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False Claims After Circuits Split on Medical Necessity Issues

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In the long-awaited appellate decision in the False Claims Act action against AseraCare, one of the largest national hospice companies, on March 4, 2020, the Eleventh Circuit largely rejected the government's arguments in its appeal of the lower court's post-verdict FCA decision to vacate a huge jury award and grant summary judgment to the defense. See *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019).

However, the Third Circuit's holding in March 2020 in *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89 (3d Cir. 2020), expressly rejected the Eleventh Circuit's rationale in favor of the views expressed by the Sixth and Tenth Circuits, and the Ninth Circuit largely followed their approach in *Winter ex rel. United States v. Gardens Regional Hosp.,* No. 18-55020 (9th Cir. Mar. 23, 2020). This article examines the circuits' conflicting interpretations of the FCA and offers guidance on defending FCA cases.

Medical Necessity Rulings

AseraCare

AseraCare involved FCA allegations that the large hospice network had admitted patients covered by federal health care benefit programs who were not terminally ill under acceptable medical standards. This case went to trial (which is somewhat unusual for FCA cases, given the threat of treble statutory damages, restitution, costs, the award of attorneys' fees to the prevailing party, and the threat of exclusion from government health-care programs).

A key trial issue was if the markedly different medical opinions provided by the government's and the defense's expert witnesses about whether the medical records of selected, representative patients met acceptable medical standards was sufficient to establish FCA liability without other indicia of fraud or without an opinion that the underlying certifications of hospice eligibility were knowingly false when made.

In many ways, the Eleventh Circuit's *AseraCare* opinion is unique to the hospice industry. The court scoured available regulations and guidance to find objective criteria that could establish that an actionable false claim was made—but it found no hook other than "acceptable medical standards."

Courts in other cases have used objective criteria to provide sufficient evidence that an opinion was objectively false. Examples include the Third Circuit's *Care Alternatives* decision mentioned above, the Sixth Circuit's holding in *United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018), where that appeals court noted that medical "opinions are not, and have never been, completely insulated from scrutiny," and the Tenth Circuit's decision in *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018), in which the court held that "a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase."

These cases have created a clear circuit court split for the U.S. Supreme Court to resolve by accepting a writ of certiorari on this important issue.

Care Alternatives

Care Alternatives also involved an FCA action against a hospice provider, but the Third Circuit expressly rejected the Eleventh Circuit's *AseraCare* rationale, explaining that an "objective falsity" is not required under the FCA and further that a "difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity."

Winter

The Ninth Circuit's holding in *Winter* involved questions related to the medical necessity of hospital admissions, not hospice certifications. In *Winter*, the plaintiff was a registered nurse who became the director of care management and emergency room at Gardens Regional Hospital with 13 years of experience as a director of case management at hospitals. Her job was to review hospital admissions based on annually updated criteria it had adopted (the InterQual Level of Care Criteria). The InterQual criteria are validated by a national panel of medical experts and Medicare uses them in evaluating

payment claims. In her work, the plaintiff would apply these criteria in reviewing and evaluating the underlying medical necessity of patient admissions.

The plaintiff filed suit after being fired following making complaints about an improper pattern of patient admissions from a nursing home that did not meet those criteria. She alleged that none of the identified patient admissions were medically necessary. Notably, the district judge dismissed Winter's FCA claims. The judge found a determination of "medical necessity" to be a "subjective medical opinion" that could not be proven objectively false.

On appeal, the Ninth Circuit rejected the argument that the FCA requires proving an objective falsehood. Instead, it held it wasn't an element of proof under the Act and wrote that its determination did not conflict with *AseraCare*. It explained that the Eleventh Circuit had not been asked to rule if a "medical opinion could ever be false or fraudulent, but [only] whether a reasonable disagreement between physicians, without more, was sufficient to prove falsity at summary judgment" and "that its 'objective falsehood' requirement did not necessarily apply to a physician's certification of medical necessity"—unlike the hospice benefit at issue in *AseraCare*, which "defers to 'whether a physician has based a recommendation for hospice treatment on a genuinely-held clinical opinion' whether a patient was terminally ill."

Although the Ninth Circuit in *Winter* attempted to distinguish its holding from the Eleventh Circuit's holding in *AseraCare*, it also remarked that "to the extent that *AseraCare* can be read to graft any type of 'objective falsity' requirement onto the FCA, we reject that proposition."

Conflicting Interpretations

From a predictive or planning role, three useful general concepts apply to a broader range of FCA cases:

- The use of valid statistical sampling to help prove up medical necessity cases
- Establishing a causal link between the alleged conduct and the alleged resulting false claims described by the plaintiff in its pleadings
- Proof of objective falsity

Sampling

First, while sampling may be a useful tool to compute damages in complex FCA cases—so long as it is done properly and for the right purposes—there has been a disconnect about how and when to use it. The government and qui tam plaintiffs broadly favor the use of sampling since it provides a cheaper way for them to argue for a larger recovery without having to spend time linking up each allegedly false claim with the underlying conduct that is contended to be wrongful.

Providers, however, have generally objected that sampling is inappropriate to evaluate liability in FCA cases, particularly in those cases that involve medical necessity judgments made by physicians. While courts generally permit valid statistical sampling to be used for extrapolating damages, sampling is less accepted when used to establish liability in False Claims Act cases.

Causal Link

Second, establishing a causal link between the alleged conduct and resulting false claims is a critical proof issue in all FCA actions. As noted, while some plaintiffs and the government have tried to rely on statistical sampling to prove FCA liability, the practice remains controversial. Compare, e.g., *United States v. Life Care Centers of America, Inc.*, 114 F.Supp.3d 549, 567 (E.D. Tenn. 2014) with *United States v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604-M (N.D. Tex. June 20, 2016).

Objective Falsity

Third, proof of objective falsity should be required for FCA cases predicated on disputed medical necessity. Even though the FCA's text does not use the term "objective falsity," nevertheless the act requires falsity, and a plaintiff bears the burden of proving that an alleged claim is false. In FCA cases involving disputed medical necessity issues, plaintiffs still have obstacles to overcome in order to prove than an opinion is false.

The current split on this important issue among the courts of appeal raises the importance of the Supreme Court resolving the matter, particularly since the nature of FCA actions provides plaintiffs with the opportunity to select favorable jurisdictions in which to file their lawsuits, which can lead to very disparate results on this question.

Roadmap for Defense

Outside the Third, Sixth, Ninth and Tenth Circuits, *AseraCare* provides a valuable roadmap for the defense to consider using when challenging those FCA cases in which the alleged misconduct is not sufficiently tied to the alleged false claims and the government or relator relies on disputed expert testimony about medical necessity.

Link False Claims to Poor Care

In the context of the so-called "worthless services" theory of FCA liability, if a relator or the government alleges a pattern of patients who experienced negative outcomes, and that their care was not proper or medically necessary, as a practical matter, a plaintiff still must link those purported false claims to the allegedly poor care since the FCA is not intended as a substitute for malpractice actions.

Link Bad Conduct to Payments

There also must be a stated connection between the allegedly bad conduct and the specific payment claims allegedly presented to a government health care program. Simply put, just making global bad conduct allegations that are unhinged from actual claims for payment are insufficient to establish FCA liability.

Conclusion

Providers should not construe *AseraCare* to mean that medical necessity issues are immune from FCA liability—particularly in the Third, Sixth, Ninth, or Tenth Circuits. In all courts, when it can be proven that other badges of fraud occurred, a medical necessity argument will not work as a defense.

Because the False Claims Act often involves bet-the-company litigation, clients and other service providers in the highly regulated health-care industry should engage experienced counsel for proper advice at the first signs of a possible FCA violation. The issues can be complex in this area of law, and the law continues to evolve.

Companies that routinely submit reimbursement claims to the government and are subject to a myriad of exacting rules and regulations may find that what appears to be a routine human resources employment issue can unexpectedly involve an unanticipated FCA matter.