

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

Medicare Conditions of Participation vs. Medicare Conditions of Payment:

Failure to Satisfy the Former Does Not Give Rise to False Claims Act Liability, According to Tennessee Federal District Court

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In a case that further signals reluctance by the courts to permit use of the False Claims Act ("FCA") to police quality of care issues, the U.S. District Court for the Western District of Tennessee recently granted summary judgment in favor of a hospital alleged to have violated the FCA by, among other things, failing properly to staff its operating rooms. The case, *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*,¹ was brought by a registered nurse formerly employed as the Associate Chief Nursing Officer at Baptist Medical Center ("Baptist"), in Memphis, Tennessee.²

The relator nurse asserted that, in the mid-1990s, Baptist underwent a major restructuring that resulted in severe staffing shortages.³ As a result, Baptist increased its nurse/patient ratios, used surgical technicians (scrub techs) as nurse circulators in the operating room, and failed to meet other applicable standards of care for surgical procedures.⁴

After the medical staff raised concerns regarding these practices, Baptist management asked the relator to evaluate the alleged staffing issues.⁵ During her review, the relator learned that scrub techs were acting as circulators in surgery without an available RN.⁶ The relator reported this practice to the Chief Nursing Officer ("CNO") and asked that surgeries be canceled pending Baptist's compliance with the applicable standards of care.⁷ The CNO declined to cancel surgeries.⁸ Additionally, the relator shared her concerns

¹ 2007 WL 4380006 (W.D. Tenn. Dec. 17, 2007).

² *See id.* at *1.

³ *See id.*

⁴ *See id.*

⁵ *See id.*

⁶ *See id.*

⁷ *See id.* at *2.

⁸ *See id.* at *2.

with Baptist's compliance officer, who expressed the opinion that the practice was illegal, but told the relator not to discuss her concerns with anyone.⁹

Over the next month, the relator continued to gather information regarding care and safety issues, and in February 1998, she submitted an unsolicited written report to her supervisors which outlined her concerns.¹⁰ On February 24, 1998, the relator was terminated.¹¹

One year later, the relator filed a *qui tam* lawsuit, alleging that Baptist falsely certified that it had complied with certain Medicare Conditions of Participation and quality of care requirements when it submitted its: (1) HCFA-1561 (Health Insurance Benefit Agreement); (2) HCFA-855 (Provider Enrollment Application); and (3) HCFA-2552 (cost reports).¹² After the Government declined to intervene, Baptist unsuccessfully sought to dismiss the lawsuit for failure to plead fraud with particularity under Fed. R. Civ. P. 9(b). Following extensive discovery, Baptist moved for summary judgment.

The court granted Baptist's summary judgment motion, holding that the alleged non-compliance with Medicare's Conditions of Participation did not impose liability because the relator had failed to adduce proof that those conditions were "a prerequisite to a particular payment."¹³ To the contrary, Conditions of Participation are quality of care standards that govern a provider's ability to participate in the Medicare program.¹⁴ Although violation of the Conditions of Participation could lead the Government to terminate Baptist's Medicare provider agreement or to invoke its administrative exclusion authorities, the relator failed to demonstrate that Baptist would have been ineligible to receive payment of its Medicare claims during a period of noncompliance.¹⁵ The court stated that "Conditions of Participation are not the equivalent of Conditions of Payment,"¹⁶ and, thus, the alleged failure to comply with the conditions of participation did not amount to a false or fraudulent claim under the FCA.¹⁷

The court further held that even if the relator had presented sufficient evidence of a false or fraudulent claim, the relator had not demonstrated that Baptist's alleged false claims were material to the Government's decision to make payments on those claims.¹⁸ As articulated in *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt Group, Inc.*,¹⁹ the Sixth Circuit follows the "natural tendency" test of materiality that "a false statement is material if it has a natural tendency to influence, or [is] capable of influencing the decision of the decision making body."²⁰ Because Medicare's own regulations did not condition payment on certifications of compliance with the Conditions of Participation, the court reasoned that the relator's alleged false certification of compliance would not have a natural tendency to influence the Government's payment decision.²¹

⁹ See *id.* at *1.

¹⁰ See *id.* at *2.

¹¹ See *id.* at *3.

¹² See *id.* at *3.

¹³ See *id.* at *4.

¹⁴ See *id.*

¹⁵ See *id.*

¹⁶ See *id.*

¹⁷ See *id.*

¹⁸ See *id.* at *5.

¹⁹ 400 F.3d 428 (6th Cir. 2005).

²⁰ *Id.* at *445.

²¹ See *United States ex rel. Landers*, 2007 WL 4380006, at *5.

Finally, the court held that the relator had failed to present sufficient evidence that Baptist's alleged violation of the standards of care were sufficient to support a "worthless services claim."²² Even if Baptist had failed to comply with Medicare's Conditions of Participation or other applicable standards of care, the court stated that such fact alone did not create a genuine issue of material fact as to a worthless services claim.²³

To date, efforts to advance FCA theories of liability based on false certification of compliance with Medicare quality of care regulations and standards have proved largely unsuccessful, although healthcare fraud cases based on substandard care have succeeded under other theories, especially in the long-term care area.²⁴ Efforts to use the FCA as a tool for enforcing quality of care have been sharply criticized by the defense bar as an attempt to use the FCA to federalize medical malpractice liability and invade quality of care issues within the purview of the states. The *Landers* court does not wade into the policy debate. Rather, it simply interprets the False Claims Act consistent with *United States ex rel. Mikes v. Straus*,²⁵ and similar cases from other circuits that the mere violation of one of the myriad regulations governing health care entities does not subject the entity to FCA liability absent proof that the Government considers compliance with the regulation to be a prerequisite to payment of Medicare claims.

If you have any questions regarding this Health Law Update, please contact any of the attorneys in our Healthcare Practice Area.

²² *See id.*

²³ *See id.*

²⁴ See, for example, our earlier Health Law Update, "American Healthcare Management Case: Alleged Understaffing as a Basis of Civil and Criminal False Claims Actions," March 19, 2007, available at www.bassberry.com.

²⁵ 274 F.3d 687 (2d Cir. 2001).

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