

# PUBLICATION

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## Court Rules That Supervision and Enrollment Issues Don't Give Rise to False Claims Act Liability [Ober|Kaler]

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Following the ever-growing progeny of cases holding that Medicare conditions of participation do not give rise to False Claims Act (FCA) liability, the United States Court of Appeals for the Sixth Circuit overturned an \$11 million *qui tam* judgment against MedQuest Associates, Inc. (MedQuest), a diagnostic testing company that purportedly submitted claims for services that did not fully comply with Medicare physician supervision requirements and enrollment rules. *United States ex. rel. Hobbs, et al., v. MedQuest, et. al.*, Case No. 11-6520 (6th Cir. April 1, 2013). The allegations related to three Nashville, Tennessee area testing facilities operated by MedQuest.

### Use of Unlisted Supervising Physicians to Directly Supervise Contrast Tests

The Government claimed that two of MedQuest's facilities used certain physicians to provide direct supervision for contrast MRI and CT scan services who were not identified in the facility's Medicare Enrollment Form (CMS-855B) nor approved by its Medicare contractor, CIGNA. CMS requires an independent diagnostic testing facility (IDTF) to have one or more supervising physicians who are responsible for providing general supervision of procedures at the facility, although some procedures require direct or personal supervision. The Medicare Enrollment Application requires an IDTF to identify its supervising physicians. In addition, the local Medicare contractor, CIGNA, imposes additional qualifications through its Local Medical Review Policies (LMRPs) required for individual procedures, including that a certified radiologist must perform a CT scan with contrast under the "direct supervision" of another certified radiologist. The Government alleged that some of the physicians used by the MedQuest centers to provide direct supervision for contrast procedures were not approved by CIGNA, and some did not even specialize in radiology.

Finding that the Enrollment Application included a certification that the physicians identified in the application would supervise the procedures performed at the IDTF, the District Court below concluded that MedQuest incurred FCA liability by submitting Medicare claims for payment for contrast testing, which certified that the tests were provided in accordance with applicable Medicare regulations and by physicians approved by Medicare. The court held that the Defendant's claims were false because the Medicare regulation requiring appropriately qualified physician supervision for contrast testing is a "condition of payment" for an IDTF's claim for contrast services and MedQuest implicitly certified compliance with the regulation when submitting its claims.

Overtaking the District Court's findings, the Sixth Circuit concluded that, while MedQuest may not have complied with the letter of Medicare's physician-supervision regulations, such regulations are not *conditions of payment* and, accordingly, do not warrant FCA penalties. The court noted that the Medicare conditions of payment for diagnostic testing require that tests be "reasonable and necessary," which includes being furnished under the appropriate level of supervision as set forth in 42 C.F.R. § 410.32. MedQuest provided the required level of supervision (albeit through physicians not identified on the 855-B) and, therefore, MedQuest did not violate the conditions of payment.

The court further noted that CIGNA's LMRP requirement that the supervising physician must be certified in radiology is not a condition of payment, because it has no bearing on whether the test is "reasonable and necessary." In addition, although the LMRP issued by CIGNA enumerates specific reasons for denying payment, such as when services are provided for screening purposes, the LMRP does not forbid payment when there are regulatory violations, such as the enrollment issue presented here. The court further noted that other CMS regulations addressing IDTF supervision are conditions of participation that are punishable only by administrative remedies, rather than FCA liability.

## Use of Acquired Practice's Billing Number

In addition to the physician supervision issue, the Government alleged that MedQuest's Charlotte Center violated the FCA when it submitted claims using the billing number for a physician practice that it acquired to operate as an IDTF. MedQuest submitted claims using the physician's billing number and did not re-enroll the facility in Medicare as an IDTF until 18 months after the stock transaction. Finding that the only condition of payment identified by the Government requires that diagnostic procedures be performed by a physician, a group practice, or an IDTF, the Sixth Circuit held that the Government failed to demonstrate that enrollment and approval are required for an entity to be an "IDTF" under the payment regulations. In addition, the court noted that the Government ignored that the physician's practice, which MedQuest asserted it was operating as a subsidiary, was already enrolled in the Medicare program. The court stated that "[t]his case, at most, represents a failure to update enrollment information, which we have held is not a violation of a condition of payment." Accordingly, the Sixth Circuit held that it was inappropriate to assess FCA penalties where payment is not conditioned on an accurate, updated enrollment form.

## Comments

Although providers and suppliers participating in Medicare should be prudent to ensure compliance with the Medicare enrollment and supervision requirements, this case underscores that the harsh penalties associated with FCA liability do not apply to regulatory violations that are not conditions for payment. To the extent a provider or supplier finds itself as the subject of a FCA suit, or a claims review audit, where the allegation is that the services should not be covered based on the failure to meet Medicare regulations or guidance, providers or suppliers should clearly understand the difference between conditions of participation, which do not necessarily give rise to overpayment liability, and conditions of payment and coverage criteria, which are a prerequisite for payment.