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# Federal Prosecutors Expand Use of the False Claims Act to Combat Opioid Epidemic

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In an effort to combat the opioid epidemic, the Department of Justice is getting more creative with the tools in its toolbox. Case in point, federal prosecutors nationwide recently started using the False Claims Act, 31 U.S.C. §§ 3729-3733, to investigate health systems' and prescribers' opioid prescribing practices.

This Litigation Update is the first in a multi-part series on the False Claims Act in the health care context. Part 1 provides a general overview of the False Claims Act.

## General Overview of the False Claims Act

The False Claims Act is a federal civil fraud statute that dates back to the Civil War. The False Claims Act applies to parties who contract with the U.S. Government and imposes liability on parties who defraud government programs. In the health care context, the False Claims Act applies to health systems and providers who submit false or fraudulent claims for payment under Medicare or Medicaid, and other federally funded programs such as Tricare.

The penalties for filing false claims are steep. Violators are currently subject to civil monetary penalties of not less than $11,181 and not more than $22,363 per false claim, plus three times the actual damages incurred by the Government due to the fraud. 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5 (2018).

## The False Claims Act and the Opioid Epidemic

Government agencies — including the Department of Justice — are under intense pressure to aggressively investigate and prosecute individuals and entities who may have contributed to the opioid epidemic. To that end, the Department of Justice is, with increasing frequency, investigating doctors and health systems with a history of prescribing high quantities of opioids to patients on Medicare or Medicaid. In such cases, the Department of Justice typically alleges that the opioids prescribed were "medically unnecessary," thereby rendering the claim for reimbursement false.

## What Makes a False Claim?

The False Claims Act creates liability for any person who knowingly presents, or causes to be presented, a false or fraudulent claim to the United States Government for payment or approval. To act knowingly requires a person to have actual knowledge, act in deliberate ignorance, or act in reckless disregard of the truth or falsity of the information. Although acting knowingly does not require proof of specific intent to defraud, innocent mistakes or negligence are not actionable.

Notably, the False Claims Act does not define "false" or "fraudulent." Courts, however, have found liability based on two theories: (1) factually false or fraudulent; and (2) legally false or fraudulent.

Factually false statements create liability for statements which themselves constitutes lies.

Legally false statements are those that contain falsity or fraudulence in their certifications. False certification liability arises when a health care provider fails to comply with ancillary requirements, such as contractual provision, statutes, and regulations.

A claim for payment to the Government has both the express representations outlining services or products provided, as well as implied certifications regarding compliance with all governing rules and regulations. As such, liability may arise under either an implied false certification theory or an express certification theory.

## Implied False Certification Liability

Implied false certification liability is based on the theory that a health care provider implicitly certifies its compliance every time it submits an invoice to the Government — even in the absence of any express certifications of compliance. Liability under the implied false certification theory arises when:

1. The health care provider submits a claim requesting payment;
2. The claim makes representations about the goods or services provided;
3. The provider's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes these representations misleading half-truths; and
4. The provider had actual knowledge that its noncompliance was material.

The Supreme Court expressly adopted the implied false certification theory in 2016 in the case *Universal Health Servs. v. United States ex rel. Escobar.* 136 S.Ct. 1989 (2016) (holding a mental healthcare facility was liable for a patient's death while undergoing treatment by doctors who lacked qualifications and licenses).

## Express False Certification Liability

Most cases which allege liability based on medically unnecessary or unreasonable services proceed under an express false certification theory. This is because Medicare and Medicaid reimbursement forms require express certification of adherence to their guidelines. To prove liability under an express false certification theory, the Government must show:

1. The provider submitted a claim;
2. The claim has expressly certified compliance with ancillary legal requirements, such as rules, regulations, standards or contractual terms;
3. This claim was false or fraudulent; and
4. This certification was material to the Government's payment decision.

### *Was the Treatment Medically Unnecessary or Unreasonable?*

Excluded from Medicare coverage are items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury. The Medicare Program Integrity Manual defines reasonable and necessary as:

1. Safe and effective;
2. Not experimental or investigational;
3. Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is: (i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; (ii) furnished in a setting appropriate to the patient's medical needs and condition; (iii) ordered and furnished by qualified personnel; (iv) one that meets, but does not exceed, the patient's medical need; and (v) at least as beneficial as an existing and available medically appropriate alternative.

Ctrs. For Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs. Medicare Program Integrity Manual (Pub 100-08), ch. 13, §5.1.

Centers for Medicare and Medicaid Services (CMS) may promulgate national coverage decisions (NCDs) that may grant, limit, or exclude Medicare coverage for a specific medical service. NCDs are binding on all Medicare contractors processing Medicare claims. 64 Fed. Reg. 22619. Because coverage decisions are made at the discretion of local contractors, local contractors may also publish local medical review policies (LMRPs) to provide guidance to the public and medical communities for when Medicare considers an item or service "reasonable and necessary." *Id*. Additionally, Medicare Administrative Contractors may issue local coverage determinations (LCDs), which are also binding on medical service providers. *United States ex rel. Youn v. Sklar*, 273 F. Supp. 3d 889 (N.D. Ill. 2017).

Absent any binding guidelines, courts generally require concrete medical, technical, or scientific context in order to allege that a treatment was medically unreasonable or unnecessary. *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770 (7th Cir. 2016).

***Was the Treatment False or Fraudulent Prescribing or was it Poor Medical Judgment?***

The Medicare Program Integrity Manual empowers courts to take into account accepted standards of medical practice for the diagnosis or treatment of the patient's condition in determining medical necessity or appropriateness. Claims which are incompatible with standards of accepted medical practice may be medically unnecessary or unreasonable. E.g., *United States v. HCA Holdings Inc.*, No. 12-20638-CIV, 2015 WL 11198933 (S.D. Fla. July 21, 2015).

Courts are, however, split as to whether poor medical judgment, without more, can create liability under the False Claims Act. Some district courts have held that a reasonable difference in of opinion between physicians, without more, is not enough to show falsity. *United States v. AseraCare Inc.*, 938 F.3d 1278, 1281 (11th Cir. 2019). The Eleventh, Fifth, and First Circuits have generally adopted the view that False Claims Act liability requires objectivity in falsity. *Urquilla–Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1052 (11th Cir. 2015); *United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 87 (1st Cir. 2012); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004). The Third Circuit joins with its view that "expression of opinion, scientific judgments or statements as to conclusions which reasonable minds may differ cannot be false." *United States ex rel. Hill v. Univ. of Med. & Dentistry of N.J.*, 448 F. App'x 314, 316 (3d Cir. 2011).

Other courts disagree. The 10th Circuit, for example, has noted that "it is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA." *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018). The 6th Circuit has similarly noted that "opinions are not, and have never been, completely insulated from scrutiny. At the very least, opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion." *United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018).

## Conclusion

Health systems and prescribers must be cognizant of the fact that the Department of Justice is using the False Claims Act to combat the opioid crisis. To ensure compliance with the False Claims Act, health systems should monitor the prescribing practices of its providers and implement policies and procedures governing the prescribing of opioids.

This Update serves as a primer to the False Claims Act. Future Updates will explore various aspects of a False Claims Act action, including Civil Investigative Demands, the interplay with the Controlled Substances Act and other federal statutes, special considerations for *qui tam* actions, cooperation credit, and settlement.