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New FCA Ruling Revives Tools To Establish Falsity

By **Lon Leavitt** (March 26, 2020, 6:06 PM EDT)

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In recent years, certain government policies and court decisions weakened or dulled some important weapons the government and whistleblowers traditionally have wielded to establish falsity in cases under the False Claims Act. These weapons include using medical necessity, clinical judgments, subregulatory guidance and statistics to establish that a claim or statement is false.

However, on March 23, the U.S. Court of Appeals for the Ninth Circuit published a significant decision in U.S. v. Gardens Regional Hospital and Medical Center Inc. strengthening and sharpening these weapons in the arsenals of government attorneys and whistleblower counsel.[1]

The Winter Decision

Jane Winter, a registered nurse with many years' experience directing case management at hospitals, reviewed admissions at the hospital where she worked. To perform her case management duties, Winter used widely accepted admissions criteria used by hospitals, experts and Medicare to evaluate claims for payment.

Winter noticed some suspicious spikes in inpatient admissions that caused her to dig deeper. Upon further investigation, Winter discovered admission and billing patterns that she believed were fraudulent, resulting in more than $1.2 million that her hospital billed to Medicare for false claims in less than two months.

Winter repeatedly tried to bring her concerns to the attention of hospital management, including the chief executive officer and chief operating officer, but had no success in rectifying the misconduct. Eventually, the hospital fired Winter and replaced her with an employee who had not questioned inpatient admissions.

Winter filed a qui tam case under the FCA alleging that defendants submitted Medicare claims falsely certifying that patients' inpatient hospitalizations were medically necessary. After the government declined to intervene, the district court dismissed Winter's case, holding that "to prevail on an FCA claim, a plaintiff must show that a defendant knowingly made an objectively false representation," so a statement that implicates a doctor's clinical judgment can never state a claim under the FCA because "subjective medical opinions ... cannot be proven to be objectively false."[2]

The Ninth Circuit, however, reversed and validated not only the theory behind and sufficiency of Winter's allegations, but also several important means of alleging and proving them.

Clinical Judgments, Like Other Opinions, Can be False Under the FCA

Like the district court in Winter, some courts require objective falsity and reject cases based on subjective opinions.[3] However, the Ninth Circuit in Winter endorsed the concept that clinical judgments and opinions may be false, for example, if they are not honestly held or if they "impl[y] the existence of facts … that do not exist."[4]

As the court explained, "the FCA imposes liability for all 'false or fraudulent claims' — it does not distinguish between 'objective' and 'subjective' falsity or carve out an exception for clinical judgments and opinions."[5] Accordingly, "an opinion with no basis in fact can be fraudulent if expressed with scienter."[6]

Medically Unnecessary Claims Can Violate the FCA

Recent attacks on subjective falsity have undermined, to some extent, the "medical necessity" theory of FCA liability, which often relies on expert testimony to establish a lack of medical necessity or reasonableness and, therefore, falsity. But the Ninth Circuit in Winter reaffirmed that submission of a claim to Medicare for medically unnecessary services, if done knowingly, can violate the FCA.

In fact, federal law prohibits the government from using Medicare funds to pay for unnecessary services:

> [N]o payment may be made ... for any expenses incurred for items or services ... [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.[7]

Similarly, Medicare pays for inpatient hospitalization "only if ... such services are required to be given on an inpatient basis for such individual's medical treatment."[8] Thus, the Ninth Circuit joined the U.S. Court of Appeals for the Third Circuit, the U.S. Court of Appeals for the Fifth Circuit and the U.S. Court of Appeals for the Tenth Circuit in holding that "a false certification of medical necessity can give rise to FCA liability."[9]

Subregulatory Guidance Can Help Establish Falsity

As numerous courts have held, billing a federal health care program in violation of the Medicare Claims Processing Manual, the Medicare Benefit Policy Manual, or other applicable billing requirements, after agreeing not to do so and certifying not to have done so, triggers liability under the FCA.[10]

However, in January 2018, the U.S. Department of Justice issued the so-called Brand memorandum, which prohibits the use of government enforcement authority to effectively convert agency documents into binding rules. Since that time, several defendants have argued, with some success, that the element of falsity under the FCA cannot be premised on a party's noncompliance with guidance documents (such as manuals, local coverage determinations and bulletins issued by the Centers for Medicare and Medicaid Services) as opposed to statutes or regulations.

However, in Winter, the Ninth Circuit upheld the relator's theory of liability and falsity based, in part, on manuals issued by the CMS.[11]

Statistics Can Help Demonstrate Falsity

The use of statistics — to prove liability, damages or both — in FCA cases has been a topic of frequent litigation resulting in various outcomes.[12]

The Ninth Circuit's decision in Winter seems to approve of the use of statistics in FCA cases, at least for some purposes, stating that "not only does Winter identify suspect trends in inpatient admissions — for example, hospitalizing patients for [urinary tract infections] — she also alleges statistics showing an overall increase in hospitalizations" and that "the daily occupancy rate jumped by almost 10%, the number of Medicare beneficiaries became the highest it had ever been by a significant margin, and the admissions rate from Rollins Nelson nursing homes was over 80%."[13]

Takeaway

The Winter decision is an important addition to key aspects of FCA jurisprudence, including whether and how medical necessity, clinical judgments, subregulatory guidance, and statistics bear on the sufficiency of allegations and proof of falsity. The Ninth Circuit's analysis of these frequently litigated topics is relevant to all FCA practitioners as a noteworthy revitalization of important weapons in the enforcement of the FCA.

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[1] See Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr. Inc., --- F.3d ----, No. 18-55020, 2020 WL 1329661 (9th Cir. Mar. 23, 2020).

[2] Winter, 2020 WL 1329661 at *1.

[3] See, e.g., U.S. v. AseraCare Inc., 938 F.3d 1278, 1296-97 (11th Cir. 2019) ("a claim that certifies that a patient is terminally ill ... cannot be 'false'—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood").

[4] Winter, 2020 WL 1329661, at *8.

[5] Id. at *6.

[6] Id.

[7] 42 U.S.C. § 1395y(a)(1)(A).

[8] 42 U.S.C. § 1395f(a)(3).

[9] Winter, 2020 WL 1329661, at *6.

[10] See, e.g., U.S. v. Mount Sinai Hosp., 256 F. Supp. 3d 443, 452 (S.D.N.Y. 2017) ("[T]here have been numerous cases imposing FCA liability, and even criminal false claims liability, based on violations of Medicare manual provisions."); In re Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 351-52 (D. Conn. 2004) (same) (collecting cases).

[11] See Winter, 2020 WL 1329661, at *2 (relying on the Medicare Program Integrity Manual and another CMS publication to inform the definition of medically reasonable and necessary); see also U.S. v. Adams, 371 F. Supp. 3d 1195, 1213-14 (N.D. Ga. 2019) ("claims submitted in contravention of a local coverage determination may still be false for purposes of the FCA," and despite the Brand memorandum, a relator "can state an FCA claim based on an alleged violation of the Medicare Program Integrity Manual").

[12] Compare U.S. ex rel. Martin v. Life Care Centers of America Inc., 114 F. Supp. 3d 549, 571-72 (E.D. Tenn. 2014) and U.S. ex rel. Loughren v. Unum Provident Corp., 604 F. Supp. 2d 259, 261 (D. Mass. 2009) with U.S. ex rel. Wall v. Vista Hospice Care Inc., No. 3:07-cv-00604-M, 2016 WL 3449833, at *13-14 (N.D. Tex. June 20, 2016) and U.S. ex rel. Michaels v. Agape Senior Cmty. Inc., No. 0:12-3466-JFA, 2015 WL 3903675, at *3 (D.S.C. June 25, 2015).

[13] Winter, 2020 WL 1329661, at *8.