Sixth Circuit Provides Powerful Authority for False Claims Act Defendants in Reversal of $83 Million Judgment

Recently, the Sixth Circuit in *United States ex rel. Williams v. Renal Care Group et al.* threw out an $83 million judgment against a dialysis provider in an opinion recognizing the ambiguity endemic in the current health care regulatory environment and rejecting the government's attempts to exploit that ambiguity under the False Claims Act.

Of particular interest to companies in the health care space is the court's analysis in confronting—and rejecting—two positions commonly advanced by the government in False Claims Act cases. First, the court rejected the notion that it is inherently wrongful for government contractors, when facing ambiguous laws and regulations governing federal programs, to interpret those rules with the goal of maximizing profit. In so doing, the court underscored the value of relying in good faith on advice of counsel when facing regulatory uncertainty. Second, the court rejected an argument commonly advanced by relators that a contractor's violation of conditions of participation in a government program automatically renders otherwise truthful claims submitted to the United States "false." On both grounds, the court ultimately found the government's case so flimsy that it not only reversed the District Court's $83 million judgment for the United States, but also granted summary judgment to the defendants.

"Why a business ought to be punished solely for seeking to maximize profits escapes us."

The defendant, Renal Care Group ("RCG")—now owned by Fresenius Medical Care Holdings—provided dialysis services at its dialysis facilities as well as supplies to patients who opted for self-care dialysis at home. RCG billed Medicare for these services and supplies, which offered reimbursements under two separate, complex payment methodologies. RCG primarily sought reimbursement for its dialysis services under Medicare's "Method I" reimbursement provision. But RCG saw an opportunity to boost its profits by applying for reimbursements under the more lucrative "Method II" reimbursement provision for some of its self-care home patients. Method II reimbursements were available exclusively for entities that provided only dialysis supplies and equipment to self-care home patients; entities providing these services at dialysis facilities were ineligible to receive the more generous reimbursements.

To take advantage of Method II reimbursement, RCG set up a wholly-owned subsidiary, Renal Care Group Supply Company ("RCGSC"), which exclusively supplied dialysis equipment to home patients and did not provide any dialysis services. Consistent with Medicare regulations, RCGSC obtained its own Medicare supplier number. RCGSC maintained a separate corporate existence but was nevertheless heavily intertwined with RCG. Key employees, officers, and directors were the same for both entities, and all of RCGSC's employees were managed by RCG. The companies shared office space, payroll, and other services. Furthermore, money in RCGSC's account was transferred nightly into RCG's corporate account.

Prior to establishing its RCGSC subsidiary, RCG sought advice from outside counsel to evaluate the propriety of the corporate arrangement in light of Medicare rules. Before blessing the arrangement, outside counsel sought clarification from a HFCA official who reportedly approved of the idea. On the advice of counsel, RCG operated RCGSC for several years, receiving Method II reimbursements while transparently disclosing the relationship between the two entities.

Relators filed a *qui tam* characterizing RCGSC as a mere "billing conduit" for "false" Method II claims. The United States intervened and in its complaint alleged that RCGSC's Method II reimbursement claims

violated the FCA on the theory that RCGSC was merely RCG's alter ego and that Congress had prohibited Method II payments for dialysis services providers like RCG. The district court agreed and entered an $83 million award against the Defendants.

The Sixth Circuit disagreed. The *Williams* opinion presents a sympathetic view of the unique challenges companies confront in government contracting, particularly in the health care space. First, the court criticized the United States' "somewhat obsessive[ ]" focus on the fact that RCG created RCGSC solely to maximize Medicare reimbursement. This attack on profit-seeking was the chief basis on which the government contended, and the district court concluded, that RCG and RCGSC's separate corporate existence should be disregarded. The Sixth Circuit declined to demagogue for-profit corporations, noting that neither the applicable reimbursement statute, 42 U.S.C. § 1395rr(b)(1)(B), nor its implementing regulations, prohibited RCG from taking advantage of the corporate form in this context and with full transparency. Taking advantage of a loophole in Medicare's reimbursement structure had no bearing on the alter-ego analysis. As the Sixth Circuit succinctly explained, "Why a business ought to be punished solely for seeking to maximize profits escapes us."

The Sixth Circuit went even further. It looked favorably on RCG's proactive, responsible steps to chart a safe course through Medicare's often-treacherous regulations, explaining that the company's good faith steps negated any allegation that RCG intentionally or recklessly violated federal law—an essential element of a False Claims Act violation. Such proactive measures need not be "burdensome"—the court observed that the FCA imposes only a "limited duty to inquire." The court credited RCG for satisfying this duty by seeking guidance from both outside counsel and the government, for following what it believed was the general industry practice, and for its candor with the government about RCGSC's ownership structure. These steps belied the notion that RCG acted in reckless disregard of the falsity of its claims. The court therefore not only *reversed* summary judgment for the government but *granted* summary judgment for the defendants on this critical element of the government's chief theory.

"The False Claims Act is not a vehicle to police technical compliance with complex federal regulations."

The court also rejected another frequent favorite government charge: that violations of conditions of participation in federal programs can constitute a "false statement" supporting False Claims Act liability. In advancing this claim, the government argued that RCGSC failed to comply with Medicare's "supplier standards" for durable medical equipment providers. *See* 42 C.F.R. § 424.57. Because suppliers like RCGSC that participate in the Medicare program must certify compliance with program standards, the argument went, any claims for reimbursement RCGSC submitted as a participant in the Medicare program were "false." The Sixth Circuit rejected this argument. Drawing on authority from several circuits, the court pointed out the critical distinction between conditions of *participation* from conditions of *payment*. While violating the former may properly result in expulsion from the program, *see* 42 C.F.R. § 424.57(d), False Claims Act liability is premised on a *knowing* or *reckless* violation of the latter. Because no statute or regulation made compliance with the supplier standards a condition of payment, the court explained that it was irrelevant whether RCGSC had complied with those standards.

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The court's opinion in *Williams* will provide valuable arguments against many typical False Claims Act theories, but it is unlikely to prevent relators or the government from pursuing these claims outright. If you would like further information, please contact the Ropes & Gray attorney who usually advises you.