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LEAD STORY

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New MD Labs Ruling Has Implications for Test Requisitions and Commissions

A federal appeals court upheld the idea that labs can rely on physician orders to justify medical necessity

By Janette Wider

A federal appeals court decision about medical necessity of clinical laboratory tests also has implications regarding test requisitions and related sales commissions.

The US Court of Appeals for the First Circuit affirmed a lower court's dismissal of *United States ex rel. OMNI Healthcare Inc. v. MD Spine Solutions LLC (MD Labs)*, which centered on whether a lab is responsible for justifying the medical necessity of a test ordered by a licensed physician.

The December 2025 appellate court's ruling confirmed that laboratories can generally rely on a physician's order that a test is medically necessary for a patient, said healthcare attorney Danielle Tangorre, a partner at Robinson+Cole. Tangorre was one of the attorneys who argued on behalf of MD Labs in the appeals case.

OMNI filed the lawsuit as a private whistleblower (formally known as a "relator"), alleging that MD Labs violated the False Claim Act through its billing practices for PCR-based urinary tract infection (UTI) testing.

OMNI's owner, Craig Deligdish, MD, instructed the company's medical assistants to order more expensive PCR tests instead of traditional bacterial urine culture test in the hopes of filing an FCA complaint against MD Labs, the appeals court noted.

Role of requisition design and marketing

A practical takeaway from the case for clinical lab directors involves the design of the test requisition form.

The court looked closely at whether MD Labs used its forms to steer doctors toward more expensive testing. The ruling suggests that while a "safe harbor" for medical necessity is strong, it is not absolute if the lab interferes with the doctor's independent choice.

"The courts emphasized that MD Labs did not improperly design its requisition. That's an important lesson. Labs need to ensure requisitions are not steering or influencing test selection," Tangorre warned. "The same applies to marketing. Overpromising test value or implying broader clinical utility than supported can create risk, even if labs can generally rely on physician orders."

Essentially, if a requisition form is pre-checked or designed in a way that makes it difficult for a physician to order only specific components, the lab loses its protection because it is no longer merely relying on a doctor's judgment. In such circumstances, the lab is actively influencing it.

Status of independent contractor commissions

While the appellate ruling focused on medical necessity, the lower court's findings on independent contractor commissions remain a vital part of the story.

For years, the industry has assumed that paying commissions to independent sales agents is a "per se" violation of the Anti-Kickback Statute (AKS) or the Eliminating Kickbacks in Recovery Act (EKRA). The MD Labs case suggests a more nuanced reality where context and compliance matter most.

"Importantly, the relator did not appeal the independent contractor issue, so the finding that commission payments are not inherently illegal stands," Tangorre pointed out. "That aligns with a growing trend in the courts: Sales commissions are not automatically violations of AKS or EKRA unless there is some additional improper conduct—what I call a 'plus factor'—such as influencing ordering behavior."

The court was persuaded by the fact that MD Labs had a robust compliance framework, Tangorre said.

"Independent contractors were treated similarly to employees, and compliance oversight was robust," she added. "That's critical."

Janette Wider *is managing editor at* The Dark Report *and* Dark Daily, *both sibling brands to* G2 Intelligence. *She has held senior editorial roles covering health information technology, clinical laboratories, diagnostics, healthcare policy, and the business of medicine, with a focus on translating complex industry developments into actionable insight for healthcare leaders*