POLSINELLI

Publications

January 9, 2026 • Updates

No Second-Guessing Required: First Circuit Limits FCA Liability for Clinical Labs

Key Takeaways

- **Reliance on Physician Orders**: Clinical laboratories may generally rely on physician orders to establish medical necessity and are not required to independently reassess clinical judgment.
- **Burden Shifting:** A physician's order generally provides a safe harbor regarding medical necessity and, once a defendant shows it acted in accordance with an order, it is up to the relator to produce evidence that undermines the lab's reliance on that order.
- **Subjective Knowledge**: The court reaffirmed that knowledge for purposes of the False Claims Act is based on the defendant's subjective beliefs, not post-hoc assessments of medical necessity.

In a case of first impression, the First Circuit Court of Appeals issued a decision in *United States ex rel. OMNI Healthcare, Inc. v. MD Spine Solutions LLC* that strengthens laboratories' defenses in False Claims Act (FCA) cases premised on knowledge of medical necessity.[1] The First Circuit clarified that physician orders can generally shield labs from scienter-based liability unless a relator can show that the lab knew, or deliberately ignored, that the orders were improper.

How the FCA Case Took Shape

The case arose from a *qui tam* brought by Omni Healthcare, a medical practice, against MD Spine Solutions (MD Labs), an independent clinical laboratory that began offering PCR-based urinary tract infection (UTI) testing in 2017. PCR tests are faster and more expensive than traditional bacterial urine culture (BUC) tests. Omni ordered hundreds of PCR UTI tests from MD Labs for its Medicare patients, many of which were reimbursed by Medicare. Unbeknownst to MD Labs, Omni's owner specifically instructed staff to exclusively order PCR tests, even when providers requested BUC tests, with the admitted purpose of "beef[ing] up" an FCA case.[2] Omni then brought a *qui tam* action alleging that MD Labs knowingly submitted claims for medically unnecessary tests in violation of Medicare's "reasonable and necessary" requirement. The district court granted summary judgment for MD Labs, finding Omni failed to show that MD Labs knowingly submitted

Related People

- Ellen H. Persons
- Alexandra A. Beato

Related Capabilities

- Government Investigations
- Health Care

false claims, and the First Circuit affirmed.

First Circuit Confirms Labs Can Rely on Physician Orders

The First Circuit offered a holding and opinion that offers significant relief and bolsters defenses for clinical labs. Specifically:

- **Reliance on Physician Orders for Medical Necessity:** The court held that in FCA cases alleging Medicare fraud based on laboratory testing, a clinical laboratory may generally rely on a physician's order to establish that a test is "reasonable and necessary" for reimbursement purposes. Relying on the Medicare statutory framework, HHS guidance and other case law, the court explained that while a lab still has the legal duty to ensure it is not submitting false or incorrect claims, "a laboratory cannot and is not required to determine medical necessity" and is "permitted to rely on the ordering physician's determination that the laboratory tests . . . are medically necessary."[3] The FCA, according to the court, is not intended to expand a lab's liability and "put [them] on the hook for doctors' professional decision," barring some other deception.[4]
- **Safe Harbor and Burden Shifting:** The court further held that, at the summary judgment stage, a physician's "order for medical testing will generally offer a safe harbor of medical necessity."[5] Once a lab shows it acted pursuant to a doctor's order, the burden shifts to the relator, and the relator must produce evidence that undermines the lab's reliance, such as evidence that the lab knew the order was tainted, misleading or induced by the lab's own improper conduct. Absent such evidence, a doctor's determination of medical necessity for a lab order demonstrates the absence of a genuine issue of fact regarding the lab's knowledge of a false claim.
- **Subjective Knowledge under the FCA:** Applying the Supreme Court's guidance in *United States ex rel. Schutte v. SuperValu*, the court reiterated that FCA scienter turns on the defendant's subjective knowledge at the time the claim was submitted, not on post submission thoughts regarding medical necessity or objective reasonableness.[6]

What the Decision Means for Clinical Labs Facing FCA Risk

Overall, the decision is a meaningful defense-side ruling for clinical labs facing FCA scrutiny. The decision confirms that clinical labs may generally rely on a physician's order to establish medical necessity and are not required to independently second-guess clinical judgment. Nevertheless, it does not provide complete immunity from the FCA. Clinical labs still have a legal duty to ensure they are not submitting false claims to the government, must maintain active compliance programs, and must be cautious of red flags including high volume of orders, unusually templated orders, inconsistent or contradictory requisition forms, etc.

Polsinelli's Government Investigations attorneys have extensive experience with U.S. Department of Justice investigations and have handled numerous investigations for lab clients and are prepared to assist with compliance or any potential enforcement action. For more information, contact the authors of this Alert or your regular Polsinelli attorney.

[1] *United States ex rel. OMNI Healthcare, Inc. v. MD Spine Solutions LLC*, 160 F.4th 248 (1st Cir. 2025).

[2] *Id*. at 256 (Omni's owner "wanted to beef up a Medicare fraud case against MD Labs").

[3] *Id.* at 259.

[4] *Id.* at 261.

[5] *Id.*

[6] *See United States ex rel. Schutte v. SuperValu, Inc.*, 598 U.S. 729 (2023); *see also* SCOTUS Rejects Defense-Friendly Scienter Standard In Schutte Opinion (June 21, 2023), https://www.polsinelli.com/publications/scotus-rejects-defense-friendly-scienter-standard-in-schutte-opinion.