Worthless or Merely Worth Less: The Current State of the Worthless Services and Quality of Care Theories of False Claims Act Liability

Matthew T. Newcomer, Esq., Barbara Rowland, Esq.[1]

Late last year, Extendicare Health Services agreed to pay $38 million to resolve allegations that it violated the federal and state False Claims Acts (FCA) by seeking government reimbursement for "materially substandard and/or worthless skilled nursing services" that were provided at Extendicare's numerous skilled nursing facilities. The Department of Justice hailed the resolution as the "largest failure of care settlement with a chain-wide skilled nursing facility" in its history.[2] The thrust of the government's theory was not that Extendicare billed the government for services that were not performed or that were medically unnecessary; rather, it alleged that Extendicare submitted claims for services that failed to meet the purported "federal standards of care" because, for example, it did not adequately staff its facilities, failed to follow certain medical protocols and failed to appropriately administer medication to some of its residents.

The government's continued success in obtaining settlements based on "quality of care" or "failure of care" theories of FCA liability stand in contrast to the federal judiciary's increasing reluctance to recognize FCA allegations based on services that allegedly did not meet a certain standard of care. In a string of recent decisions, courts have taken a narrow view of the "worthless services" and "implied certification" theories of FCA liability in the health care context. This article will examine these recent decisions and attempt to distill the current impediments - and opportunities - for prosecutors and *qui tam* relators attempting to bring "quality of care" or "worthless services" FCA actions against healthcare providers. It will conclude that notwithstanding the string of arguably defense-friendly judicial decisions, the federal government and whistleblowers alike will continue to adapt their theories to pursue these lucrative claims.

The Allegations Against Extendicare

Extendicare was the subject of a *qui tam* lawsuit filed in 2010 by its former Area Director of Rehabilitation. Although the relator's original complaint alleged that Extendicare submitted false claims for levels of rehabilitation services that were not actually provided, as well as for "upcoding" rehabilitation services, the settlement agreement – which was entered more than four years later – instead alleged FCA violations based on the "materially substandard and/or

[1] Matthew Newcomer and Barbara Rowland are Principals in the Internal Investigations and White Collar Defense Group at Post & Schell, P.C.'s Philadelphia and Washington D.C. offices, respectively.

[2] Department of Justice Press Release, October 14, 2014, available at http://www.justice.gov/opa/pr/extendicare-health-services-inc-agrees-pay-38-million-settle-false-claims-act-allegations.

worthless" medical services, which purportedly resulted in residents receiving care that did not meet "federal standards of care and federal statutory and regulatory requirements."[3]

As examples of the substandard care, the government cited the following alleged deficiencies: (1) the failure to have a "sufficient number and skill-level of nursing staff to adequately care" for residents; (2) the failure to provide "adequate catheter care" to residents; (3) the failure to follow "appropriate" pressure ulcer and falls protocols; and (4) the failure to appropriately administer medications "to avoid medication errors."[4] Although the government did not identify the source of these alleged duties, they all appear related to the numerous regulatory conditions of Medicare and Medicaid participation that require nursing homes to ensure that residents receive adequate supervision and assistive devices to prevent accidents, to ensure that residents are free of any significant medication errors and to ensure the facility has sufficient nursing staff to provide nursing and related services.[5] These conditions, among others, represent the "the requirements that an institution must meet in order to qualify to participate as a [skilled nursing facility] in the Medicare program, and as a nursing facility in the Medicaid program."[6]

As noted, the government complained that Extendicare's failure to meet these participation standards meant that the nursing home had, in seeking federal reimbursement for the care provided to these residents, submitted "false claims" because the underlying care was "materially substandard and/or worthless." This type of allegation raises an important question that federal courts continue to struggle with: namely, whether the FCA is a vehicle by which a health care provider can be liable for providing substandard care. The answer to this question is further complicated by the government's use of the "and/or" conjuncture, which muddies two distinct theories of FCA liability: (1) the "worthless services" theory, under which an individual may be liable for submitting a claim for services that were "so deficient that for all practical purposes it is the equivalent of no performance at all;" and (2) the false certification theory, under which an individual may be liable for certifying that the services underlying the submitted claim met certain statutory, regulatory or contractual standards.[7]

The Seventh Circuit's *Absher* Decision

The Seventh Circuit's recent decision in *United States ex rel. Absher v. Momence Meadows Nursing Center, Inc.*,[8] is instructive on the core question of whether substandard care is actionable under the FCA, and challenges the type of worthless services theory advanced against Extendicare. The *qui tam* plaintiffs in *Absher* were two nurses formerly employed by the defendant nursing home, Momence Meadows Nursing Center, which they allege submitted "thousands" of false claims for substandard care resulting in problems with infection, pest

[3] Extendicare Settlement Agreement, at ¶ G.1.

[4] *Id.*

[5] 42 C.F.R. § 483 *et seq*.; specifically 42 C.F.R. § 483.25 (facility must ensure that the resident receives adequate supervision and assistive devices to prevent accidents, and ensure that residents are free of any significant medication errors) and 42 C.F.R. § 483.30 ("facility must have sufficient nursing staff to provide nursing and related services").

[6] 42 C.F.R. § 483.1.

[7] *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001).

[8] *United States ex rel. Absher v. Momence Meadows Nursing Center, Inc.*, 764 F.3d 699 (7th Cir. 2014).

control, medication and patient accidents. The United States declined to intervene and the case went to trial.

The centerpiece of the plaintiffs' FCA claim was that the nursing home billed the federal government for allegedly worthless services. When charging the jury on this theory, the trial court expressed its view that a service could be considered "worthless" under the FCA even if some portion of the service had been performed appropriately. The trial court provided the following illustration in support of its view: "If Uncle Sam paid [the nursing home] 200 bucks and they only got $120 of value, [then the nursing home] defrauded them of $80 worth of services."[9] Based in part on this instruction – which the Seventh Circuit later determined was erroneous – the jury concluded that the nursing home had submitted 1,729 false claims. The court entered judgment for the United States in the amount of $9,091,227.[10]

On appeal, the Seventh Circuit adopted the Second Circuit's definition of a worthless service as one that is "so deficient that for all practical purposes it is the equivalent of no performance at all."[11] It reasoned that it was not enough for the plaintiffs to have established that the provided services were "worth less" than the amount paid for them. In other words, a "diminished value of services theory" does not qualify as "worthless." As the court concisely concluded, "[s]ervices that are "worth less" are not "worthless" for purposes of establishing liability under the FCA.[12]

Turning to the evidence at trial, the Seventh Circuit held that any claim that the services rendered by the nursing home were truly worthless "would be absurd in light of the undisputed fact that [the nursing home] was allowed to continue operating and rendering services of some value despite regular visits by government surveyors."[13] It also noted that one of the relators had a mother who was a resident of the nursing home, and this relator testified at trial that her mother had received good care from the defendant.[14] For these reasons, the Seventh Circuit concluded that the worthless services theory of FCA liability – which it declined to specifically adopt – could not support the jury's verdict under these facts.

Other Recent Circuit Decisions on the Worthless Services Theory

Apart from *Absher*, few Circuit opinions have addressed the substantive merits of a true worthless service claim under the FCA.[15] The decisions that have addressed this theory, however, appear consistent with the Seventh Circuit's narrow view of "worthless" as meaning devoid of any value.

---

[9] *Id*. at 709.

[10] The court entered judgment for treble the amount of compensatory damages awarded by the jury. *Id*. at 705.

[11] *Id*. at 710 (quoting *Mikes*, 274 F.3d at 703).

[12] *Id*.

[13] *Id*.

[14] *Id*.

[15] In *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2008), the Eighth Circuit refused to consider the plaintiff's worthless services theory regarding allegedly defective blood glucose monitoring systems because he failed to plead it in his complaint. Similarly, the Third Circuit declined to address the substance of the worthless services theory due to the plaintiff's failure to raise the argument until his appellate reply brief. *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 446 n.18 (3d Cir. 2004).

In *Mikes*, the Second Circuit considered whether a group of physicians submitted false reimbursement requests for spirometry services, tests designed to measure a patient's pulmonary function. Because defendants allegedly failed to calibrate the machines daily as recommended by published industry guidelines, the whistleblowers based their FCA theory on the contention that the spirometry results were unreliable – and thus worthless.[16] The Second Circuit appeared to accept the premise that a completely unreliable spirometry result could be "worthless" and therefore give rise to a false claim, but nevertheless rejected the plaintiffs' theory because the defendants provided ample evidence of their good faith belief that their spirometry tests had medical value (*e.g.*, the spirometers' instruction manual indicated that daily calibration was not required).[17]

The Sixth Circuit in *Chesbrough v. VPA. P.C.*, addressed an FCA whistleblower complaint premised on the defendant having billed the government for radiology studies that were "of either no diagnostic value or limited diagnostic value."[18] The Sixth Circuit held that only the small number of radiology studies that had absolutely no diagnostic value – but not the studies with "limited" diagnostic value – could support a worthless services theory of FCA liability because they were of no medical value and, for all practical purposes, had not been provided.[19]

The Eleventh Circuit has also recently addressed the worthless services theory, but in the context of a criminal health care fraud prosecution as opposed to a FCA *qui tam* lawsuit. The defendant nursing home owner in *United States v. Houser*[20] was convicted of health care fraud in connection with his receipt of Medicare and Medicaid funding for care provided at the "barbaric" nursing homes he operated, at which statutorily-mandated services were not performed at all. The court declined to "draw the proverbial line in the sand for purposes of determining when clearly substandard services become 'worthless,'" and instead upheld the defendant's conviction based on the fact that he sought reimbursement for "required services – pharmaceutical, diagnostic, medical and dietary – that simply were not provided."[21] The Eleventh Circuit believed its result was "consonant" with the Sixth Circuit's *Chesbrough* decision.[22]

These decisions are consistent in their holdings that for purposes of the FCA, a service is not "worthless" unless it is totally without value. This narrow definition of worthless does not easily lend itself to an FCA action based on the quality of the rendered care except in those cases where the care had no medical benefit whatsoever. For this reason, it seems unlikely that quality of care allegations of the type asserted against Extendicare – *e.g.*, "inadequate" catheter care, medication administration and staffing – could substantiate an allegation that the nursing home services provided were completely devoid of value. This is especially true given that the government reimburses nursing homes a flat per diem rate for each patient and does not reimburse the facility for each individual service it performs. In fact, the "worthless services"

---

[16] *Mikes*, 274 F.3d at 693 - 694. The United States declined to intervene.

[17] *Id*. at 703-704.

[18] *Chesbrough v. VPA. P.C.*, 655 F.3d 461, 465 (6th Cir. 2011). The United States declined to intervene.

[19] *Id*. Note that the Sixth Circuit ultimately affirmed the district court's dismissal of these claims because the plaintiffs failed to establish that the offending claims had actually been submitted to the government. *Id*. at 470.

[20] *United States v. Houser*, 754 F.3d 1335 (11 Cir. 2014).

[21] *Id*. at 1348.

[22] *Id*.

allegations against Extendicare appear nearly identical to the allegedly deficient services the Seventh Circuit rejected in *Absher*, only months after the announcement of the Extendicare settlement. Because hospitals, like nursing homes, are also paid a per diem rate per patient and are not typically paid for each drug dispensed or each service provided, it would be similarly difficult to make out a worthless service claim against a hospital based on isolated deficiencies in care of the sort alleged against Extendicare.

False Certification Theories of FCA Liability

A second basis of FCA liability for allegedly deficient quality of care rests on the theory that the Medicare and Medicaid programs condition payment on the provider's certification that the submitted claims have met a certain level of care as set forth by statute, regulation or contract. Of course, a provider who certifies compliance with a particular standard of care in the claims submitted may be liable under the FCA if he or she knew that the service billed had not met that particular standard and if the government specifically conditions its payment on the satisfaction of that standard.[23] This is known as the express false certification theory, the recognition of which is generally not in dispute.[24]

The more controversial theory of FCA liability is premised on the notion that a provider, by the very act of submitting a claim for government reimbursement, has *impliedly* certified compliance with the myriad of statutes, regulations and contractual arrangements that govern the federal healthcare program being billed. This appears to be one of the theories underpinning the Extendicare settlement given that the settlement does not make reference to any direct false certification of compliance as the basis for liability. Instead, the government alleged that in providing deficient services to its patients, the nursing home "violated certain essential requirements that the United States expects nursing facilities to meet and that were therefore material to payment within the meaning of the False Claims Act."[25] Put another way, this theory would hold that Extendicare's submission of claims for payment created an implied certification of its compliance with the regulatory conditions of participation discussed above, including the conditions concerning adequate staffing and medication administration.

Recent Rejections of the Implied Certification Theory

The circuit courts that have addressed the implied certification theory are split, with the Fifth and Seventh having recently declined to apply it in certain cases. The Fifth Circuit declined to adopt the implied certification theory in the context of Cardinal Health's sale of allegedly defective medical equipment to the U.S. Department of Veterans Affairs.[26] The relator in this case alleged that Cardinal impliedly – not expressly – certified that the infusion pumps it sold to the government met the warranty of merchantability (*i.e.*, that the equipment was "safe,

[23] For example, Medicare reimbursement form HCFA-1500 and its electronic equivalent contain an express certification that the submitted claim was "medically indicated and necessary for the health of the patient…", and both the form and the Medicare regulations state that this certification is a precondition to reimbursement. *See Mikes*, 274 F.3d at 698. Thus, the submission of a Medicare claim for services that were known to be medically unnecessary could support an FCA claim based on the express certification of compliance with a clear condition of payment. *Id*.

[24] *See e.g. id.* at 697.

[25] Extendicare Settlement Agreement, at ¶ G.1.

[26] *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 264 (5th Cir. 2010).

reliable and quality-tested").[27] The court reasoned that an implied, albeit false, certification of compliance with a warranty of merchantability does not give rise to a false claim unless the government specifically conditions payment on such compliance, and that "a contractor's mere request for payment does not fairly imply such certification." The court explained that this "prerequisite requirement" is necessary to "maintain a crucial distinction between punitive FCA liability and ordinary breaches of contract."[28] The Fifth Circuit concluded that there was no contractual, statutory or regulatory basis to support the relator's position that the federal government conditioned payment on a certification that the pumps complied with the warranty of merchantability. Thus, the court upheld the dismissal of the whistleblower's claim while declining to specifically adopt the implied certification theory.[29]

In addition to the worthless services theory addressed by the Seventh Circuit in *Absher*, discussed above, the relators in that case also argued that the nursing home "impliedly certified" that it was in compliance with Medicare and Medicaid regulations when in fact it was systematically violating a number of these requirements.[30] The Seventh Circuit declined to directly address this theory because the relators had failed to present it to the jury. However, it noted that the relators' implied certification theory – if taken to its logical conclusion – would mean that "even a single regulatory violation would be a condition of any and all payments subsequently received by the facility," which it viewed as an "absurd" result.[31]

Building off its reasoning in *Absher*, and citing the Fifth Circuit's decision in *Steury*, this past June the Seventh Circuit conclusively rejected the "so-called doctrine of implied false certification" in a case involving an educational institution's alleged implied certification of compliance with the "panoply of statutory, regulatory, and contractual requirements" related to Title IV of the Higher Education Act.[32] The theory of the relator and the government (supported by amicus briefing) was that the institution certified, by entering into a Program Participation Agreement (PPA) necessary to receive federal education subsidies, that it would comply with numerous restrictions that were conditions of its participation in Title IV programs. The relator argued that because the institution certified in the PPA that it would comply with all necessary statutes and regulations, compliance with these statutes and regulations became a condition of payment. The relator claimed that the institution impliedly certified compliance with these conditions of payment every time that it received a government payment, and that these implied certifications were false because the institution allegedly knew it had violated some of the Title IV restrictions.[33]

---

[27] *Id*. at 268.

[28] *Id*. (internal quotations and citation omitted).

[29] Note that in *United States ex rel. Gage v. Davis S.R. Aviation, L.L.C.*, 2015 U.S. App. LEXIS 12230 (5th Cir. July 14, 2015), the Fifth Circuit once again declined to adopt the implied certification theory while affirming the dismissal of a qui tam lawsuit against a government contractor who allegedly sold the Air Force defective parts from a crashed aircraft.

[30] *Absher*, 764 F.3d at 711.

[31] *Id*. at 712. The court also noted that even if the evidence had established the existence of implied certifications which were material to payment, the relators claim still would have failed because of their inability to identify the specific or even approximate number of allegedly false claims. *Id*. at 714, n15.

[32] *United States v. Sanford-Brown, Limited*, 2015 U.S. App. LEXIS 9508, at *4, *33 (7th Cir. June 8, 2015).

[33] *Id*. at *23 – 30.

The Seventh Circuit refused to join the circuits that had adopted the implied certification theory because "distilled to its core…the theory of liability lacks a discerning limiting principle." It held that the conditions of participation "contained in – or incorporated by reference into – a PPA" do not somehow transform into the conditions of payment necessary to establish FCA liability. It held, "under the FCA, evidence that an entity has violated conditions of participation after good faith entry into its agreement with the agency is for the agency – not a court – to evaluate and adjudicate."[34] The court also noted that the U.S. Department of Education had the authority to terminate the institution from its subsidy program, but declined to do so after multiple examinations. The Seventh Circuit concluded that the agency's regulations – not the FCA – provide the government with an adequate enforcement method to ensure program compliance.[35]

In reaching its conclusion, the Seventh Circuit specifically referenced the "foreshadowing" it had provided the previous year in *Absher*, in which it "rejected as 'absurd' the relators' argument that compliance with regulations were conditions of payment in the Medicare and Medicaid context."[36] Moreover, the court's view that the Department of Education – empowered by its own regulations – chose not to take action against the institution despite the alleged program violations runs parallel to the court's finding in *Absher* that federal regulators had inspected the nursing home on numerous occasions and had allowed it to keep operating. For these reasons, the Seventh Circuit's *Sanford-Brown* decision can be fairly read as a rejection of the implied certification theory that it declined to rule on specifically in *Absher*.

The quality of care standards that Extendicare allegedly violated all appear to be regulatory conditions of participation in Medicare and Medicaid, as discussed above. The government's apparent theory of FCA liability against Extendicare – that its agreement to participate in the Medicare and Medicaid programs means that it impliedly certified compliance with these various regulations each time it submitted a claim – would not appear to pass muster under the Seventh Circuit's reasoning in *Sanford-Brown* and *Absher*, absent some express certification of compliance as a condition of payment.[37] This article will now address how this theory might fare in the Circuits that have adopted the implied certification theory.

Restrictive Adoption of the Implied Certification Theory

Although a number of Circuits have adopted the implied certification theory of FCA liability, many of these courts have been circumspect about its widespread application in the health care sector. In *Mikes*, the Second Circuit recognized the implied certification theory but warned that the FCA "was not designed for use as a blunt instrument to enforce compliance with all medical regulations – but rather only those regulations that are a precondition to payment – and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the [FCA's] reach."[38] The court also cautioned that allowing *qui tam* plaintiffs to assert that a provider's quality of care failed to meet medical standards would "promote federalization

[34] *Id*. at *34.
[35] *Id*. at *35.
[36] *Id*. at *31.
[37] The qui tam lawsuit against Extendicare was filed in the Third Circuit, which has adopted a restrictive view of the implied certification theory as discussed below.
[38] *Mikes*, 274 F.3d at 699.

of medical malpractice, as the federal government or the *qui tam* relator would replace the aggrieved patient as plaintiff."[39] For these reasons, the court only recognized the theory in the limited circumstances where the provider impliedly certified compliance with a statute or regulation that *expressly* states a provider must comply with it in order to be paid.

Applying this standard to the relator's claim that the defendant physicians improperly billed Medicare for unreliable spirometry tests, the Second Circuit found that although the Medicare statute conditions payment on services that are medically necessary, it does not condition payment on conforming the service to a particular standard of care. The court also held that a section of the Medicaid statute requiring each health care practitioner to provide "professionally recognized standards of health care" – 42 U.S.C. § 1320c-5(a) – is a condition of participation, not a condition of payment.[40] As support for this conclusion, the court pointed to the statute's empowerment of peer review organizations to recommend sanctions against providers who fail to meet the quality standards in a substantial number of cases, which *may* lead to exclusion from the Medicare program. In other words, an "individual incident of noncompliance" does not trigger automatic exclusion.[41] For these reasons, the Second Circuit dismissed the relator's implied certification claim due to her failure to tether the allegedly deficient services to a regulation or statute that expressly conditions Medicare reimbursement on the exercise of a specific standard of care.

The Third Circuit – where the case against Extendicare was filed – considered the implied certification theory in *United States ex rel. Wilkins v. United Health Group*, in which a whistleblower alleged that his former employer, United Health, improperly submitted claims for federal reimbursement while failing to comply with Medicare laws and regulations regarding kickback and off-label marketing prohibitions.[42] The relator argued that United Health's monthly certification to the Centers for Medicare and Medicaid Services (CMS) that it complied with all of CMS' Medicare guidelines, including the prohibitions on off-label marketing and illegal kickbacks, were conditions of payment.

The Third Circuit adopted the implied certification theory of FCA liability, which it described as "premised on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment."[43] Despite adopting this theory, the court joined the Second Circuit in cautioning against applying this theory too expansively to claims submitted for federal health care funding, out of concern that the FCA could turn into a "blunt instrument" to enforce compliance with all regulations. Thus, the Third Circuit required the plaintiff to show that the government would not have paid United Health's claims if it had known about the violations at issue.

The Third Circuit partially affirmed the dismissal of the relator's complaint due to the failure to identify "any regulation demonstrating that a participant's compliance with Medicare

[39] *Id*. at 700.
[40] *Id*. at 701 – 702.
[41] *Id*. at 702.
[42] *U.S. ex rel. Wilkins v. United Health Group*, 659 F.3d 295 (3d Cir. 2011). The government did not intervene in this case.
[43] *Id*. at 305 (internal quotations and citation omitted).

marketing regulations is a condition for its receipt of payment from the Government."[44] The court also noted that the regulations through which CMS may terminate its contract with a Medicaid sponsor like United Health establish mechanisms "for managing and correcting Medicare marketing violations other than the withholding of payment otherwise due," which meant that CMS "does not require perfect compliance as an absolute condition for receiving Medicare payments for services rendered."[45] The court expressed its view that federal agencies, as opposed to federal courts, are better suited to ensure compliance with marketing regulations.

The Third Circuit also held, however, that the relator had sufficiently pleaded an implied certification theory of FCA liability by alleging that United Health received federal reimbursements despite its knowing violation of the Anti-Kickback Statute (AKS).[46] The court reasoned that unlike CMS's marketing regulations, compliance with the AKS is a condition for receiving payment under Medicare Parts C and D. The court explained that while compliance does not require "perfect adherence to regulations which are not prerequisites to payment," compliance does require a participant in a federal health care program to refrain from participating in illegal kickbacks.[47]

The Ninth Circuit recognized the implied certification theory in *U.S. ex rel. Ebeid v. Lungwitz*, but nevertheless affirmed the district court's dismissal of the relator's complaint, which alleged that all of the claims for federal healthcare reimbursement by several healthcare businesses were false because by submitting these claims the defendants impliedly certified that they were not violating various state and federal laws including the Stark Act, which prohibits physician self-referral arrangements.[48] Although the court found that the Stark Act itself conditions government payment on compliance with its prohibitions, it concluded that the relator had failed to plead sufficient facts to establish an improper self-referral arrangement.[49]

The Sixth Circuit recognized the implied certification theory while simultaneously corralling its use in the health care arena. In *Chesbrough*, discussed above, the relators alleged that the defendants, by submitting claims for radiology studies, impliedly and falsely certified that the studies met the industry standard.[50] The court rejected this theory because the relators were unable to identify any "specific Medicare or Medicaid regulation that mentions the [alleged] standards." The Sixth Circuit ruled that Medicare "does not require compliance with an industry standard as a condition to payment;" thus, "requesting payment for tests that allegedly did not comply with a particular standard of care does not amount to a 'fraudulent scheme' actionable under the FCA."[51]

---

[44] *Id*. at 309-310.

[45] *Id*. at 310.

[46] *Id*. at 313.

[47] *Id*. at 314. The Eleventh Circuit also held that compliance with the AKS is a condition of receiving payment from Medicare. *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005).

[48] *Ebeid v. Lungwitz*, 616 F.3d 993 (9th Cir. 2010), *cert. denied*, 562 U.S. 1102 (2010).

[49] *Id*. at 1000. The court distinguished the Stark Act from the Medicare conditions of participation discussed by the Second Circuit in *Mikes*, which the Second Circuit found were conditions of participation, not payment.

[50] *Chesbrough*, 655 F.3d at 467-468.

[51] *Id*. at 468.

More Expansive Views of the Implied Certification Theory

A handful of Circuits have adopted a more expansive definition of the implied certification theory. In *United States ex rel. Hutcheson v. Blackstone Med., Inc.,* the First Circuit considered a *qui tam* relator's claim that a medical device company paid kickbacks to physicians to induce them to use its devices, thereby knowingly causing hospitals and physicians to submit materially false claims for reimbursement. In reversing the district court's dismissal of this claim, the First Circuit rejected the reasoning of *Mikes* and its progeny that, absent an express certification, a claim can only be false if it fails to comply with a statutory or regulatory condition of payment.[52] Although the court disavowed the "judicially-created categories" of express and implied certification, it nevertheless recognized that an implied representation of compliance with a material condition of payment could support an FCA claim even where there was no statutory or regulatory basis to establish that compliance was in fact a condition of payment. The First Circuit ruled that the Provider Agreement between CMS and the health care provider as well as the Hospital Cost Report both established that compliance with the AKS is a condition of payment.[53] The court reasoned that strict enforcement of the FCA's materiality and scienter requirements were a better guard against the potential overextension of the FCA in the health care sector, as opposed to the Second Circuit's categorical rule that a condition of payment must be grounded in regulation or statute.

The D.C. Circuit reached a similar conclusion in *United States v. Sci. Applications Int'l Corp.*, which was cited favorably by the First Circuit in *Blackstone*.[54] The FCA claim addressed in *Sci. Applications Int'l* was not a health care claim; rather, it was a claim that a contractor of the Nuclear Regulatory Commission (NRC) falsely certified compliance with a contract requirement regarding conflicts of interest as defined by applicable regulations. The court held that the FCA plaintiff need only show that the contractor withheld information about its noncompliance with a material contractual requirement, and that the "existence of express contractual language specifically linking compliance to eligibility for payment" was not necessary to establish liability.[55] The court distinguished the Second Circuit's *Mikes* decision because the issue before it did not implicate any concern about federalizing medical malpractice, and because the contract at issue in *Mikes*, unlike the NRC contract, did not actually incorporate the regulatory requirements. Nevertheless, the court emphasized that payment requests by a contractor who has violated contractual provisions that are ancillary and not material to the parties' bargain are neither false nor fraudulent under the FCA.[56]

Conclusion

Given the Circuits' consistently narrow interpretation of the worthless services theory of FCA liability, actually proving such a case at trial would present difficulty to the government or *qui tam* plaintiff unless it can establish that the allegedly defective service was entirely devoid of medical value, *i.e.*, actually "worthless," and not merely "worth less" than the same procedure

[52] *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 379 (1st Cir. 2011), *cert. denied*, 132 S. Ct. 815 (2011).

[53] *Id*. at 392 – 393.

[54] *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010).

[55] *Id*. at 1269.

[56] *Id*. at 1271.

properly performed. While it would be simpler to establish that individually billed services – such as the spirometry tests in *Mikes* – were devoid of medical value, meeting this burden for the bundled services for which hospitals and nursing homes are reimbursed at a per diem rate would be much harder for the reasons articulated in *Absher*. Most notably, it would be difficult to establish that the health care entity provided no medical care whatsoever to its patients, particularly where government regulators have inspected the facility and found no reason to sanction it.

Presently, the ability to establish a quality of care FCA claim under the implied certification theory appears largely dependent on the circuit in which the claim is raised. On the one hand, many of the decisions discussed above – particularly those of the Second and Sixth Circuits – require an implied certification to be based on a statutory or regulatory precondition of payment, as opposed to conditions of participation of the type cited in the Extendicare settlement. It seems unlikely that a pure quality of care, implied certification claim would survive appellate scrutiny in these jurisdictions because these courts did not identify a statutory or regulatory precondition of payment (as opposed to a precondition of participation) that requires a health care provider to provide a certain standard of care.

On the other hand, using the implied certification theory to establish an FCA claim based on deficient quality of care would fare better in the circuits that focus their analysis not on whether there is a statutory or regulatory basis to establish that a certain level of care was a precondition of payment, but rather on whether the breach of that standard would have been material to the government's willingness to pay for the defective services. This less formulaic approach to the implied certification theory allows the government and *qui tam* plaintiffs alike to argue that the government would not have paid for certain services had the government known they were materially deficient, regardless of whether there exists a specific statute that establishes quality care as a condition of payment.

Notwithstanding the challenges to quality of care FCA lawsuits identified in this article, there can be little doubt that the government and *qui tam* plaintiffs alike will continue to find ways to pursue these lucrative claims. Indeed, Extendicare agreed to settle the quality of care FCA claims it was facing despite the potentially successful defenses it might have been able to mount. Until there is consensus among the circuits or clarity from the U.S. Supreme Court, health care providers must continue to assume that there is potential exposure under the FCA for the provision of deficient medical services.