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Disagreements over Medical Judgment Cannot Form the Basis for Liability Under the False Claims Act

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A new federal court decision offers a ray of light to those providers defending false claims actions based on an alleged lack of medical necessity. On September 9, 2019, the United States Court of Appeals for the Eleventh Circuit issued an opinion which could drastically affect both criminal health care fraud cases and civil False Claims Act (FCA) cases where liability turns on the medical necessity of the services underlying the claims. The Court in *U.S. v. AseraCare Inc., et al,* No. 16-13004 (11th Cir. Sept. 9, 2019) held that Medicare claims are not capable of being "false" under the False Claims Act if the claim of falsity amounts to a disagreement over medical judgment.

Background

For many years, the U.S. Department of Justice (DOJ) has pursued a civil FCA enforcement strategy that alleges when a provider files a claim for services which are found not medically necessary, it has misrepresented facts or has not accurately described the services. Claim denials based solely on medical necessity have thus resulted in liability because it is alleged providers "knew or should have known" that their claims were not accurate.

Practically speaking, the "knew or should have known" standard means that Medicare providers have an affirmative duty to ensure the accuracy of claims they submit, that coverage criteria are met, and that the services rendered are medically necessary. Significantly, Medicare law and regulations do not address the criteria to be applied to determine "reasonableness and necessity." Therefore, these terms are subject to reasonable interpretation by providers, physicians, and medical reviewers. The open question has been how much reliance providers may place on the medical judgment of the ordering and treating of physicians.

The AseraCare Case

In the *AseraCare* trial, the jury was directed to answer "special interrogatories" in its verdict to determine if any of the claims in that case were "false." These interrogatories essentially asked the jury to choose between dueling experts – to determine whether the government's expert was correct or the defendant's expert was correct in their after-the-fact assessments of medical judgments relating to eligibility for Medicare reimbursements for hospice.

The government experts suggested the Medicare claims were not supported by sound medical judgment. The defense experts countered that the *AseraCare* claims were all properly supported by sound medical judgment. Ultimately, the jury found False Claims Act liability, concluding in the special interrogatories that AseraCare submitted "false" claims for 104 patients of the 123 patients at issue.

The district court granted a judgment notwithstanding the verdict, as a matter of law, in AseraCare's favor, overturning the jury's verdict. The district court concluded that it had erred in allowing the case to go to the jury under the wrong legal standards. The district court determined that it should have instructed the jury that a difference of opinion between physicians without more is insufficient to show "falsity" in the claim. The district court noted:

If the court were to find that all the Government needed to prove falsity in a hospice provider case was one medical expert who reviewed the medical records and disagreed with the certifying physician, hospice providers would be subject to potential FCA liability any time the Government could find a medical expert who disagreed with the certifying physician's clinical judgment. The court refuses to go down that road.

U.S. ex rel. Paradies v. AseraCare, Inc., 176 F.Supp.3d 1282, 1285, (N.D. Ala. 2016).

On appeal, the Eleventh Circuit confirmed that a difference of opinion with a medical reviewer will not constitute evidence that the claims are false. The Eleventh Circuit held 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." *AseraCare*, slip op. at 34. A mere difference of opinion between physicians, without more, is not sufficient to show falsity. The Court noted that CMS commentary signals that "well-founded clinical judgments should be granted deference." *AseraCare*, slip op. at 33. The Court found it significant that CMS regulations for hospice care do not require checkbox-like requisites to justify the physician's certification of terminal illness, but instead call for "the physician or medical director's clinical judgment regarding the normal course of the individual's illness." *AseraCare*, slip op. at 28-29.

The opinion also noted that Medicare's hospice benefit scheme is dependent on medical evaluation of the unknowable: how imminent is a patient's demise. CMS and the Medicare contractor at trial supported the view that the Medicare hospice benefit was structured to consider good-faith, subjective clinical opinions on whether a patient is terminally ill. The Medicare hospice program should not penalize the rendering of legitimate health care services simply because physicians may differ on a patient's prognosis and eligibility.

In reaching this conclusion, the Eleventh Circuit distinguished this case from other situations in which the claimant could prove objective falsity in the exercise of professional judgment, thus indicating that there remain circumstances in which proof of objective falsity could support liability.

Although the Eleventh Circuit remanded the case back to the district court, the remand was essentially to allow the government to expound on facts that it had not been allowed to present in a unique bifurcated process during the first trial. The Eleventh Circuit opinion was very clear that the remanded case would be constricted by the holding that disagreements over medical judgments cannot support a finding of "falsity" under the False Claims Act.

Analysis

This decision unquestionably allows providers to feel some relief from the oppressive weight of retrospective medical review. Notably, however, the decision is not a free pass for providers to rely solely on the physician's plan of care to establish medical necessity. Providers still bear the obligation to make rational determinations about whether services supplied are provided at times and in quantities likely to be medically necessary. Physician orders alone will not override Medicare's coverage decisions or its direct guidance on what it will consider a valid claim. Moreover, if medical documentation is inconsistent with the physician's certification, or if inconsistent with the proper exercise of a physician's clinical judgment, liability may still exist.

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