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Fraud and Abuse

Whistleblower Charges New Mexico Hospital Laboratory Ignored Quality Control Measures

A federal trial judge Aug. 8 unsealed a qui tam whistleblower's lawsuit alleging that New Mexico-based Deming Hospital Corp. submitted claims to Medicare and Medicaid for microbiology lab services performed without adhering to required quality control procedures (*United States ex rel. Hansen v. Deming Hospital Corp.*, D.N.M., No. 2:11-cv-00566, unsealed 8/8/12).

In her complaint, whistleblower Sally Hansen alleged that Deming Hospital, d/b/a/ Mimbres Memorial Hospital, Deming, N.M., submitted claims to Medicare and Medicaid based on lab services performed in violation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Because reimbursement eligibility depends on compliance with CLIA, Mimbres's submissions violated federal and state false claims act and similar state statutes, the complaint said. Hansen worked as a medical technologist for Mimbres.

She alleged that as a result of the violation of the quality control procedures, Mimbres and the other defendants received millions of dollars in Medicare and Medicaid reimbursements for work that "placed patients' lives at risk by failing to meet minimum quality standards." The complaint was filed in the U.S. District Court for the District of New Mexico,

'Worthless Services' Theory. The issue of subpar performance of services caught the attention of False Claims Act expert Karen S. Lovitch, with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC, Washington, who told BNA Aug. 14, "This case might signal a trend toward application of the worthless services theory in the clinical lab context."

"The bases for FCA cases are becoming more complex," Lovitch said.

The worthless services theory implicates the FCA when "the performance of services is so deficient that for all practical purposes it is the equivalent of no per-

formance at all." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001).

Quality Control Violations. Hansen alleged that Mimbres "failed to conduct routine quality control procedures on instruments and equipment, from complex microbiology analyzers to commonly-used testing media such as agar plates, and on processes used during laboratory testing."

These violations included using outdated equipment instructions, failing to conduct required monitoring and internal reviews, and failing to perform required quality control testing on instruments and equipment to ensure they produce accurate and verifiable results, according to the complaint.

Consequently, the accuracy of lab results used for diagnosis and treatment could not be validated or verified, and Mimbres knowingly ignored the risks to patient health and safety, the complaint alleged.

Retaliation Alleged. Hansen also alleged that after she raised concerns internally regarding problem with lab procedures, she was placed on administrative leave. While on leave, a compliance officer from Mimbres's corporate owner conducted an investigation into her allegations.

Based on that investigation, the complaint said, the microbiology lab was shut down.

After the investigation, Hansen was allowed to return to work but to a "less desirable shift," leaving her with "no choice but to quit," the complaint said.

The United States and the state of New Mexico have declined to intervene.

The hospital did not return a call for comment.

Robert R. Rothstein, of The Rothstein Law Firm, in Santa Fe, N.M.; Brendan K. Egan, of The Rothstein Law Firm, in Albuquerque, N.M.; and Michael Kanovitz and Anand Swaminathan, of Loevy & Loevy, in Chicago, represent Hansen.

By DAVID PARDO

The complaint is at <http://op.bna.com/hl.nsf/r?Open=dpa0-8x6qc3>.