Updates
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AseraCare Settlement Ends Medical Judgment False Claims Act Case With a Whimper

The U.S. Department of Justice (DOJ) has reached a settlement with hospice company AseraCare, closing a 12-year-old saga that carries substantial implications for False Claims Act (FCA) enforcement in cases involving a clinician's medical judgment. In recent years, whistleblowers and the government have launched multiple FCA civil enforcement actions, including the case against AseraCare, based on a theory that medical claims were false because they lacked medical necessity or were otherwise based upon dubious medical judgment.

Recently, the U.S. Court of Appeals for the Eleventh Circuit dealt those efforts a significant blow, ruling that a reasonable disagreement among experts as to that clinical judgment was an insufficient basis to establish "falsity" for purposes of an FCA claim. *U.S. v. AseraCare Inc.*, 938 F.3d 1278 (11th Cir. 2019). The case was remanded on other grounds, and, according to a company statement, AseraCare has now agreed to pay DOJ $1 million to resolve the matter, a far cry from the $200 million that the government alleged AseraCare was overpaid.

AseraCare Litigation Background

Showing falsity is a required element of an FCA action. Under the FCA, providers seeking payment from government insurance programs, such as Medicare, are subject to draconian penalties if a court finds that the claims are false and knowingly filed. In 2019 alone, government recoveries from false claim litigation involving the U.S. Department of Health and Human Services, which oversees the Medicare program, totaled over $3 billion.

Medicare generally prohibits payment for services that are "not reasonable and necessary for the diagnosis of treatment of illness…" 42 U.S.C. §1395y(a)(1)(A). As such, in some FCA cases, the whistleblowers and the government have alleged that claims were "false" because the services were not medically necessary, an issue that typically requires evaluation of the provider's medical judgment. Medicare limits coverage for hospice care to individuals deemed to be "terminally ill," meaning "a medical prognosis" that his or her "life expectancy is 6 months or less." 42 U.S.C. § 1395x(dd)(3)(A). In *AseraCare,* DOJ alleged that AseraCare's patients were not credibly "terminally ill" and its certification that the patients were eligible for hospice care coverage was false.

After declining to enter summary judgment, the district court bifurcated the issue of falsity from all other issues. During an approximately eight-week trial on the question of falsity, each side's testifying experts offered opposing views on whether the AseraCare patients in question met the statutory definition of "terminally ill." DOJ's medical expert testified that the medical records for 123 sampled patients did not support the AseraCare certification of terminal illness. AseraCare's experts concluded otherwise and offered that criteria put forth in the local coverage rules were not necessarily determinative of whether the patients were terminally ill as Medicare requires for coverage. The jury ultimately entered a verdict against AseraCare on falsity as to 104 of 123 patients. But the district court then granted AseraCare's motion for a new trial, concluding that its own jury instructions on the legal standard for falsity were flawed. The court then went further and entered summary judgment in favor of AseraCare, holding that the government could not prove falsity because it had not presented evidence of an "objective falsehood" for any of the patients at issue.

On the government's appeal, the Eleventh Circuit was asked to opine whether differences in clinical judgment meant that the claims submitted were objectively false. Its answer: no.

Affirming the district court's grant of a new trial, the Eleventh Circuit found that under the relevant statutory and regulatory framework, a provider's clinical judgment "lies at the center of the eligibility inquiry" and "[n]othing in the statutory or regulatory framework suggests that a clinical judgment regarding a patient's prognosis is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees with that clinical judgment." The court held that a hospice claim "cannot be 'false'—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood." The court explained that while objective falsehood can be shown in a "variety of ways," "in order to show objective falsity as to a claim for hospice benefits, the Government must show something more than the mere difference of reasonable opinion concerning the prognosis of a patient's likely longevity." The court concluded, however, that the district court erred in granting summary judgment without hearing all the evidence and remanded the case to the district court to reconsider its order in light of all relevant evidence, not just the trial record.

Implications

While the *AseraCare* case has now settled, the Eleventh Circuit's decision has several significant implications for future FCA cases.

- **Proving lack of medical necessity based on medical record review may be more difficult in FCA cases.** Although it dealt specifically with hospice care, the court's opinion recognized that converting medical judgments exercised while practicing the art of medicine into objectively factual scientifically provable assessments is a hazardous business. The court suggested that it should be "more challenging for [an FCA] plaintiff to present evidence of an objective falsehood than to find an expert witness willing to testify to a contrasting clinical judgment regarding cold medical records." The application of the court's decision beyond the context of hospice care is as yet unclear, however, as the decision specifically applies to the determination whether someone is "terminally ill," which in turn requires evaluation of a "prognosis." Such a determination is inherently speculative and thus susceptible to conflicting clinical judgments. One district court has interpreted *AseraCare* as confined to the hospice context. *See United States ex rel. Bell v. Cross Garden Care Center*, 2019 WL 6493972, at *5 n.5 (M.D. Fla. Dec. 3, 2019). But the Eleventh Circuit's reasoning arguably applies to other areas in which medical necessity rests on subjective clinical judgment. Defense counsel in such cases will undoubtedly cite the decision, and it would be surprising if its reasoning were not followed by courts in other FCA medical necessity cases.
- **The medical record need not provide conclusive proof of medical necessity.** In *AseraCare*, DOJ argued that eligibility for hospice care under Medicare turns on whether the underlying medical records support a physician's certification that an individual was within six months of death. The court rejected this approach, writing that the coverage statute does not require the supporting documentation, standing alone, to prove the validity of the doctor's clinical judgment. As the court put it, "the physician's clinical judgment dictates eligibility as long as it represents a reasonable interpretation of the relevant medical records." The court also noted that "the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding." Similar arguments can be made in other FCA contexts where alleged falsity turns on medical record documentation that is incomplete, internally inconsistent, or partially deficient.
- **Which circuit court's thinking applies?** The Eleventh Circuit is not the first circuit court to assess whether differences in medical opinion establish falsity, nor is it likely to be the last. The *AseraCare* panel distinguished two opinions—*United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018) and *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. 2018)—which support the contention that a

mere difference of medical opinion may be sufficient to show falsity of a statement. The *AseraCare* panel found that these opinions involved providers who ultimately dealt with an objectively true-or-false fact, such as whether a blockage existed (*Paulus*) or whether recurrent stroke therapy guidelines were applied to a patient who lacked the underlying condition (*Polukoff*). On March 4, 2020, the U.S. Court of Appeals for the Third Circuit disagreed with the *AseraCare* holding and expressly found that "subjective opinions may be considered false and that medical opinions can be false." *United States v. Care Alternatives*, 2020 WL 1038083, at *8 (3rd Cir. Mar. 4, 2020). According to the Third Circuit, "a difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity" under the statute. This circuit split may require U.S. Supreme Court resolution, but in the interim, in multiple circuit courts, *AseraCare* could complicate future whistleblower and DOJ medical necessity FCA cases.

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