Court of Appeals Rejects Quality of Care Standard for False Claims Act Liability

United States ex rel. Mikes v. Straus

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The United States Court of Appeals for the Second Circuit recently issued a decision that could narrow the scope of the prosecution of cases brought against health care providers under the False Claims Act, 31 U.S.C. § 3729, *et seq*. (the "Act"). This decision, *United States ex rel. Mikes v. Straus*,[1] (http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=2nd&navby=case&no=006269) does significant harm to the theory that reimbursement claims for services not meeting alleged "quality of care" standards qualify as false claims under the Act.

The *Mikes* case was initiated by relator Patricia Mikes against her former employers, three physicians specializing in oncology and hematology, under the *qui tam* provisions of the Act.[2] In September 1991, relator allegedly discussed with defendant Straus her concerns relating to spirometry tests that were being performed in defendants' offices. These concerns stemmed from her belief that defendants failed to comply with applicable standards for calibrating the equipment on which such tests were performed. Three months after voicing her concerns, she was fired.

Relator contended that the American Thoracic Society ("ATS") guidelines recommended daily calibration of spirometers, that the tests be performed in a certain manner, and that spirometer technicians be appropriately trained. She maintained that defendants did not follow these guidelines and, consequently, their performance of spirometry yielded inherently unreliable data.

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1 274 F.3d 687 (2d Cir. Dec. 19, 2001).

2 The government declined to intervene in this case.

Relator alleged that the physician defendants' failure to properly calibrate the spirometers rendered the results so unreliable as to be "false". She also asserted that defendants sought Medicare reimbursement for 1034 claims for spirometry services during the period 1985 through 1993 in the total amount of $28,922.89. Her complaint alleged that defendants violated the Act by submitting false claims for reimbursement of spirometry services as well as discharging her in retaliation for her investigation of their false claims.

Defendants moved for summary judgment, and their motion was granted. However, their request for attorneys fees pursuant to the False Claims Act, 31 U.S.C. § 3730(d)(4), was only partially approved based on the court's finding that relator's claim pertaining to MRI referral fees was vexatious.

The Second Circuit noted that liability under the Act occurs when a person:

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government … a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or]

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

Mikes, 274 F.3d at 695, citing 31 U.S.C. § 3729(a). Thus, to impose liability, relator was required to show that defendants (1) made a claim, (2) to the United States Government, (3) that was false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury. *Id.*

A "claim" includes "any request or demand, whether under a contract or otherwise, for money or property … if the United States Government provides any portion of the money or property which is requested or demanded." *Id.*, citing 31 U.S.C. § 3729(c). Defendants submitted claims for reimbursement for spirometry services to the Medicare program. The court found that each submission of the HCFA-1500 forms through which defendants made these requests for reimbursement met the first two elements of a False Claims Act violation in that each submission qualifies as a "claim" under the Act.

The court next turned to whether the claims submitted by defendants were "false" or "fraudulent". According to the court, this determination hinges on whether the improper claim is aimed at convincing the government to pay money it otherwise would not have paid. Thus, "[t]he language of these provisions [at 31 U.S.C. § 3729(a)] plainly links the wrongful activity to the government's decision to pay." *Id.* at 696.

At the heart of the court's resolution of this case was whether the claims for reimbursement of spirometry services were false or fraudulent and were knowingly made.

Relator's theory of the case, as described by the court, was that the submission of Medicare reimbursement claims for spirometry procedures not performed in accordance with the relevant standard of care (the ATS guidelines, according to relator) violated the Act. Her claims rested on the viability of the "certification theory" of liability, "which is predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term." *Id.* at 696. The court explained that this theory has also been called the "legally false" certification theory as opposed to "factually false" certification, in that defendants purportedly falsely certified their compliance with legal requirements rather than falsely described the items or services for which they sought reimbursement.

While the court recognized the potential viability of a "legally false" certification theory, it joined the Fourth, Fifth, Ninth and District of Columbia Circuits and ruled that "a claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment." *Id.* at 697. This holding stems from the court's analysis that false claims under the Act must be tied to claims seeking to extract from the government monies it otherwise would not have paid. Thus, the court ruled "simply that not all instances of regulatory noncompliance will cause a claim to become false." *Id.*

The court distinguished between "express" and "implied" false certifications and held that relator failed to support her contention that defendants had submitted false claims premised on either type of certification. An "expressly" false claim is one that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite for payment. In the *Mikes* case, relator contended that defendants falsely certified their compliance with the terms set out on the Form HCFA-1500. The certification there states: "I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate supervision." *Id.* at 698. This certification is a precondition to Medicare reimbursement.

The court agreed that falsely completing the Form HCFA-1500 certification could potentially form the basis for a False Claims Act violation. Nevertheless, the court found that the certification on the Form

HCFA-1500 pertains to the medical *necessity*, not the quality, of the services for which reimbursement is being sought. "Medical necessity ordinarily indicates the level—not the quality—of the service." *Id.* Because relator only challenged the *quality* of defendants' spirometry tests and not the decisions to order the tests, she failed to support her contention that the tests were not medically necessary.

An "impliedly" false claim is one that implicitly certifies compliance with a particular rule as a condition for reimbursement. The court reviewed a previous decision of the Court of Federal Claims in which this theory of liability was recognized and contrasted its relevance to certifications made in the context of the Medicare program. Specifically, the court was concerned that this theory should not be applied too expansively, as "the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations, but rather only those regulations that are precondition to payment." *Id.* at 699. Of particular concern was that application of the False Claims Act to quality of care concerns would serve to federalize medical malpractice actions and replace the patient with the government or *qui tam* relators as enforcers of medical standards of care. Thus, the court held that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Id.* at 700 (emphasis in original).

This latter ruling is the most significant. The court rejected the notion that a claim is false simply because a provider failed to comply with some statute or regulation pertaining to the Medicare program. Only if such statute or regulation expressly requires compliance with its terms as a prerequisite for Medicare payment can a violation of the Act rest upon a false certification of compliance.

With respect to the allegations in the *Mikes* case, the court found that each of the statutory provisions of the Medicare Act with which relator claimed defendants were not compliant did not render their requests for reimbursement false. The first provision, 42 U.S.C. § 1395y(a)(1)(A), states that only services that are reasonable and necessary for the diagnosis or treatment of illness or injury are reimbursable. Because the "reasonable and necessary" requirement generally pertains to the selection of a particular procedure and not its performance, relator's contention that defendants' spirometry services were qualitatively deficient could not support a violation of the Act based on certification of compliance with this statutory provision.

The second provision, 42 U.S.C. § 1320c-5(a), does not expressly require compliance as a condition of payment. Indeed, the court noted that although the latter provision mandates a qualitative standard of care for providers, it sets conditions of *participation* in the Medicare program, not payment.[3] Hence, relator's allegation that defendants' certification falsely implied compliance with this statutory provision could not as a matter of law support her claims under the Act.

The court also dealt a significant blow to the notion that "quality of care" concerns could form the basis of False Claims Act allegations by holding that the submission of a HCFA-1500 form does not implicitly certify compliance with the qualitative requirement of § 1320c-5(a). According to the court, the quality of care standard of this statutory provision "is best enforced by those professionals most versed in the nuances of providing adequate health care" and not the courts. *Id.* at 702. Thus, while a provider's submission of a HCFA-1500 form for reimbursement might constitute a representation concerning the medical necessity of the services rendered, it does not constitute a representation concerning the quality of those services. As a result, it is hard to imagine how a claim for reimbursement under the Medicare program could be false based on a provider's rendition of allegedly negligent medical services.

Finally, the court addressed the arguments made by the government in its *amicus* brief and relator at oral argument that defendants' submission of Medicare claims for substandard spirometry essentially constituted requests for reimbursement of worthless services. The court noted that this theory is not really a false certification theory or even an issue of quality of care, in that the knowing request for federal reimbursement of worthless services is tantamount to requesting reimbursement for services that were not provided at all. Thus, it is what the court would deem a factually false rather than legally false claim.

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3 42 U.S.C. § 1320c-5(a) provides in part:

> It shall be the obligation of any health care practitioner … who provides health care services for which payment may be made … to assure, to the extent of is authority that services or items ordered or provided by such practitioner …
>
> (1) will be provided economically and only when, and to the extent, medically necessary;
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> (2) will be of a quality which meets professionally recognized standards of health care; and
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> (3) will be supported by evidence of medical necessity and quality … as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

The court rejected relator's claim that defendants were liable under this theory because she failed to substantiate that defendants had the requisite intent. This is because they believed that they were following applicable standards of care in the maintenance of the practice's spirometers and had a good faith belief that the services they provided were of medical value.

As reflected in the *Mikes* decision, the Second Circuit was loath to broadly interpret certifications providers make to the government in seeking reimbursement under the Medicare program. Not only is this decision significant in reasonably limiting the circumstances in which such a claim could be false, but it also nearly eliminates medical negligence as a basis for False Claims Act liability. Unless a provider's services are so qualitatively deficient as to render them worthless and, therefore, tantamount to the provision of no services, claims for their reimbursement should not be deemed false under the Act.