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Increasing understanding between CMS and health plans

an interview with Gail McGrath
Chief Executive Officer
MAPA Compliance Forum
Washington, DC

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by Daniel Kiehl, JD, LLM

The uncertainty of the implied certification theory

» The False Claims Act prohibits submitting false or fraudulent claims to the government.
» The Supreme Court in Escobar did not define what it determines to be a material misrepresentation.
» The appellate court circuits were split in regards to the scope of the implied certification theory.
» Escobar does not consider whether the misrepresentation involves a condition of payment.
» The False Claims Act provides for triple damages for violations.

Daniel Kiehl *(danielkiehl@cokergroup.com) is an Associate Consultant with the Coker Group in Alpharetta, GA.* /in/danielkiehl

In June of 2016, the Supreme Court, through *Universal Health Services, Inc. v. United States ex rel. Escobar*, fundamentally altered the liability theory of prosecution under the False Claims Act (FCA) by allowing government officials and *qui tam* litigants to pursue FCA allegations based upon the provider certifying they are compliant with federal healthcare regulations, regardless of whether the perceived violation related to a condition of payment. Compliance departments would be wise to take notice of this landmark case to avoid hefty fines and judgments.


Kiehl

The FCA is a potent tool used by the federal government in prosecuting healthcare providers for fraudulent transactions and practices. The FCA prohibits organizations and individuals from knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval.[1] Organizations that have been required to pay tens (if not hundreds) of millions of dollars in penalties have been required to do so because the FCA imposes treble (i.e., triple) damages for alleged violations.

False claims

Factual and legal false claims represent the majority of types of violations that constitute FCA violations. Factually false claims are claims that incorrectly and falsely certify that certain services were provided when in fact they were not.[2] Legally false claims are claims that certify compliance with a particular statute (such as the Stark Laws or the Anti-Kickback Statute) when in fact the provider is not in compliance with that particular statute.[3] The implied certification theory derives from legally false claims, wherein a provider certifies that they are in compliance with statutory and/or regulatory obligations when in fact they are not.[4]

Until very recently, the appellate courts have been split as how to enforce the implied certification theory. The Fourth and D.C. Circuit Courts of Appeals have held that any knowing material breach of a statute or regulation that is a condition of payment constitutes an FCA violation.[5] The Seventh Circuit Court of Appeals has rejected the implied certification theory altogether.[6] However, a majority of the

appellate circuits have held that there is only liability under the false certification theory when a violation of a statute or regulation is an express condition of payment, such as the services must be medically necessary or that CMS must be treated as a secondary payer when the patient has commercial insurance.[7] This view has provided a shield to many providers, as violations that involve Medicare or Medicaid Conditions of Participation, but not conditions of payment, have not resulted in FCA liability. Note that because the Stark and Anti-Kickback statutes regard conditions of payment, a violation of these statutes constitutes a violation of the False Claims Act.

The *Escobar* case

However, the Supreme Court, in *Escobar*, resolved the appellate circuit split and shifted the implied certification theory paradigm. *Escobar* involved a scenario where Yaruskha Rivera, a teenage beneficiary of Massachusetts' Medicaid program, received counseling services at a mental health facility. During her treatment, and as a result of medication prescribed by her purported doctor, she later died at 17 years old. Afterward, it was discovered that the providers were not licensed to provide mental health counseling, that there was little supervision of those individuals, and that the person prescribing the medication was not authorized to prescribe medication. The reimbursement codes submitted for payment to the Massachusetts' Medicaid program corresponded with different codes that corresponded to various services that the staff provided Yaruskha, and the staff also misrepresented their qualifications and licensed status to the government.[8]

In holding that the providers violated the FCA, the Court expressly rejected the Seventh Circuit's position that the implied false certification theory is not a valid FCA-prosecution theory. Specifically, the Court stated, "When, as here, a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided."[9] Citing the common law, the Court found that fraudulent (or false) conduct includes certain misrepresentations by omission. The Court determined that if claims represented to the government state the truth but omit important qualifying information, such as not being licensed to prescribe medication to a patient, those omissions can be a basis for violating the FCA.[10]

In the end, the Court held that the implied certification theory is a basis for liability when two conditions are met: (1) the claim does not merely request payment but also makes specific representations about the goods or services provided; and (2) the failure to disclose non-compliance with *material* statutory, regulatory, or contractual requirements makes these representations misleading half-truths (emphasis added).[11]

Materiality

It is irrelevant whether the government designates the alleged misrepresentation as a condition of payment; the extent of the violation will be determined through the two-pronged analysis stated earlier, and in particular, whether the non-disclosed violation is material to the government's decision on whether or not to pay the claim. The Court opined that materiality

requirement is "demanding," and that minor violations will be insufficient under the implied false certification theory.[12] The Court did not elaborate on what types of misrepresentations it considers to be material.

Even though *Escobar*, at first glance, appears to be favorable to the government and *qui tam* relators (i.e., private citizens pursuing FCA allegations on behalf of the government), the decision in *Escobar* presents new hurdles to those litigants, such as those entities having to show now with specificity that the allegations are material and not just that the misrepresentations were a condition of payment. Providers can expect to be required to defend more FCA cases as a result of *Escobar* (as the crux of the FCA case is no longer limited to alleged express misrepresentations regarding conditions of payment). Conversely, lower district courts have shown more of a willingness to dismiss the case through motions to dismiss and motions for summary judgment due to the alleged misrepresentations not meeting the materiality requirement.[13]

However, while providing a materiality defense to providers, *Escobar* presents unresolved questions, such as which misrepresentations will be considered material. Will violations of Conditions of Participation involving patient safety or patient's rights materially affect the government's decision to issue a payment on a claim? Will medical record and provision of care regulations materially affect the government's decision to issue payment on a claim? It is likely that the impact of *Escobar* will be an increase in FCA cases and that the different appellate circuits will have varying interpretations as to what constitutes materiality. This activity will create uncertainty for providers until more guidance can be issued from the courts or the various governmental agencies, such as the Department of Justice or the Centers for Medicare & Medicaid Services.

Conclusion

Because providers will likely be forced to defend more FCA cases, it is ever more important for those providers to have an active and proactive compliance program. As articulated by the OIG and the Federal Sentencing Guidelines, it is imperative that the compliance program is supported by the top-level management of the organizations and that the program provides rigorous education and training to the employees of the organization. Perhaps more important is that to mitigate against the risks, the organization's compliance program must actively monitor and audit the employees to ensure that they understand the compliance risks and also to make sure that the organization remains compliant in the organization's high-risk areas, such as billing, coding, and personal health information privacy.

Only through an effective compliance program will the organization be proactive in avoiding FCA liability.

1. 31 U.S.C. § 3729 (2016)
2. Sean Hennessy: "The Fate of the Implied Certification Theory of False Claims Act Liability" American Bar Association, YLD Committee, (Spring 2016). Available at http://bit.ly/2ktez1X
3. Id.
4. Id.
5. Steven Kaufmann, Marc Hearron, and Aaron Rauh: "Navigating the Circuit Split on Implied False Certification" *Law360*, November 16, 2015. Available at http://bit.ly/2jpSFuA
6. Id.
7. Id.
8. *Universal Health Services. Inc. v. U.S. ex. rel. Escobar*, No. 15-7, 2016 WL 3317565 (June 16, 2016). Available at http://bit.ly/2kjnY8P.
9. Id. at 13.
10. Id. at 13-14.
11. Id. at 15.
12. Id.
13. John Bentivoglio, et. al.: "*Escobar* and the Implied Certification Theory: Initial Cases Raise the Bar on Materiality in False Claims Act Litigation" Skadden, Arps, Slate, Meagher & Flom LLP; November 7, 2016. Available at http://bit.ly/2k3GUuU