*, the relator alleged that the defendants engaged in a practice of separately billing services required to be bundled under the 3 day and 1 day rules.

In addition, the relator alleged violations of the MSP rules. Under these rules, Medicare payment is secondary to, among other things, (i) workers' compensation, (ii) liability insurance, and (iii) no fault insurance.

Hospitals in many cases are entitled to conditional primary payment, which is then refunded when the primary insurance payment is collected. As in the case of the 3 day and 1 day rules, the MSP rules are administered through coding and other billing information.

The relator alleged the hospital submitted bills without accident or injury information coded on the bills to avoid the MSP rules.

The defendants argued that violations of the 3 day and 1 day rules, and the MSP rules, cannot be the basis of FCA liability because the rules are not express conditions of payment. The Court disagreed.

After examining *Escobar* and the Medicare program practices regarding violations of the 3 day, 1 day and MSP rules, the Court found that the relator had "stated a plausible claim for the alleged violations" of the rules, and therefore the FCA. *Id.* at 25; see also *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, [836 F.3d 770](#) (7th Cir. 2016) (allegations of upcoding satisfy falsity element under the FCA, citing *Escobar*).

Quartararo

United States ex rel. Quartararo v. Catholic Health System of Long Island, Inc., BL 108938 (E.D.N.Y. March 31, 2017), involved a claim of implied false certification based on the defendant's alleged siphoning off of Medicare reimbursement of a nursing home to support a hospital, allegedly in violation of the prohibition of conversion of Medicare funds.

Compliance with this provision is not an express condition of Medicare payment. Nevertheless, the relator argued that compliance is material under Escobar. That is, the relator argued that the government would be likely to have refused to pay the claims had it been aware of the noncompliance.

The Quartararo Court agreed with the relator. It found that the relator had stated a viable claim that the defendants had submitted false claims based on the alleged conversion of funds, under the FCA as construed by Escobar. The Court ruled against the relator on another, different count, based on Escobar, discussed below.

Celgene

In United States ex rel. Brown v. Celgene Corp., [226 F. Supp. 3d 1032](#) (C.D. Cal. 2016), the Court addressed the issue of whether Celgene's promotion of off-label uses of two drugs, including facilitation of submission of Medicare claims, could be a basis of FCA liability under the theory of implied certification.

The Court noted that no express condition of Medicare payment was involved. However, the Court found it important that the relevant Medicare coverage provisions provided coverage only for medically accepted uses of drugs.

To be a medically accepted use, in turn, the use must be approved by the FDA or listed in one of three specified compendia. The involved uses of the drugs were not listed in the compendia, and therefore the uses were not medically accepted for Medicare purposes.

After acknowledging that medical acceptance is not an express condition of payment, the Court turned to an analysis of materiality under the principles established in Escobar. Celgene argued that the statute established when Medicare must pay, but that Medicare has the discretion to pay for uses that are not medically accepted.

The Court in Celgene rejected this argument. It found that Congress had struck a balance in the statute between what drugs Medicare would pay for and what drugs it would not pay for, to provide benefits yet contain costs.

The Court further found this balance central to the statutory scheme, and determined that the requirement of a medically accepted use is an explicit requirement of payment. While not dispositive of the materiality inquiry, the Court reasoned that under Escobar, it is "highly relevant." *Id.* at 1049.

The Court rejected Celgene's arguments for non-materiality, including notably that Medicare routinely paid claims for the off-label uses of the two drugs which were promoted by Celgene. The Court therefore ruled that the case could proceed under an FCA implied certification theory.

Materiality Not Found

Quartararo

As discussed above, the Quartararo Court found that the relator's allegations of misappropriation or "siphoning" of payments to the nursing home could proceed under an implied certification theory. However, the Court rejected the relator's argument that the defendants also submitted false claims by using an incorrect base year for purposes of Medicaid reimbursement of nursing home costs.

Catholic Health System of Long Island is located in New York. For New York Medicaid payment purposes, nursing homes are reimbursed base year costs, adjusted by factors defined in New York's Medicaid regulations.

In general, when there is a change of ownership a new base year is established. In Quartararo, Catholic Health System of Long Island acquired a nursing home. However, the System did not change the base year of the nursing home. This resulted in greater Medicaid payment than if the base year had been changed. The relator therefore argued that the failure to change the base year gave rise to violations of the FCA under the implied certification theory.

The Court disagreed. In New York, changing the base year and recalculating Medicaid reimbursement requires the active engagement and activity of the New York Department of Health ("DOH").

The record reflected ongoing communication between the nursing home and the DOH regarding the base year. Consequently, the Court reasoned the DOH was aware of the base year issue and nevertheless paid claims.

Under these circumstances, defendants were correct that the base year issue was not material to the DOH's decision to pay the nursing home's claims, within the meaning of Escobar. Therefore, under Escobar, an FCA case could not proceed in relation to the base year issue.

Lee

In *United States ex rel. Lee v. Northern Adult Daily Health Care Center*, [205 F. Supp. 3d 276](#) (E.D.N.Y. 2016), the relators claimed that Northern Adult Daily Health Care Center (the "Center") violated the FCA under an implied certification theory. Relators alleged an array of violations including substandard food and racial discrimination against patients. Therefore, the relators claimed the Center's Medicaid claims were false.

The Court disagreed, finding that the relators failed to allege that the violations were material to the Medicaid payment decisions of the New York Department of Health. Consequently, the Court dismissed these counts of the complaint.

Petratos

The Court in *United States ex rel. Petratos v. Genentech, Inc.*, [855 F.3d 481](#) (3d Cir. 2017), addressed the circumstances of alleged false statements to the FDA violating the FCA because of their purported effect on Medicare payment.

The relator alleged that Genentech filed reports to the FDA regarding its approved anti-cancer drug Avastin, which falsely mischaracterized the dangers of the approved uses of the drug. The relator further alleged that this led to greater Medicare payments than would otherwise have been made and therefore gave rise to violations of the FCA under the implied certification theory.

The Court found that the FDA was aware of the relator's allegations and did not change the labeling or approval of the drug, and did not otherwise take action adverse to Genentech. The Court emphasized that what was involved was approved uses of the drug. The Court therefore reasoned that the alleged misstatements by Genentech were not material to Medicare's decision to pay for the drug. Therefore, the alleged misstatements did not violate the FCA.

Sanford-Brown

In *United States v. Sanford-Brown, Ltd.*, [840 F.3d 445](#) (7th Cir. 2016) reh. en banc den. (November 30, 2016), the relator claimed that the defendant violated the FCA under an implied certification theory in submitting student loan applications notwithstanding alleged violations of the regulations under Title IV of the Higher Education Act.

The alleged violations included violations of the incentive compensation ban, violations of the requirement to maintain accreditation, as well as other matters.

The Court ruled that the relator failed to show materiality because it failed to show that payment would have been different had the government been aware of the alleged regulatory violations.

The Court found it significant that "the subsidizing agency and other federal agencies in this case have already examined SBC [the defendant] multiple times over and concluded that neither administrative penalties nor termination was warranted." *Id.* at 447 (internal quotation and citations omitted). The multiple examinations by the government distinguish this case from *Rose*, discussed above.

D'Agostino

Finally, in *United States ex rel. D'Agostino v. EV3, Inc.*, [845 F.3d 1](#) (1st Cir. 2016), EV3, Inc. marketed a device to treat malformed blood vessels in the brain. The plaintiff alleged the defendant made misrepresentations to the FDA in obtaining approval of the device.

The plaintiff further alleged that, because they were part of the basis for the approval, the misrepresentations were material to Medicare's decisions to pay for use of the device.

The Court disagreed. Like the case in *Petratos*, here the Court found that Medicare regularly paid for the device despite actual knowledge of the plaintiff's allegations. It also found that the FDA did not withdraw or modify its approval of the device despite the plaintiff's allegations.

Therefore, the Court found both that the allegations were not material to the decision to pay for the device, and that the plaintiff had failed to show that the alleged fraud in obtaining FDA approval had any causal relationship to governmental payment for the device (in view of the FDA's continued approval of the device notwithstanding the alleged fraud).

Implications

The case law following *Escobar* makes it clear that a violation will be found material if it is likely to impact payment, whether or not the violation is a violation of an express condition of payment.

Escobar suggests that if the government would pay a claim regardless of a violation, then there is no violation of the FCA. However, as illustrated by the cases, for health care providers that bill Medicare or Medicaid, there are few violations of Medicare law, regulations or instructions that do not affect payment.

Therefore, by eliminating the requirement that a violation be of an express condition of payment (as well as by establishing implied certification in Circuits that did not recognize it), *Escobar* has significantly expanded the scope of exposure under the FCA for health care providers that bill Medicare or Medicaid.

As suggested in *Escobar*, an exception is being carved out where it can be shown that the government had actual knowledge of a violation and paid notwithstanding that knowledge.

For health care providers, *Escobar*, and its thus far nascent progeny, highlight the importance of broad-based regulatory compliance. As suggested above, for health care providers, many aspects of compliance affect payment and are material within the meaning of *Escobar*.

Although *Escobar* suggests some stated conditions of payment may not be material, because they may not in fact affect payment, this may be less relevant for health care providers than it is for other entities that bill the government, in view of the plethora of compliance obligations in health care that affect payment.

Escobar's emphasis on materiality to payment heightens, and does not diminish, the importance of rigorous health care compliance efforts.