Bloomberg BNA

BNA's
Medicare Report™

Supreme Court in *Escobar* Imposes Conditions on Applying Implied Certification Theory in False Claims Cases



By Eric W. Sitarchuk, Rebecca J. Hillyer, Christopher J. Mannion

The U.S. Supreme Court issued a landmark decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, addressing the viability and scope of the implied certification theory of liability under the federal False Claims Act ("FCA"). Although the Court recognized in its June 16, 2016, decision that the implied certification theory—which posits that, by submitting a claim for payment to the government, a contractor implicitly certifies that it has complied with all conditions of payment set forth in statutes, regulations and contractual provisions—could provide a basis for liability under the FCA, it imposed two significant conditions to application of the theory:

Eric Sitarchuk serves as chair of the white collar and corporate investigations practice at Morgan Lewis. He represents clients in a wide variety of white-collar crime matters, False Claims Act and qui tam litigation, and Foreign Corrupt Practices Act and other complex federal and state investigations. He can be reached at eric.sitarchuk@morganlewis.com.

White-collar and commercial partner Rebecca Hillyer concentrates her practice on False Claims Act and qui tam litigation, complex business fraud and disputes, and product liability cases. She can be reached at rebecca.hillyer@morganlewis.com.

Christopher Mannion, an associate, defends clients in white collar matters and also represents businesses involved in complex civil litigation. He can be reached at christopher.mannion@morganlewis.com.

- First, the claim must be more than a mere request for payment, but instead must make specific representations about the goods or services provided.

- Second, the defendant's "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements" must make those representations "misleading half-truths."

The Court further emphasized that the standard for determining materiality under the second condition is both "rigorous" and "demanding." It, of course, remains to be seen how the lower courts will interpret these new limitations. Nonetheless, *Escobar* provides significant new opportunities for FCA defendants to challenge FCA cases premised on underlying contractual or regulatory violations.

The False Claims Act

At its core, the FCA prohibits causing the "knowing" submission to the federal government of a "false or fraudulent claim for payment or approval." False claims fall into one of two categories.

A "factually false" claim is one that is based upon false information about the product or service billed. Classic examples are where a physician knowingly bills a government payor for services that were not actually performed, or a contractor knowingly bills for products not provided.

A "legally false" claim, on the other hand, may occur where, in seeking payment, a party expressly or implicitly certifies that it has complied with relevant statutes,

 ISSN 1049-7986

regulations or contractual terms that underlie the provision of the good or service involved. For example, by submitting a claim for payment from a federal payor, a physician may certify on a claim form that she has not violated the federal Anti-Kickback Statute (''AKS''). If the physician had, in fact, accepted kickbacks, this claim for payment could be legally false.

The Court in *Escobar* considered whether and, if so, how noncompliance with a requirement set forth in an underlying statute, regulation or contract could form the basis for an implied false certification theory of FCA liability. Previously, there was a three-way split among the federal courts on this question.

The Seventh Circuit had rejected the implied certification theory altogether, holding that mere submission of a claim for payment does not serve as an implicit certification that the party has complied with the panoply of applicable statutory, regulatory and contractual requirements. *See United States v. Sanford-Brown, Ltd.*, 2015 BL 179905, 12-14 (7th Cir. 2015). Instead, according to the Seventh Circuit, only express falsehoods can be false or fraudulent.

Other circuits, including the Second, had recognized the implied certification theory as viable but limited its application to violation of those requirements that are expressly designated as conditions of payment. *See, e.g.*, *Mikes v. Straus*, (2d Cir. 2001).

Finally, certain other circuits to have addressed the issue held that violations of requirements that are not expressly designated as conditions of payment could give rise to FCA liability. *See e.g.* , *United States v. Science Applications Int'l Corp.*, 2010 BL 287300, 10-11 (D.C. Cir. 2010).

Factual Background

In *Escobar*, relators' claims arose out of medical treatment that their seventeen year old daughter, Yarushka Rivera, had received from Arbour Counseling Services, a subsidiary of defendant Universal Health Services. Rivera, a beneficiary of the Massachusetts Medicaid program, had received counseling services at Arbour and been treated by Arbour staff for bipolar disorder. Rivera died after suffering seizures caused by an adverse reaction to a medication she had been prescribed.

After Rivera's death, her parents learned of a number of alleged deficiencies in their daughter's treatment by Arbour. For example, of the five counselors that had treated their daughter, only one was properly licensed. Additionally, the Arbour employee who diagnosed and treated Rivera's bipolar disorder held herself out as a Ph.D., but failed to disclose that her degree came from an unaccredited, online institution, and that Massachusetts had rejected her application to be licensed as a psychologist. Finally, the purported Arbour psychiatrist who prescribed the medication which led to Rivera's death was, in fact, a nurse who lacked authority to prescribe medication without appropriate supervision.

Arbour also misrepresented its employees' qualifications and licensing in seeking National Provider Identification (''NPI'') numbers from the federal government. One employee, for example, registered for an NPI number that corresponded to ''social worker, clinical'' despite lacking the required credentials and licensing. The amount Medicaid paid for services depended in part on the qualifications of the provider, which were represented by the NPI number.

In response to complaints filed by relators, Massachusetts conducted an investigation into Arbour's practices, and found that Arbour had violated more than a dozen regulations in its treatment of Rivera, including by failing to employ staff members with appropriate qualifications and failing to provide appropriate medical supervision. Arbour voluntarily entered into a remedial plan, and certain of its employees also entered into consent agreements.

Procedural Posture

Armed with the results of the State's investigation, relators filed suit in federal district court, alleging that defendant had violated the FCA by submitting claims for payment despite knowing that it had not complied with the Massachusetts regulations relating to licensure and supervision.

The district court dismissed relators' FCA claims, on the grounds that the regulations defendant had violated were not conditions of payment under the Massachusetts Medicaid program, and therefore the violations could not give rise to FCA liability.

The First Circuit disagreed, holding that the regulations themselves ''constitut[ed] dispositive evidence of materiality'' because they required adequate supervision as an ''express and absolute'' condition of payment and ''repeated[ly] reference[d]'' supervision. In light of this conclusion, the court held that ''each time [the defendant] submitted a claim, [it] implicitly communicated that it had conformed to the relevant program requirements, such that it was entitled to payments.''

The Supreme Court granted *certiorari* on two questions:

(1) ''Whether the 'implied certification' theory of legal falsity under the FCA—applied by the First Circuit below but recently rejected by the Seventh Circuit—is viable''; and

(2) ''If the 'implied certification' theory is viable, whether a Government contractor's reimbursement claim can be legally 'false' under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment, as held by the First, Fourth, and D.C. Circuits; or whether liability for a legally 'false' reimbursement claim requires that the statute, regulation, or contractual provision expressly state that it is a condition of payment, as held by the Second and Sixth Circuits.''

The Implied Certification Theory Is Viable—But With Important Limitations

The Court answered the first question presented in the affirmative, holding that, subject to two significant conditions, the implied false certification theory can provide a basis for liability under the FCA.

The first condition is that the ''claim'' must be more than a mere request for payment. Instead, the claim must make ''*specific representations about the goods or services provided*.''

The Court noted that this condition was likely satisfied under the facts of *Escobar* because defendant had

   ISSN 1049-7986

done more than simply submit a request for payment. Rather, it had submitted claims using payment codes which identified the specific services claimed to have been provided. The claims also identified, through the NPI numbers, the individuals who had allegedly provided the services.

The second condition is that ''the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.'' The Court observed that this condition would be satisfied in the case before it because:

> [B]y submitting claims for payment using payment codes that corresponded to specific counseling services, Universal Health represented that it had provided individual therapy, family therapy, preventative medication counseling, and other types of treatment. Moreover, Arbour staff members allegedly made further representations in submitting Medicaid reimbursement claims by using [NPI] numbers corresponding to specific job titles. And these representations were clearly misleading in context. . . . By using payment and other codes that conveyed this basic information without disclosing Arbour's many violations of basic staff and licensing requirements for mental health facilities, Universal Health's claims constituted misrepresentations.

Materiality Is Critical

On the second question before the Court—whether a requirement must expressly state that it is a condition of payment in order to support FCA liability—defendant argued that the underlying regulation or contractual provision offered as the basis for FCA liability must expressly state that it is a condition of payment. The Court rejected this express condition of payment test. Instead, the Court applied a materiality standard to identify which underlying requirements could give rise to FCA liability. Specifically, the Court held that, in order to give rise to liability under the FCA, a misrepresentation about compliance with a requirement must be ''material to the government's payment decision.''

The Court cautioned, however, that ''the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations.''

Thus, the materiality standard it imposed is a ''rigorous'' and ''demanding'' one. A misrepresentation is less likely to be material if there is evidence that the government routinely pays claims, even though it has actual knowledge of noncompliance. On the other hand, a misrepresentation of compliance with a requirement may be material for the purposes of the FCA if there is evidence that the government consistently refuses to pay claims that are tainted by the violation of that requirement.

However, ''minor or insubstantial'' noncompliance does not satisfy the materiality requirement.

The Court expressly rejected the view that the government's labeling of a requirement as a ''condition of payment'' renders noncompliance with that requirement material.

Such labels, according to the Court, may be relevant but are not dispositive. In so holding, the Court rejected the First Circuit's view that a violation is material ''so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation.''

Applying the inquiry adopted by the Court, the critical question is not whether the government *could* refuse to make payment based on a violation, but whether there is evidence that it actually *would* refuse to make payment.

Despite emphasizing the seemingly fact-sensitive nature of the materiality inquiry, the Court pointed out that challenges based on materiality present important barriers to relators at both the motion to dismiss and summary judgment stages of a case.

With respect to motions to dismiss, FCA plaintiffs must allege facts supporting each element of their claims—including materiality—with both ''plausibility and particularity.''

Thus, FCA complaints must allege with particularity facts, rather than conclusions, with regard to the specific representations in the alleged false claims and how those representations are made misleading by the nondisclosure of violations that would have led to a refusal to pay by the government.

Practical Implications

The Court's adoption of the specific representation and rigorous materiality requirements will lead to a sea change in how courts analyze future claims under the FCA. Although the Court affirmed the viability of implied certification, this was not a surprise to most. However, the conditions the Court imposed by the Court had not been utilized in the manner set forth by the Court in any circuit.

The Court's unanimous emphasis on a rigorous materiality standard and foreseeability of claim acceptance by the government provides defendants with a number of opportunities at the motion to dismiss and summary judgment pleading stages.

It also confirms that mere noncompliance with any of the thousands of applicable laws, regulations or contractual provisions to which companies in regulated industries are subject does not automatically give rise to FCA liability. While it remains to be seen how courts will interpret which violations are ''minor'' or ''insubstantial,'' the Court's ruling should ensure that the FCA is used to punish only true fraud on the government, while precluding cases brought under the FCA for regulatory or contractual violations that do not cut to the heart of the government's decision to pay.

An essential part of the analysis is now the question: what does the alleged false claim for payment say? If it is silent on matters that involve the aspects of the good or service to which the alleged underlying regulatory violations relate, under *Escobar*, the specific representation requirement may not be met. If the paying agency regularly considered mitigating factors in deciding whether to pay a claim notwithstanding the alleged violation at issue, the materiality standard may not be met.

In preparing motions to dismiss, or developing the factual record for summary judgment or trial, defendants will need to closely examine the actual claim forms and agency payment and recoupment patterns. Actual claim forms will need to be obtained in discovery to identify specific representations beyond the request for payment.

In many contexts, an FCA plaintiff may not be able to identify any such specific representation. In the healthcare industry, this will mean analyzing claims data to understand both the representations made and any agency payment and denial patterns, as well as agency post hoc auditing and recoupment practices to determine how similar violations have been addressed in the past at the administrative level. Discovery requests of agency personnel and records, including Fed. R. Civ. P. 30(b)(6) depositions, will be essential.

Thus, for example, in FCA claims brought pursuant to theories of alleged off-label promotion and marketing, relevant questions will include the following: Do the claims make any specific representations regarding how the product was promoted or even the diagnosis made? Did the defendant provide the relevant marketing materials to the government in advance, and receive approval?

Did the defendant make presentations to state governments about off-label use, and did those state governments make individual decisions to approve off-label uses for reimbursement? These types of inquiries will be critical for assessing materiality, and supporting a motion for summary judgment.

Likewise, *Escobar* raises further questions regarding FCA cases premised on technical violations of Current Good Manufacturing Practice (''cGMP'') standards, or related standards and guidance. In the absence of proof of defective product or patient harm (factual falsity), it is questionable whether the requisite specific representations are made or materiality exists.

The government and relators will be hard-pressed to show that the government refuses to pay claims because of noncompliance with cGMP standards, without more. *Escobar* may even provide a basis for courts to reconsider whether certain alleged historical violations of the AKS are material, such that they can give rise to FCA violations.

Although the Affordable Care Act (''ACA'') provides that AKS violations that post-date the ACA can give rise to FCA liability, whether that is true for AKS violations that pre-date the ACA is an open question.

Finally, the Court's holding in *Escobar* would appear to apply with equal force to FCA violations premised on express false certifications. Presumably, the materiality element of the FCA should be interpreted the same under both implied and express theories of false certification. This is because the Court's rigorous materiality standard goes directly to the question of whether the omission of the underlying noncompliance in fact renders the certification false. Thus, any time a contractor expressly certifies compliance with a statute or regulation, the alleged non-compliance also should be required to meet *Escobar's* exacting materiality standards in order for the certification to be actionable under the FCA.

Conclusion

The Court's rejection of the condition of payment analysis and adoption of a rigorous materiality standard represents a significant shift in how courts must analyze FCA cases premised on underlying statutory, regulatory or contractual violations. Because the majority of significant FCA cases are premised on those theories, this ruling will have a direct impact on both pending litigation and investigations. At the same time, the Court's materiality safeguard would appear to inject a true fraud analysis into a statute that had morphed into an onerous and excessive regulatory enforcement tool.

MCR ISSN 1049-7986