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Qui tam relators and the Department of Justice continually push the FCA envelope with implied certification cases. A recent case from the District of Massachusetts, *U.S. ex rel. Julio Escobar, et al. v. Universal Health Services, Inc.*, illustrates how FCA plaintiffs try to use this theory to shoehorn non-fraudulent regulatory non-compliances into FCA violations—and how to beat such claims.

The implied certification theory, which dates back to the mid-1990s, posits that where the government pays funds to a party, but would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contains an implied false certification of compliance with that law or regulation, in violation of the FCA. For example, in *U.S. ex rel. Pogue v. American Healthcorp, Inc.*, one of the seminal implied certification cases, the relator alleged that Medicare reimbursement claims were rendered "false" under the FCA because the defendant was knowingly violating the federal Anti-Kickback Statute at the time that the Medicare claims were submitted. The court concluded that this theory was viable if the defendant's implied false certification of compliance with a federal statute or regulation resulted in payment of government funds that would not otherwise have been paid. Numerous implied certification cases followed. FCA plaintiffs tried to use the implied certification theory to expand FCA liability to cases involving little more than regulatory non-compliances, with some success. Fortunately, the pendulum has been swinging back, and many courts have clarified that the implied certification theory must be limited to those cases where the government's payment of funds was conditioned on compliance with the statute or regulation. In these cases, non-compliance with a statute or regulation that is a prerequisite to participation in a government program (but is not a condition of receiving payment) does not give rise to FCA liability.

One such case is *Escobar*, in which *qui tam* relators Julio Escobar and Carmen Correara sued Universal Health Services, which owned and operated hospitals throughout Massachusetts, alleging that it violated the federal FCA and Massachusetts FCA by submitting claims for reimbursement to Medicaid despite systematically violating Massachusetts health regulations regarding patient care, supervision and core staffing requirements. Relators alleged that each of these claims was false because the requests for reimbursement carried with them an implied certification of compliance with all applicable federal and state regulations. Relators further argued that the First Circuit, in *Hutcheson*, had abandoned the distinction between conditions of participation and conditions of payment, and that they needn't prove that compliance with the pertinent regulations was a prerequisite to payment for their FCA claims to survive.

Mr. Escobar and Ms Correara were sympathetic *qui tam* relators. Their daughter, Yarushka Rivera, died after suffering a series of seizures. The seizures allegedly occurred after she stopped taking Trileptal, a medication prescribed by a Universal Health Services-owned clinic, and allegedly known to cause seizures after abrupt withdrawal. The care administered by the Universal Health Services-owned facility was allegedly poor. Ms. Rivera was allegedly counseled by two different counselors who held no professional licenses at all, and subsequently treated by a PhD who was not board certified, in part because she earned her doctorate from Southern California University, an internet college that was not recognized by the state Board of Licensure.

The court acknowledged that the care allegedly provided by Universal Health Services may have violated state regulations, but noted that "not every regulatory violation gives rise to a potential FCA action" and that "[a] plaintiff may not use the FCA to act as an ombudsman for compliance with regulatory requirements that do not necessarily impact government payment." It rejected relators' reading of *Hutcheson*, holding that "before a regulation can give rise to FCA liability, it must, in fact, be a condition of payment." The court recognized that relators' allegations, if true, raised serious questions about the quality of care provided to relators' daughter, but cautioned that "the False Claims Act is not the vehicle to explore those questions." Instead, because the state regulations that United Health Services allegedly violated were mere conditions of participation, not prerequisites to payment, it dismissed relators' FCA claims.

Escobar is part of a growing trend of decisions by courts that refuse to use the FCA as an all-purpose regulatory enforcement tool. The Fourth Circuit's recent *Omnicare* decision and the Fifth Circuit's 2013 *Steury* decision are other examples. At its broadest, the implied certification theory would subject any entity that does business with the federal government to FCA liability for any violation of any applicable federal statute or regulation—a result plainly incompatible with the text, history and purpose of the FCA. If your organization faces an implied certification FCA theory of liability, but the relator has failed to plead or prove that compliance with the statute or regulation at issue was a condition of payment, that shortcoming may be the key to your defense strategy.

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