

## SIXTH CIRCUIT REJECTS FCA CLAIMS INVOLVING ‘INCIDENT TO’ SERVICES AND IMPLIED CERTIFICATION THEORIES

In *United States ex rel. O’Laughlin v. Radiation Therapy Services, P.S.C.*, the Sixth Circuit (also referred to as the “Court”) recently affirmed dismissal of a relator’s False Claims Act (“FCA”) action, concluding that he failed to plead or prove with particularity that radiation service providers submitted false claims for radiation or chemotherapy services, relying instead on misguided faulty regulatory interpretations, unreliable evidence and abandoned arguments.

### BACKGROUND

The FCA, codified at 31 U.S.C. §§ 3729-3733, empowers private individuals, known as relators, to bring *qui tam* lawsuits on behalf of the U.S. government for false or fraudulent claims submitted for federal reimbursement. 31 U.S.C. § 3729(a)(1)(A) prohibits knowingly presenting, or causing to be presented, a false or fraudulent claim for payment, while § 3729(a)(1)(B) prohibits knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim. When relators sue under the FCA, they need to satisfy the heightened pleading standard of Rule 9(b). Specifically, relators must “state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b).

Here, in 2016, Dr. Robert O’Laughlin (“Relator”) filed a *qui tam* action alleging the government was defrauded by a group of radiation therapy and chemotherapy providers (“Radiation Services”) who falsely represented that their services were either supervised or performed by qualified physicians when, in fact, either unqualified physicians were used or no physicians were present in the offices. The government reached a settlement with one of the providers but declined to intervene for the remaining claims. The district court dismissed Relator’s claims. On appeal, the Sixth Circuit affirmed dismissal of the radiation therapy claims for two reasons: (1) Relator misapplied 42 C.F.R. § 410.26(b)(7), arguing incorrectly that it required radiologists to perform or supervise certain services billed to Medicare, and (2) Relator abandoned his remaining arguments.

### SERVICES “INCIDENT TO” THE SERVICE OF A PHYSICIAN

Relator first contended that radiation services were fraudulently billed because no physician was present, relying on 42 C.F.R. § 410.26(b)(7), which conditions Medicare reimbursement for “incident to” services on state-law compliance.

The Court rejected this argument, holding that § 410.26(b)(7) does not apply to radiation services, which fall under a distinct Medicare benefit category. The Court also found that the Kentucky regulation cited by Relator does not restrict supervision to radiologists or radiation oncologists. Radiation Services further explained that Relator failed to distinguish between “professional” and “technical” components of radiation services, noting that professional components could be performed remotely and did not require an on-site physician. Because Relator did not address these points, the Court deemed these claims abandoned.

### IMPLIED CERTIFICATION

Relator next pursued an implied certification theory, asserting that Radiation Services falsely billed for radiation and chemotherapy services by certifying compliance with regulations that he claimed required on-site supervision by radiation oncologists. To support his chemotherapy claims, he alleged that the centers administered chemotherapy on weekends without physicians present and relied on a Master Schedule to show alleged gaps in coverage. The Court, however, found the schedule unreliable and emphasized that Radiation Services routinely used temporary physicians to cover staffing gaps.

Relator also argued that weekend Leukine injections violated the FCA because the billing code required physician supervision. The Court rejected this argument, holding that Leukine is not classified as chemotherapy and therefore does not trigger the supervision requirement. Because Relator failed to show that any regulatory noncompliance rendered the claims false, the Court affirmed summary judgment in favor of Radiation Services.

### PRACTICAL TAKEAWAYS

- **Physicians are not automatically liable under implied certification theories for regulatory noncompliance.** The Court

reinforced that billing claims are not “false” merely because a relator interprets a regulation differently, especially when services comply with Medicare rules and state law, or when physician supervision can be provided remotely.

- **Accurate documentation of physician involvement is critical.** Courts will closely scrutinize evidence of supervision and service delivery, so maintaining clear records of which physicians performed or supervised services—including temporary or remote coverage—can protect physicians from FCA exposure.

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