



## Another Court Rejects Statistical Sampling and Rules That Difference of Opinion About Hospice Eligibility Is Insufficient for False Claims Act Liability

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Back in March of this year, in <u>U.S. ex rel. Paradies v. AseraCare, Inc.</u>, a district court in Alabama granted summary judgment to a defendant hospice finding that an expert physician's disagreement with a certifying physician's determination of hospice eligibility is insufficient to show falsity in a False Claims Act (FCA) case.<sup>1</sup> Last month, in <u>U.S. ex rel. Wall v. Vista Hospice Care, Inc.</u>,<sup>2</sup> another district court, this time in Dallas, Texas, similarly granted summary judgment in favor of a defendant hospice. That court also rejected the relator's attempt to use statistical sampling to prove liability. The Texas case is important to hospices and other providers defending eligibility-based FCA cases by providing further support for the proposition that a mere clinical disagreement on a subjective view of patient eligibility does not equate to a FCA violation, and that there are limitations to the use of statistical sampling in such cases.

#### **Background**

In <u>Vista Hospice</u>, the relator, a social worker employed at one of defendants' hospice offices, filed suit claiming that VistaCare violated the FCA by (1) submitting claims for patients who were not eligible for the Medicare Hospice Benefit, (2) certifying compliance with the Anti-Kickback Statute (AKS) while engaging in schemes to pay kickbacks to promote hospice enrollment, and (3) retaliating against the relator for raising such complaints. The court granted summary judgment to VistaCare on the eligibility and AKS claims but denied summary judgment on the retaliation claim. Also, the court struck the testimony of relator's experts.

The relator claimed that VistaCare had a culture of admitting and maintaining patients who were not eligible for hospice and pressured employees to admit patients. Additionally, the relator had a statistical sampling expert who pulled a sample of 291 patients from a potential universe of 12,000 patients with long lengths of stay throughout all of VistaCare's locations and a medical expert who reviewed a sampling of medical charts to opine that the patients were not eligible for hospice care. Finally, the relator claimed that VistaCare paid various bonuses to its employees to obtain referrals.

The court struck the testimony of the relator's statistical sampling expert finding that sampling cannot establish liability for fraud for the entire patient universe because "the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians." The court noted that "[w]here the nature of the claim requires an individualized determination, that determination cannot be replaced by 'Trial by Formula,'" citing Wal-Mart Stores, Inc. v. Dukes. The court noted that no circuit court had yet addressed whether statistical sampling and extrapolation can be used to establish FCA liability where falsity is dependent on individual physicians' judgment about individual patients. The court cited additional cases showing the unsuitability of using statistical sampling where each potential false claim was fact-dependent and unrelated to each other claim. The court did note that other district courts had allowed extrapolation in some FCA cases but distinguished them as not requiring "examination of the subjective clinical judgment of a number of certifying physicians applying the uncertain,

<sup>1 &</sup>lt;u>U.S. ex rel. Paradies v. Aseracare, Inc.</u>, 2016 WL 1270521, at \*1 (N.D.Ala. March 31, 2016).

<sup>2 &</sup>lt;u>U.S. ex rel. Wall v. Vista Hospice Care, Inc.</u>, 2016 WL 3449833, 3:07-CV-604, Doc. 48 (N.D.Tex. June 20, 2016).

<sup>3 &</sup>lt;u>Wall</u>, 2016 WL 3449833, \*11.

<sup>4 564</sup> U.S. 338, 367 (2011).

<sup>5</sup> See, e.g., U.S. ex rel. Michaels v. Agape Senior Cmty., Inc., 2015 WL 3903675, at \*2 (D.S.C. June 25, 2015).

changeable, and inexact science in predicting an individual's expectancy." The court ultimately decided that "when a relator alleges the falsity of [Medicare Hospice Benefit] claims because various doctors improperly found patients were terminally ill, the relator cannot extrapolate based on an expert's after-the-fact examination of the medical charts of a sample of patients."

Additionally, and more specific to the facts of the VistaCare Hospice case, the court identified various flaws in the relator's expert's methodology such that, even if extrapolation were proper in general, it would not be allowed in this case. The court found that the relator's statistical expert methodology was flawed because his original defined universe of patients from which he drew his sample was not valid in that it contained duplicate patients and misclassified over 1000 patients. He also failed to control for relevant variables. "[H]e did not differentiate geographically across the fourteen states where VistaCare operated, with different clinical staffs and doctors, or by disease type."

The court then granted summary judgment on the claim that defendants violated the FCA by admitting and re-certifying patients who were not eligible for hospice. The key to the court's analysis is that there must be an objectively verifiable falsehood and that a testifying physician's disagreement with a certifying physician's view of a patient's eligibility is insufficient to show such falsehood. In doing so, the Texas court agreed with the recent <u>AseraCare</u> case, in which a federal district court in Alabama granted summary judgment to the defendant hospice, finding that, like in <u>AseraCare</u>, the "opinion of one medical expert alone cannot prove falsity without further evidence of an objective falsehood." If it could, then "hospice providers would be subject to potential FCA liability any time a relator could find a medical expert who disagreed with the certifying physician's clinical judgment." The notion that a disagreement among experts or treating physicians does not equate to a false claim is even more compelling where, in the hospice context, CMS has recognized that prognostication as to a patient's prognosis (and therefore hospice eligibility) is uncertain and not an exact science. While the relator argued that she provided evidence of a corporate culture pushing admission of ineligible patients, the court ruled that the relator was missing a causal link between the defendants' policies and actual false claims. Thus, the court granted summary judgment in favor of the defendants.

Finally, the court granted summary judgment to the defendants on the Anti-Kickback Statute claims but denied summary judgment on the employee retaliation claims. With respect to the AKS allegation, the court found that defendants' payments to their employees, including bonuses, was covered under the Bona Fide Employee exception to the AKS and that relator did not connect any AKS violation to a false certification or claim. Thus, summary judgment in favor of the defendants was warranted. With respect to the retaliation claim, the court found disputed questions of fact precluding summary judgment on that claim.

### **Analysis**

VistaCare Hospice is an important decision because it addresses two looming issues in FCA cases, particularly in the hospice context – whether statistical sampling and extrapolation to a larger universe of claims can be used to support liability, and what constitutes a false claim in the context of a review of medical charts. Here, the court rejected sampling and extrapolation where the alleged falsities relate to subjective, fact-specific claims that require individualized assessment. And, even if there are some cases where sampling and extrapolation could be proper, the court noted that such sampling still must be exacting and account for all relevant variables. The court further provided additional guidance on defining a false claim that is helpful for defendants. In that regard, the court followed the reasoning in <u>AseraCare</u>, noting the subjective nature of the hospice benefit and that a disagreement over subjective criteria does not equal falsity.

Over the past few years, the government and relators' bar has been increasing its focus on hospice providers. While the ruling in <u>U.S. ex rel. Wall v. Vista Hospice</u> won't necessarily stem the tide of such cases, it is helpful for hospice <u>defendants and adds</u> to a growing body of case law addressing the use of sampling and what is required to prove a FCA

6 Wall, 2016 WL 3449833, \*12 (quotations omitted).

- 7 <u>Id.</u> at \*13.
- 8 Id. at \*14.
- 9 Id. at \*17 (citation omitted).
- 10 Id. at \*18 (citation omitted).
- 11 <u>Id.</u> at \*3, 18 (citation omitted).
- 12 <u>Id.</u> at \*21(citation omitted).



violation where the practice or regulation at issue is subjective and open to reasonable disagreement among experts.



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