Since its expansion in 1986, the False Claims Act (FCA) has been the subject of numerous creative theories that seek to apply that law to healthcare providers. One of the more recent trends is for the government and private plaintiffs to argue that FCA liability may be premised on the failure to meet a minimum level of quality in providing care. Even though the so-called “quality of care” theory (or its first cousin, the “worthless services” theory) under the FCA has been used for several years (without much success), courts continue to struggle with the limits of such claims and routinely look to early “quality of care” cases for guidance.

Since 1986, the FCA has been utilized by the government and qui tam plaintiffs alike in an effort to hold healthcare providers responsible for claims submitted to the government under Medicare or Medicaid programs for services that allegedly failed to meet the applicable standard of care. This theory has been used in particular against senior living care providers with regularity. Despite an increase in the focus of FCA cases over the past 25 years, United States ex rel. Mikes v. Strauss has maintained its place as the decision of first resort for analysis of quality of care claims under the FCA.

Quality of care claims under the FCA are usually based on allegations either that a defendant falsely certified to the government that medical services complied with the applicable standard of care, or that medical services actually provided and billed accurately by a provider were worthless. When a plaintiff relies on a defendant’s false certification of compliance, such certification may either have been expressly stated, or may be implied by the defendant’s certification of compliance with an underlying regulation or statute that requires compliance with a specified standard of care.

**Mikes v. Strauss**

In *Mikes*, the qui tam plaintiff claimed that spirometry procedures performed by the defendants failed to comply with guidelines issued by the American Thoracic Society (ATS) for calibration of spirometry equipment. The plaintiff argued that submission of claims to Medicare for those procedures therefore violated the FCA. The court addressed plaintiff’s
claims under both express and implied false certification theories, as well as the worthless services theory.

In considering the plaintiff’s false certification arguments, the court stated that “a claim for reimbursement made to the government is not legally false simply because the particular service furnished failed to comply with the mandates of a statute, regulation or contractual term that is only tangential to the service for which reimbursement is sought.”[4] The FCA “does not encompass those instances of regulatory noncompliance that are irrelevant to the government’s disbursement decisions.”[5] Rather, a claim for payment is legally false under the FCA “only where a party certifies compliance with a statute or regulation as a condition to governmental payment.”[6]

The court in Mikes quickly dispatched with the plaintiff’s argument that the defendants had expressly certified full compliance with ATS calibration guidelines by certifying that the services for which reimbursement was sought were “medically indicated and necessary for the health of the patient.” The court noted that the plaintiff had not challenged the decision to order the procedure for patients in the first place and agreed with the defendants that “medical necessity” is not qualitative.[7]

The plaintiff’s implied false certification arguments fared no better. In support, the plaintiff cited to 42 U.S.C. § 1320c-5(a), a portion of the Medicare statute mandating care that “meets professionally recognized standards of health care.” The Mikes court expressed concern that the judiciary was not suited to take on the role of primary monitor of the quality of medical care, noting that “permitting qui tam plaintiffs to assert that defendants’ quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government or the qui tam relator would replace the aggrieved patient as plaintiff.”[8] The court stated that “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 a pre-condition for payment – and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act’s reach.”[9] With these concerns in mind, the court took the position that application of the implied false certification theory requires that the underlying statute or regulation expressly state that compliance is a prerequisite for payment. The court rejected plaintiff’s reliance on section 1320c-5(a) because the Medicare statute did not explicitly condition payment on compliance, rendering the provision a mere condition of participation in Medicare, not a condition of payment.

The court in Mikes was careful to distinguish the plaintiff’s worthless services claim from claims based on alleged false certification. The court noted that a request for payment for procedures with no medical value whatsoever violates the FCA regardless of any certification because “for all practical purposes it is the equivalent of no performance at all.”[10] In rejecting the plaintiff’s worthless services claims, the court credited evidence provided by the defendants of their good faith belief that they had used the spirometry equipment correctly, including evidence that the defendants had relied on calibration instructions in the manuals provided for the equipment, as well as on outside training and equipment servicing.
“Quality of Care” False Claims Act Litigation Since Mikes v. Strauss: Has Anything Changed?

United States v. NHC Health Care Corp.

Although Mikes remains the leading FCA quality of care decision, it is closely followed in importance by United States v. NHC Health Care Corp., in which the court reached a slightly different result.[11] In NHC, the government alleged that the defendant nursing home operators submitted fraudulent bills to Medicare and Medicaid for reimbursement in violation of the FCA for services known not to have been performed. In support, the government cited evidence of understaffing, neglect of the defendants’ facility, and billing for care allegedly provided to two specific residents who were the victims of severe neglect.

In considering the government’s claims, the court observed that the per diem billing system used by Medicaid and Medicare makes it very difficult to prove that services for which the government was billed were worthless or never performed. [12] The court pointed out that the per diem billing system allows nursing homes to bill for overall care of each resident on a per day basis, as opposed to, for example, billing the government “$4 for turning Resident 1 on July 18, 1998.” Id. On the other hand, the court also noted that NHC agreed generally to provide “the quality of care which promotes the maintenance and the enhancement of the quality of life,” and that “[a]t some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary care activities required to promote the patient’s quality of life.”[13] The NHC court held that presenting claims for reimbursement after reaching that “blurry point” constitutes fraud.

Based on the evidence presented by the government, the NHC court held that a reasonable jury could conclude that the defendant did not have enough staff to properly care for its residents and denied the defendant’s motion for summary judgment. [14] In particular, the court relied on the following as establishing a genuine issue of material fact as to whether the defendant submitted bills for services that were never performed: (1) direct evidence that two specific residents had suffered gross neglect, and (2) expert opinions that staffing was not adequate to meet residents’ needs and that specific residents’ physical conditions were caused by a lack of care. The court also pointed to evidence of extreme staffing shortages during billing periods, as well as neglect and general lack of care, as relevant circumstantial evidence that a jury could consider, even if not directly demonstrative of fraud on the government.

Quality of Care Litigation After Mikes and NHC

In the 12 years since Mikes and NHC, FCA litigation over quality of care has focused on both the implied false certification and worthless services theories of liability. Of course, the first significant amendment to the FCA since 1986, the Fraud Enforcement and Recovery Act of 2009 (FERA), went into effect several years after Mikes and NHC. Given that FERA is relatively new, it is difficult to determine whether that expansion of the FCA will be viewed by courts as a broadening of enforcement policy such that courts will move away from the relatively conservative approaches to implied certification and worthless services theories. Even with the addition of a definition of “material,” the FERA amendments do not directly address those two theories.
“Quality of Care” False Claims Act Litigation Since Mikes v. Strauss: Has Anything Changed?

So far, courts have not generally found that the FERA amendments justify rejection of the Mikes analysis of certification claims.[15] Instead, courts have tended to adopt the Mikes court’s requirement in implied certification cases that the underlying governing regulation be a condition of payment.[16] For example, in Chesbrough v. VP A, P.C. d/b/a Visiting Physicians Assoc., the court considered claims that the defendant had fraudulently billed Medicaid and Medicare for defective x-ray and vascular ultrasound studies that allegedly failed to meet the applicable standards of care, including industry standards established by the American College of Radiology and the Society for Vascular Ultrasound.[17] The court noted that the plaintiffs relied solely on an implied certification theory of liability, and had not argued that the defendant had expressly certified that the tests at issue complied with industry standards. The court in Chesbrough relied on the “prerequisite to payment” analysis from Mikes in upholding dismissal of the plaintiffs’ claims based on their failure to allege that compliance with industry standards for diagnostic tests was an explicit prerequisite to payment under Medicare or Medicaid.

In addition to generally agreeing with Mikes’ concerns about whether federal courts are properly equipped to act as arbiters of the quality of medical care, courts have also expressed concerns that an overly broad view of FCA liability could undermine the government’s own carefully crafted regulatory compliance schemes. For example, in United States ex rel. Swan v. Covenant Care, Inc., the court pointed out that the Social Security Act sets up a comprehensive scheme of sanctions applicable to nursing homes that fail to meet quality of care guidelines.[18] Failing to enforce a strict interpretation of the prerequisite to payment requirement would “improperly permit qui tam plaintiffs to supplant regulatory discretion granted to [Health and Human Services] under the Social Security Act, essentially turning a discretionary denial of payment into a mandatory penalty for failure to meet Medicare requirements.”[19] Similarly, in United States ex rel. Conner v. Salina Regional Health Center, Inc., the court stated that a relaxed view of certification would mean that “an individual private litigant, ostensibly acting on behalf of the United States, could prevent the government from proceeding deliberately through the carefully crafted [Medicare] remedial process and could demand damages far in excess of the entire value of Medicare services performed by a hospital.”[20]

With respect to the worthless services theory of liability, as stated in Mikes, a claim that a defendant violated the FCA by seeking and receiving reimbursement for provision of services that were known to be medically worthless is not dependent on the defendant’s express or implied certification of regulatory compliance. In United States ex rel. Lee v. SmithKline Beecham, Inc, the defendant was alleged to have submitted bills to Medicare for falsified tests from its clinical laboratories. [21] Although the court affirmed dismissal of the plaintiff’s claims for failure to meet the pleading standard applicable to fraud claims under Rule 9(b), the court ruled that the district court erred by not considering whether the defendant violated the FCA by seeking payment for medically worthless tests. In granting dismissal of the plaintiff’s claims with prejudice, the lower court held that any amendment by the plaintiff would be futile because the applicable Medicare form contained no certification that the defendants had complied with all applicable rules and regulations as a prerequisite for payment. On appeal, the Ninth Circuit held that that the district court should have considered worthless services claims as wholly separate from a false certification theory of liability, noting that “knowingly billing for worthless services
or recklessly doing so with deliberate ignorance may be actionable [under the False Claims Act], regardless of any false certification conduct.”[22]

As in Mikes, the cases in which courts have considered a “worthless services” theory of liability under the FCA make clear that a plaintiff cannot merely challenge the level of care, but must allege that any care provided was the equivalent of no care at all. For example, in United States ex rel. Swan v. Covenant Care, Inc., the plaintiff claimed that the defendants falsified nursing home patient records in order to conceal inadequate care caused by staffing and funding shortages.[23] The court held that the plaintiff’s claims were not true worthless services claims because the government paid a per diem rate for the defendant’s services, and the defendant’s billing did not include line-item charges for specific services for specific patients that were not provided. The court also noted that the claimed neglect could not properly be characterized as the equivalent of no care at all.

Other decisions have generally been in accord with the results in Mikes, SmithKline, and Swan, and appear to set a high bar for a plaintiff seeking to assert FCA liability based on provision of worthless services.[24] In United States ex rel. Sanchez—Smith v. AHS Tulsa Regional Medical Center, LLC, the plaintiff’s claims concerned the defendant’s failure to comply with Medicaid’s “active treatment” requirements for therapy.[25] The court cited approvingly to Mikes and NHC, stating that “in order to reach a jury on a factual falsity theory in the context of ‘bundled’ per diem Medicaid billing, a plaintiff must present facts amounting to (1) the provision of ‘worthless services’ . . . or (2) at a minimum, the provision of grossly negligent services with regard to a particular standard of care or regulatory requirement.”[26] The court noted that even the patient identified as having suffered the most egregious violation of the active treatment requirements had still received over 50% of required therapy hours, and concluded that no reasonable jury could find that this was worthless or even grossly negligent.

However, in at least one decision, United States v. Villaspring Health Care Center, Inc., the court held that a determination of whether services rendered were in fact worthless is not appropriate for consideration at the motion to dismiss stage.[27] In Villaspring, the defendants argued that a worthless services claim was inapplicable because the nursing home at issue billed for services on a per diem basis and the complaint would have had to allege that residents were provided with no services at all. The court disagreed, holding that a per diem billing arrangement “presupposes” a nursing facility that provides the quality of care that meets the standard articulated in NHC. According to the Villaspring court, whether the care provided falls into the grey area below NHC’s “blurry point” is a fact intensive inquiry and not proper for determination on a motion to dismiss.

Conclusion

The Mikes court’s requirement that regulatory compliance must be a prerequisite to payment appears to be well established for FCA claims based on implied false certification. Moreover, courts have continued to set a high bar for allowing claims to proceed on the theory that the medical services provided were worthless. However, given the government’s ongoing efforts to expand the scope of required certifications, it remains to be seen
“Quality of Care” False Claims Act Litigation Since Mikes v. Strauss: Has Anything Changed?

how aggressively federal courts will push back against being forced to serve as the primary monitors of the quality of medical care in the United States.


[4] Id. at 697.

[5] Id.

[6] Id.

[7] Id. at 698.

[8] Id. at 700.

[9] Id. at 699.

[10] Id. at 703.


[12] Id. at 1055-56.

[13] Id.

[14] Id. at 1056-57.

“Quality of Care” False Claims Act Litigation Since Mikes v. Strauss: Has Anything Changed?

[16] See, e.g., U.S. ex rel. Lockyer v. Hawaii Pacific Health, 490 F. Supp. 2d 1062 (D. Haw. 2007) (holding that even if plaintiff could show that defendant’s nurses were not qualified to perform chemotherapy, plaintiff’s claim under the FCA still failed because the Medicare billing requirements did not contain a qualitative standard of care); Sweeney v. ManorCare Health Services, Inc., No. C03-5320RJB (W.D. Wash. Mar. 4, 2005) (dismissing FCA claim based on nursing home’s failure to deliver snacks and dietary supplements to residents for lack of allegation that regulatory violations constituted conditions of payment).


[19] Id. at 1222.

[20] 543 F.3d 1211, 1221 (10th Cir. 2008).

[21] 245 F.3d 1048 (9th Cir. 2001).

[22] Id. at 1053.


[24] See U.S. ex rel. Bailey v. Ector County Hosp., 386 F. Supp. 2d 759 (W.D. Tex. 2004) (holding that even though the defendants had sought reimbursement for surgery that may have endangered the plaintiff’s life, there was no evidence that the defendants’ services were so deficient as to be worthless); U.S. ex rel. Phillips v. Permian Residential Care Center, 386 F. Supp. 2d 879 (W.D. Tex. 2005) (dismissing plaintiffs’ worthless services claim as “mere speculation” because “the record does not show the Defendants’ services were so deficient as to be worthless,” despite the fact that plaintiffs’ mother died after being removed from defendant’s nursing home to be treated for dehydration, malnutrition and bed sores).


[26] Id. at 1287 (internal citation omitted).