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STRATEGIES FOR AVOIDING THE "BATTLE OF THE EXPERTS" IN FALSE CLAIMS ACT CASES BASED ON MEDICAL NECESSITY

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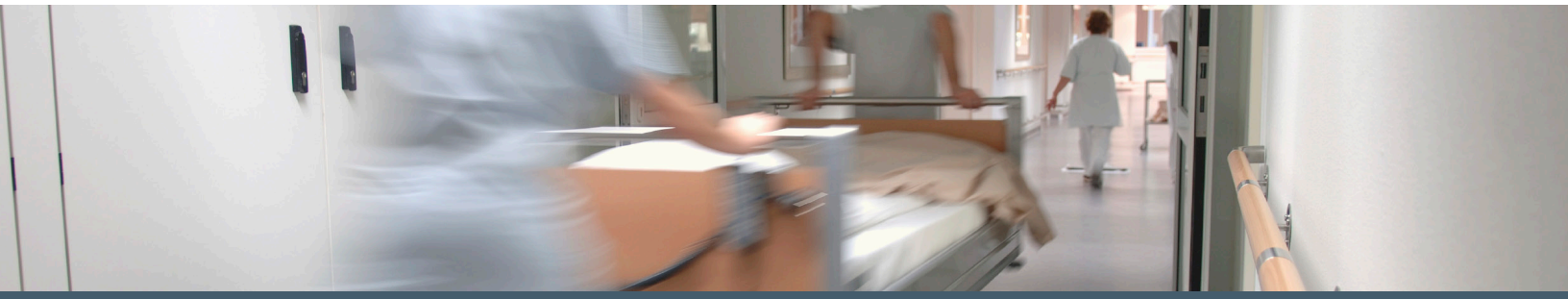

Medical necessity cases continue to be a focal point for False Claims Act (FCA)[2] investigations and lawsuits. With this focus comes an age-old problem for health care providers and entities defending these actions: the so-called "Battle of the Experts." In these types of cases, the U.S. Department of Justice (DOJ) and/or a relator challenge a diagnosing doctor's opinion that a procedure or service was medically necessary. As a result, the complaint alleges that the follow-on reimbursement claim submitted to the applicable federal health care program was "false" for the purposes of the FCA. A successful defense in these cases may ultimately hinge simply on whether the jury believes (or likes) the plaintiff's or the defendant's testifying expert more.

The time and expense to reach that point—and the accompanying litigation costs—usually leave most FCA defendants with little option but to settle medical necessity cases regardless of the merits of the underlying allegations. This issue of K&L Gates' *Qui Tam Quarterly* examines two recent federal circuit court decisions analyzing the critical litigation issue in these Battle of the Expert cases: whether a plaintiff's expert's testimony that the diagnosing doctor's medical opinion was wrong is sufficient to create a question of fact as to whether the underlying claim was "false" for FCA purposes. This article offers practical tips to proactively address—and, ideally, to avoid—the Battle of the Experts that results from medical necessity claims.

The Eleventh Circuit's "Objective Falsehood" Standard

In its September 2019 decision in *United States v. AseraCare, Inc.*,[3] the U.S. Court of Appeals for the Eleventh Circuit (Eleventh Circuit) considered whether a "provider's clinical judgment that a patient is terminally ill [can] be deemed false based merely on the existence of a reasonable difference of opinion between experts as to the accuracy of that prognosis."[4] In *AseraCare*, the defendant certified that certain elderly patients qualified for Medicare's hospice benefit. The government argued that the hospice certifications were based on erroneous clinical judgments and presented expert testimony at trial that the "patients at issue were not, in fact, terminally ill at the time of certification, meaning that [AseraCare's] claims to the contrary were false under the False Claims Act."[5]

According to the government, it was the jury's role to determine which doctor's judgment—the AseraCare physician's or the government expert's—was correct. Thus, DOJ argued, "to the extent the jury found [the government expert's] prognosis to be more persuasive," the jury should find that AseraCare "had thereby submitted a false statement when it filed a claim based on a prognosis that differed" from what the government expert deemed correct.[6] In analyzing this claim, the Eleventh Circuit concluded that the only question with respect to falsity "related to the sufficiency of the clinical judgments on which the claims" to Medicare were based.[7]

The Eleventh Circuit rejected DOJ's argument and instead held that where a claim is based on properly exercised clinical judgment, "the claim cannot be false—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood."[8] The Eleventh Circuit stated that the requirements for hospice eligibility do not require that "the documentary record underpinning a physician's clinical judgment…prove the

prognosis as a matter of medical fact."[9] For this reason, the Eleventh Circuit disagreed with the government's argument that documentation requirements in the regulations should be interpreted to require information that would independently validate a physician's medical judgment.[10]

Accordingly, given the absence of facts and circumstances tending to show that the challenged clinical judgment was objectively false, "the FCA claim fail[ed] as a matter of law."[11] The Eleventh Circuit stressed that "a reasonable difference of opinion among physicians reviewing medical documentation ex post is not sufficient on its own" to demonstrate that the original judgment is objectively false.[12] The Eleventh Circuit then provided several scenarios in which a doctor's clinical judgment could constitute an "objective falsehood" for purposes of the FCA: (i) a "certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition"; (ii) a "physician did not, in fact, subjectively believe" her clinical assertion at the time of certification; or (iii) expert evidence proves that "no reasonable physician" could have formulated the clinical opinion under the given facts and circumstances.[13]

The Third Circuit Takes a "Straightforward" Course on Falsity

Six months later, in March 2020, the U.S. Court of Appeals for the Third Circuit (Third Circuit) examined the same question—whether a hospice provider's claim for reimbursement can be considered false under the FCA on the basis of expert testimony that patient certifications did not support a prognosis of terminal illness—and rejected the Eleventh Circuit's objective-falsehood requirement for FCA falsity.[14] As in *AseraCare*, the qui tam relators in *United States ex rel. Druding v. Care Alternatives* alleged that their former employer submitted false hospice reimbursement claims to Medicare and Medicaid and admitted ineligible patients to hospice. Accordingly, the Third Circuit was asked to resolve whether an expert medical opinion can provide the basis for a false claim under the FCA. The Third Circuit answered with a "straightforward yes": for purposes of falsity under the FCA, "a claim may be 'false' under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements."[15] Consequently, a "physician's expert testimony challenging a hospice certification creates a triable issue of fact for the jury regarding falsity."[16]

According to the Third Circuit, an examination of factual falsity or legal falsity aims at the same ultimate question: "FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government."[17] The Third Circuit rejected the Eleventh Circuit's reasoning in *AseraCare* because "limiting falsity to factual falsity is inconsistent with our case law, which reads FCA falsity more broadly as legal falsity, encompassing circumstances where a claim for reimbursement is non-compliant with requirements under the statute and regulations."[18] In contrast, under a theory of legal falsity, "a medical opinion that differs from the certifying physician's opinion is therefore relevant evidence" of "whether there was documentation accompanying the certification that supported the medical prognosis."[19]

STRATEGIES FOR AVOIDING THE BATTLE OF THE EXPERTS

As this emerging line of split authority demonstrates, whether a judge or jury finds that a clinical judgment of a diagnosing physician regarding medical necessity is "false" for purposes of the FCA may turn on what a "hired gun" testifying doctor thinks about the appropriateness of any given procedure years later, with the benefit of hindsight (and compensation for their opinion). What is more troublesome is that differing medical opinions alone may be enough to create a question of fact on the "falsity" element of an FCA claim, leaving a health care provider or entity no economic avenue to resolve a qui tam case short of a trial. The following practical tips may help health care providers and other entities avoid the Battle of the Experts altogether or at least partially curtail the burdensome and costly litigation that frequently accompanies the battle.

An Ounce of Prevention: Tips for Addressing Medical Necessity Issues Before a Qui Tam Action Is Filed

Even better than winning the Battle of the Experts is avoiding it altogether. Before touching on the litigation strategies below, it is critical that health care providers remember that their various compliance tools—most of which are up and running with the appropriate infrastructure—are available to vet potential issues that may be percolating within the system.

The primary preventative tool is the compliance program itself. Indeed, a driving factor in DOJ's evaluation of whether to intervene in a qui tam action is "the nature and effectiveness of a company's compliance system in making the determination of whether the False Claims Act is the appropriate remedy."[20] This is, DOJ has explained, because "a key element of the False Claims Act is scienter, and a robust compliance program executed in good faith could demonstrate the lack of scienter."[21]

Although each compliance program must be appropriately tailored to an organization's size and needs, a review of certain attributes contained in some recent Corporate Integrity Agreements with the Department of Health and Human Services Office of Inspector General (HHS OIG)[22] can provide a sneak peek into what DOJ and HHS OIG may consider critical components of a "robust and effective" compliance program. With respect to preventing or addressing medical necessity issues specifically, health care providers and entities should ensure that the annual audit plan considers and implements testing to ensure legal compliance with federal health care programs. Most importantly, this should include some form of third-party review on the medical necessity opinions of a statistically valid sample of the procedure in question.

A second, and often overlooked, preventive tool may be using the medical staff's peer review committee, which requires physicians to evaluate "the quality of their colleagues' work in order to ensure that prevailing standards of care are being met."[23] In addition to an effective compliance program, providers and health care entities can rely on peer review to analyze and remedy potential violations—and to demonstrate a proactive commitment to compliance.

An added benefit of utilizing the peer review process is the additional layers of confidentiality provided for under certain federal and state laws, which are designed to facilitate the ability of providers and health care entities to analyze and address allegations critically. Each state's protections differ, but they address two general subjects: liability and confidentiality.[24] At the federal level, professional review actions and individuals who assist the action or provide information to the review body are shielded from "damages under any law of the United States or of any State."[25]

When translating the relevance of a peer review to a FCA investigation, the important part is not the result but rather the process. DOJ should place value on a health care provider's or entity's willingness to allow medical professionals to address a concern of medical necessity in the ordinary course, exercising their collective professional judgment in a way to improve the delivery of quality health care.

Finally, if a health care provider or entity becomes convinced that medically unnecessary claims have been submitted to a federal health care program (through its compliance program, a peer review, or some other source), it is prudent to consider whether voluntary self-disclosure is the most efficient course. As discussed in the July 2019 edition of *Qui Tam Quarterly*, "The Department of Justice False Claims Act Policy Issue,"[26] in May 2019, DOJ released formal guidance on how to assess cooperation by entities and individuals in FCA cases.[27] The guidance defines "voluntary disclosure" as "proactive, timely, and voluntary self-disclosure" to DOJ about misconduct that "benefits the government by revealing, and enabling the government to make itself whole from, previously unknown false claims and fraud."[28] Disclosures occurring both before a federal investigation has begun as well as during the course of an internal investigation into the government's concerns may also qualify for cooperation credit.[29] DOJ leadership has said that it "want[s] to reward companies" that "police themselves, detect problems early, conduct internal investigations, take corrective measures, and cooperate with law enforcement."[30]

As the case law emerging from *AseraCare* and *Care Alternatives* reveals, after a FCA lawsuit involving medical necessity allegations is filed and DOJ begins its investigation in earnest, it becomes more difficult to "unring the bell" or to halt or slow the march to unsealing the lawsuit.

Finding the Off-Ramp: How to Avoid the Battle of the Experts After Litigation Ensues

Regardless of whether DOJ decides to intervene, once an FCA lawsuit based on allegations of medically unnecessary procedures is unsealed, health care providers and entities need to focus their litigation strategies on the two primary litigation milestones: the motion to dismiss and the motion for summary judgment. The goal is the same—convince the court to dismiss the case before trial—but the strategies differ.

At the motion-to-dismiss[31] stage, because qui tam plaintiffs who bring an FCA lawsuit based on medical necessity are alleging a scheme to defraud the United States, they must satisfy the heightened pleading standard under Federal Rule of Civil Procedure 9(b) and "state with particularity the circumstances surrounding the fraudulent activity."[32] How rigorous this particular standard is applied varies in federal courts across the nation; but as a general matter, courts will require an FCA plaintiff to plead specific facts to support its allegations regarding the existence of the allegedly fraudulent conduct, as well as facts that support its contention that claims for payment were actually submitted, not that they were merely contemplated or created a hypothetical risk of loss to the government.[33] Many courts require qui tam relators to plead facts that illustrate a "representative example of a fraudulent claim"—a list of allegedly false claims or an allegation based on personal knowledge alone may not be sufficient.[34]

In order to demonstrate that the plaintiff failed to state a claim upon which relief could be granted,[35] providers and health care entities should dissect the plaintiff's complaint and attack its failure to allege more than the scientific inaccuracy of the defendant's medical judgment. An FCA plaintiff must also allege facts establishing that

the defendant had the requisite scienter, that is, that the defendant acted knowingly, recklessly, or in deliberate ignorance of the truth or falsity of the claims it made for payment. The motion to dismiss should identify a plaintiff's failure to establish that the defendant's medical opinions were not honestly held, such as by adducing evidence or particularized allegations that the defendant's doctors did not in fact subjectively believe their own opinions or referencing more objective indicators that a defendant's doctors never reviewed records or otherwise familiarize themselves with the patient. For example, in *United States v. Paulus*, the government was able to show that the defendant cardiologist "recorded severe blockages even when the angiograms only showed mild blockages or no blockage at all."[36]

It is also important to remember that in a motion to dismiss, the government or relator must plead facts that satisfy the FCA's causation requirement for each alleged false claim and must identify which medical opinion resulted in which false submissions for payment.[37]

If not successful at the motion to dismiss stage, qui tam defendants facing allegations of medically unnecessary procedures need to focus on building a record of undisputed facts to support a summary judgment motion. As the colliding holdings of *AseraCare* and *Care Alternatives* illustrate, it is difficult to avoid the dueling opinions that unavoidably accompany every Battle of the Experts. The lesson gleaned from the emerging line of cases demonstrates that the best course of action on summary judgment is to focus on establishing that the dispute boils down to (1) only a difference of medical opinion and that (2) the diagnosing doctor's opinion is not so unreasonable that it could not be held by any other doctor.

During discovery, defendants should focus on developing a record that eliminates disputed factual questions. Through interrogatories and document requests, defendants should seek to force the plaintiff to identify each and every fact—not opinion—that is alleged to be false in each claim. For example, does the plaintiff have any evidence that the diagnosing doctor misstated a fact from a record in reaching her opinion? Does it have any evidence that the diagnosing doctor did not honestly hold the belief that the procedure at issue was medically necessary? Defendants may also follow up with timely requests for admission that confirm those specific facts—or the absence thereof.

This should set the stage to allow a defendant to nail down the plaintiff's expert during deposition by adducing testimony that the only basis for plaintiff's allegations regarding medical necessity is a difference of medical opinion with the defendant's doctor. Importantly, defendants frequently will want to go a step further and press the plaintiff's expert to opine not only as to the reasonableness of the defendant's doctor's medical opinion but also as to whether the plaintiff's expert is willing to rule out the possibility that no reasonable doctor could agree with the defendant's doctor. The goal here is not to establish a mere difference in expert opinions but to extract an admission that the defendant's medical opinion, although at odds with plaintiff's, is within the realm of reasonableness—a critical fact that the Eleventh Circuit relied upon in granting summary judgment.

Offensively, it is important not to use the defendant's expert to simply vouch for the defendant doctor's medical opinion; rather, a health care provider or entity should use discovery and its expert's deposition to establish the reasonableness of the diagnosing doctor's medical opinion. Put otherwise, it is not critical that the defendant's expert necessarily agrees with the diagnosing doctor's opinion. It is more important for the defendant's expert to testify that a reasonable doctor could have reached the same medical opinion as the diagnosing doctor. Since the upshot of the Eleventh Circuit's decision in AseraCare is that a plaintiff must have at least some disputed evidence of an "objective falsehood" in order to bring the case to a jury, a mere difference of expert opinions is not enough to survive summary judgment in courts that follow the reasoning of *AseraCare*.

Ultimately, the lesson learned from circuits with tougher standards like the Third Circuit is to focus your argument at the summary judgment stage on evidence establishing scienter rather than falsity. Additionally, it is important not to fall into the trap highlighted by the Third Circuit in lumping the analysis of the "falsity" element with that of the evidence to support the "scienter" element: "More than a mere formality, we seek to avoid the precise outcome in *AseraCare II*, where the district court folded the element of scienter into its 'objective' falsity test, but failed to fully consider evidence of scienter and, as a result, prematurely granted summary judgment."[38]

Building on the teaser from the Third Circuit, a defendant should focus on building a record and arguing at summary judgment that even if the plaintiff could present evidence through the Battle of the Experts that the diagnosing doctor's opinion was "false," there is still no evidence sufficient to create a question of fact with respect to whether the diagnosing doctor held such a belief with the requisite scienter necessary to render the claim an FCA violation. Indeed, the Third Circuit punted on this issue for another day: "Nor do we opine as to Appellants' odds of surviving summary judgment on the other prima facie elements, which the District Court did not reach."[39]

CONCLUSION

Given current trends, FCA investigations and qui tam lawsuits based on allegations of medically unnecessary procedures will become more common across the health care sector. The developing split of authority highlighted in this article underscores why health care providers should use preventive tools now more than ever to identify and remedy any potential issues regarding medical necessity that may be lurking. Then, when forced to litigate, they will be prepared from the outset to shape their case in such a way that it does not turn solely on a difference of medical opinion and devolve into the formidable Battle of the Experts.

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[1] The authors are members of the K&L Gates Health Care Fraud & Abuse group, which brings together experienced lawyers from across offices and practice groups to offer a collaborative and unique perspective to inform and drive the defense strategies and teams deployed for clients in the health care industry facing a health care fraud investigation or litigation. More information can be found here.

[2] 31 U.S.C. §§ 3729, *et seq.*

[3] 938 F.3d 1278, 1288-89 (11th Cir. 2019).

[4] *AseraCare*, 938 F.3d at 1281.

[5] *Id*

[6] *Id.* at 1289; *see also id.* at 1291 ("As applied to this case, the Government argues that it can show falsity by producing expert testimony that a patient's medical records do not support a terminal-illness prognosis as a factual matter. Where the parties present competing expert views on a patient's prognosis, the 'falsity' of the defendant's prognosis is put to a jury.").

[7] *Id.* at 1285.

[8] *Id.* at 1296–97 (internal quotation marks omitted); *see also id.* at 1301 (finding that "a new trial was warranted to allow the giving of a more complete charge: specifically, a charge that would convey that the mere difference of reasonable opinion between physicians, without more, as to the prognosis for a patient seeking hospice benefits does not constitute an objective falsehood").

[9] *Id.* at 1293.

[10] *Id.* at 1294.

[11] *Id.* at 1297.

[12] *Id.*

[13] *Id.*; see also id. at 1286.

[14] *United States ex rel. Druding v. Care Alts.*, 952 F.3d 89, 91 (3d Cir. 2020).

[15] *Id.* at 95, 100. Under the FCA, a claim can be factually false "when the facts contained within the claim are untrue" or legally false if a claimant "falsely certifies that it has complied with a *statute* or *regulation* the compliance with which is a *condition* for Government payment." *Id.* at 96 (emphasis in original) (citations and quotation marks omitted).

[16] *Id.* at 100-01.

[17] *Id.* at 97.

[18] *Id.* at 00-100.

[19] *Id.* at 100. Indeed, the Third Circuit's reasoning seems to be gaining traction. *Winter ex rel. United States v. Gardens Reg'l Hosp. and Med. Ctr., Inc.*, 953 F.3d 1108, 1113 (9th Cir. 2020) (reversing a ruling on a motion to dismiss, holding that "FCA does not require a plaintiff to plead an 'objective falsehood'" and that a physician's certification of medical necessity "can be false or fraudulent for the same reasons any opinion can be false or fraudulent. These reasons include if the opinion is not honestly held or if it implies the existence of facts—namely, that inpatient hospitalization is needed to diagnose or treat a medical condition, in accordance with accepted standards of medical practice—that do not exist.").

[20] U.S. Dep't of Justice, Press Release, "Deputy Associate Attorney General Stephen Cox Provides Keynote Remarks at the 2020 Advanced Forum on False Claims and Qui Tam Enforcement" (Jan. 27, 2020), https://www.justice.gov/opa/speech/deputy-associate-attorney-general-stephen-cox-provides-keynote-remarks-2020-advanced.

[21] *Id.*

[22] For a complete list of entities subject to Corporate Integrity Agreements and links to those agreements, *see* https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp#e.

[23] Dinesh Vyas & Ahmed E Hozain, *Clinical peer review in the United States: History, legal development and subsequent abuse*, WORLD J GASTROENTEROL. (June 7, 2014), https://www.wjgnet.com/1007-9327/full/v20/i21/6357.htm. The Joint Commission on Accreditation of Healthcare Organizations first began requiring peer review in hospitals in order to ensure maintenance of prevailing standards of care. *Id.*

[24] See 63 PA. CONS. STAT. § 425; S.D. CODIFIED LAWS ANN. §§ 36-4-25 to -26; TEX. HEALTH AND SAFETY CODE ANN. § 161.032; N.M. STAT. ANN. § 41-9-6.

[25] 24 U.S.C. § 11111.

[26] Clifford C. Histed et al., *The Department of Justice False Claims Act Policy Issue*, QUI TAM QUARTERLY (July 8, 2019), http://www.klgates.com/files/Publication/8f6668f1-b167-4189-bc29-cd8261cff535/Presentation/PublicationAttachment/547d76c7-96f1-4e00-83b4-e6c5160209a1/QuiTamQuarterly_FalseClaimsActPolicyIssue.pdf.

[27] *See id.* ("Press Release, Dep't of Justice, Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual (May 7, 2019), https://www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual.

[28] U.S. Dep't of Justice, Justice Manual § 4-4.112.

[29] *See* Histed et al., *supra* note 25.

[30] U.S. Dep't of Justice, *supra* note 27.

31 FED. R. CIV. P. 12(b)(6).

32 *Id.* at 9(b)

33 *See, e.g., United States ex rel. Holloway v. Heartland Hospice*, 386 F. Supp. 3d 884, 900 (N.D. Ohio 2019) ("In order to comply with Rule 9(b) in FCA cases, [the Sixth Circuit] require[s] the relator to identify a specific false claim in the complaint, or, where the complaint describes a complex and far-reaching fraudulent scheme, a representative example of a fraudulent claim.") (quoting *United States ex rel. Hockenberry v. OhioHealth Corp.*, 2017 WL 4315016, *2 (6th Cir. Apr. 14, 2017)).

34 Id.. *But see United States ex rel. Streck v. Takeda Pharm. Am., Inc.*, 381 F. Supp. 3d 932, 940 (N.D. Ill. 2019) (holding that Rule 9(b) was satisfied when qui tam relator described "specific contracts" and the fraud scheme generally but did not specify "the exact claims" alleged to be false).

35 FED. R. CIV. P. 12(b)(6).

[36] *United States v. Paulus*, 894 F.3d 267, 277 (2018) (citing government's expert evidence).

[37] *Care Alts* 952 F.3d at 100.

[38] *Id.* at 101.

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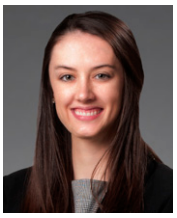

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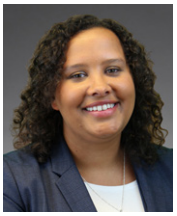

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