

United States Court of Appeals For the First Circuit

No. 10-1505

UNITED STATES OF AMERICA EX REL.
SUSAN HUTCHESON AND PHILIP BROWN,

Plaintiffs, Appellants,

v.

BLACKSTONE MEDICAL, INC.,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. William G. Young, U.S. District Judge]

Before

Lynch, Chief Judge,
Lipez and Howard, Circuit Judges.

Jennifer M. Verkamp, with whom Frederick M. Morgan, Jr. and
Morgan Verkamp LLC were on brief, for appellants.

Charles W. Scarborough, Appellate Staff, Civil Division,
Department of Justice, with whom Tony West, Assistant Attorney
General, Carmen Ortiz, United States Attorney, and Douglas N.
Letter, Appellate Staff, Civil Division, Department of Justice,
were on brief, for the United States, amicus curiae.

Catherine E. Stetson, with whom Peter S. Spivack, Jonathan
L. Diesenhaus, Jessica L. Ellsworth, Lillian S. Hardy, Stephanie
L. Carman, Hogan Lovells US LLP, Douglas Hallward-Driemeier,
Kirsten V. Mayer, and Ropes & Gray LLP were on brief, for
appellee.

June 1, 2011

LYNCH, Chief Judge. In this qui tam action brought under the False Claims Act (FCA), 31 U.S.C. § 3729 et seq., relator Susan Hutcheson appeals from a Rule 12(b)(6) dismissal of her claims against Blackstone Medical, Inc. (Blackstone).

Hutcheson argues that Blackstone "knowingly" "cause[d]" hospitals and physicians to submit materially "false or fraudulent" claims to Medicare, Medicaid, and TRICARE in violation of 31 U.S.C. § 3729(a)(1) & (2). She alleges that Blackstone engaged in a nationwide kickback scheme to induce physicians to use its medical devices in spinal surgeries and that Blackstone knew this scheme would cause physicians and hospitals (unwittingly) to present federal healthcare programs with payment claims that contained material misrepresentations. We need only address Hutcheson's claims as they relate to the Medicare program. The United States has not intervened in this suit brought on its behalf, though it has supported Hutcheson as an amicus, both in the district court and on appeal.

Hutcheson and the United States argue that a claim is "false or fraudulent" under the FCA if it does not meet a material precondition of payment. They argue that compliance with the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b, is a precondition for Medicare reimbursement and thus that Blackstone, in providing the alleged kickbacks, caused the hospitals and physicians at issue in this suit to submit false or fraudulent claims. In making this

argument, Hutcheson and the United States invoke both the specific terms of provider agreements and hospital cost reports as well as elements of the broader statutory scheme. They argue, moreover, that the hospital and physician claims at issue in this suit were materially false or fraudulent because the alleged kickbacks would have been capable of influencing Medicare's decision whether to pay the claims had it been aware of them.¹

Blackstone argues that a claim can only be false or fraudulent under the FCA if it (1) misstates facts, (2) incorrectly certifies compliance with a statute or regulation, or (3) does not meet an express condition of payment stated in a statute or regulation. Blackstone argues that the claims at issue here do not meet any of these criteria. It argues that Hutcheson has neither alleged that the claims contain factual misstatements, nor identified an express certification or an express condition of payment from a statute or regulation that would disallow payment in light of the alleged kickbacks. Blackstone also argues that even if the claims were false or fraudulent, they were not materially false or fraudulent because the claims made by hospitals and the services provided by physicians were not influenced by kickbacks.

¹ Hutcheson and the United States also argue that violations of the AKS inherently render claims to federal healthcare programs materially false or fraudulent under the FCA. We need not reach this broader argument.

The district court held that Hutcheson's allegations did not state a claim under the FCA for purposes of Rule 12(b)(6).

United States ex rel. Hutcheson v. Blackstone Med., Inc., 694 F. Supp. 2d 48 (D. Mass. 2010). It held that the hospital claims were not false or fraudulent, and that while the doctor claims were false or fraudulent, those claims were not materially false or fraudulent. We reverse.

After reviewing the facts and the district court's analysis, we reject two purported limitations on FCA liability Blackstone advances, one of which was adopted by the district court and the other of which appears to draw support from the district court's opinion. First, we reject the argument that, in the absence of an express legal representation or factual misstatement, a claim can only be false or fraudulent if it fails to comply with a precondition of payment expressly stated in a statute or regulation. Second, we reject the argument that a submitting entity's representations about its own legal compliance cannot incorporate an implied representation concerning the behavior of non-submitting entities. These purported limitations do not appear in the text of the FCA and are inconsistent with our case law.

Having rejected these two purported limitations, we hold that Hutcheson's complaint, in alleging that the hospital and physician claims represented compliance with a material condition of payment that was not in fact met, states a claim under the FCA

that the hospital and physician claims for payment at issue in this case were materially false or fraudulent. It follows that Hutcheson has stated a claim that Blackstone knowingly caused the submission of materially false or fraudulent claims in violation of the FCA. In reaching this conclusion, we do not adopt the judicially created conceptual framework employed by the district court, nor do we adopt any categorical rules as to what counts as a materially false or fraudulent claim under the FCA.

I.

Hutcheson was employed by Blackstone as a Regional Manager from January 2004 until she was terminated in January 2006. She filed this qui tam action against Blackstone on September 29, 2006.² On November 21, 2008, more than two years later, the case was unsealed after the United States filed a notice stating that it would not intervene at that time because it was still investigating the claim.

At the time Hutcheson filed her complaint, the FCA imposed liability on any person who either "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," 31 U.S.C. § 3729(a)(1), or "knowingly makes, uses, or

² Originally, Philip Brown was also named as a relator in this suit. Brown worked as an independent distributor for Blackstone in 2004. The district court dismissed Brown for failure to satisfy the "original source" requirement of 31 U.S.C. § 3730(e)(4)(B), and that dismissal has not been appealed.

causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government," id. § 3729(a)(2). A person acts "knowingly" if he or she "(1) had actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." Id. § 3729(b). The FCA also stated that the term "knowingly" requires "no proof of specific intent to defraud." Id. The statute has since been amended, but we refer to the provisions in force at the time of filing.³

Hutcheson's complaint alleges that Blackstone paid kickbacks to doctors across the country so they would use its

³ In 2009, Congress passed the Fraud Enforcement Recovery Act (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which amended the FCA and re-designated § 3729(a)(1) as § 3729(a)(1)(A), § 3729(a)(2) as § 3729(a)(1)(B), and § 3729(b) as §§ 3729(b)(1)(A) & (B). Hutcheson's amended complaint cited to the re-designated FCA provisions. In dismissing Hutcheson's complaint, the district court did not address the application of FERA to the FCA.

Under the revised provisions, FCA liability attaches to any individual who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," id. § 3729(a)(1)(B). The amended § 3729(b) is identical to the prior version except for internal subdivisions.

We have recognized that § 3729(a)(1)(B), but not § 3729(a)(1)(A), was made retroactive to "all claims" under the FCA pending on or after June 7, 2008. United States ex rel. Loughren v. Unum, 613 F.3d 300, 306 n.7 (1st Cir. 2010) (quoting FERA § 4(f), 123 Stat. at 1625). We have not addressed the meaning of "claims" under FERA, and we need not do so here. Neither party argues that § 3729(a)(1)(B) is relevantly different from the earlier provision.

products in certain spinal surgeries. These kickbacks, Hutcheson alleges, included "monthly payments under sham consulting agreements; paid development projects; research grants; royalties; exorbitant and sometimes illicit entertainment expenses; high-end travel and accommodations; speaking engagements and seminars[;] and other illegal incentives." Hutcheson alleged that Blackstone's management supervised the kickback scheme and "knew that Medicare, Medicaid, and other federal program beneficiaries represent a significant percentage of spine-surgery patients," and that as a result of the kickbacks, doctors across the country had performed spinal surgeries on Medicare and Medicaid patients using Blackstone's devices.

Hutcheson argues that compliance with the AKS is a condition of receiving payment from federally-funded healthcare programs, including Medicare, Medicaid, and TRICARE. The AKS prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. § 1320a-7b(b). Hutcheson alleges that through its kickback scheme, Blackstone "knowingly cause[d]" healthcare providers to present "false or fraudulent" claims for payment to federal healthcare programs.⁴ The complaint focuses on the

⁴ Hutcheson has not distinguished between the requirements of 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(2). However, she appears to assert a violation under § 3729(a)(1). That sub-section

submission of claims to Medicare; it only summarily references the submission of claims to Medicaid and TRICARE, so we address these types of claims for payment no further.⁵

The complaint detailed the contents of two types of documents pertinent to the claims for Medicare reimbursement. Both hospitals and physicians must sign a Provider Agreement in order to establish eligibility to receive reimbursement from Medicare. This states:

I agree to abide by the Medicare laws, regulations and program instructions that apply to [me] . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

(Alterations in Complaint). Hospitals, but not doctors, must submit a Hospital Cost Report along with their claims for reimbursement. This states:

refers to the submission of false or fraudulent claims, while § 3729(a)(2) refers to statements that accompany false or fraudulent claims. We need not reach questions concerning the distinction between these provisions, which have not been asserted by either party.

⁵ As the district court held, Hutcheson's complaint "contains no allegations regarding certifications or requirements" for federal healthcare programs other than Medicare, "such as Medicaid and TRICARE." United States ex rel. Hutcheson v. Blackstone Med., Inc., 694 F. Supp. 2d 48, 65 (D. Mass. 2010).

Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report [were] provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

The signatory of the Hospital Cost Report must certify:

To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

The federal Centers for Medicare and Medicaid Services (CMS) standardizes these forms. Hutcheson argues that the forms establish that claims for Medicare reimbursement may only be paid if they comply with the AKS. Before the district court, Hutcheson also argued that Congress has independently made clear that compliance with the AKS is a precondition of Medicare payment.

Blackstone moved to dismiss the case,⁶ raising three arguments. First, it argued that the complaint was barred by the

⁶ Blackstone also moved to transfer the case on the ground that it was similar to a then-pending case against Blackstone in the Eastern District of Arkansas, United States ex rel. Thomas v. Bailey, No. 4:06CV465, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008). The district court rejected Blackstone's transfer motion.

FCA's first-to-file and public disclosure rules. See 31 U.S.C. § 3730(b)(5), (e)(4)(A). Second, it argued that the complaint failed to state a claim under the FCA for purposes of Rule 12(b)(6). Third, it argued that the complaint failed to meet the pleading standard for fraud under Rule 9(b).

The district court held that the case was not jurisdictionally barred by the FCA's first-to-file rule or public disclosure rule. As to the first-to-file rule, it held that under United States ex rel. Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13 (1st Cir. 2009), the action had sufficiently different facts from a previously filed case, United States ex rel. Thomas v. Bailey, No. 4:06CV465, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008), such that it was not barred. As to the public disclosure rule, it held that though Blackstone's alleged kickback scheme had been publicly disclosed in a complaint in another action, Berrios v. Blackstone Medical, Inc., No. 05-17339 (Brevard Co., Fla., filed May 16, 2005), Hutcheson's claims were not barred because she was an "original source" within the meaning of the FCA. See 31 U.S.C. § 3730(e)(4)(B).

On the merits, the district court dismissed Hutcheson's complaint for failure to state a claim under Rule 12(b)(6). Drawing on case law from beyond this circuit, the district court outlined a framework it thought appropriate to analyze claims under the FCA. It held that to state a claim under the FCA, a plaintiff

must allege that the defendant "(1) knowingly presented or caused to be presented, (2) a false claim, (3) to the United States government, (4) knowing its falsity, (5) which was material, (6) seeking payment from the federal treasury." Hutcheson, 694 F. Supp. 2d at 61. The district court's definition of "false," a shorthand for "false or fraudulent," and its definition of "material" are particularly relevant on appeal.

Although the FCA itself does not contain the following distinctions, the district court construed the statute such that a claim is "false or fraudulent" if it is either "factually false" or "legally false." A factually false claim, it held, is a claim "in which the goods or services provided are either incorrectly described, or make [a] claim for a good or service never provided." Id. at 62. A legally false claim, it held, is a claim in which "a party certifies compliance with a statute or regulation as a condition to government payment, but did not actually comply with the statute or regulation." Id.

The district court further construed the statute such that a claim can be legally false either "under an express certification theory" or "under an implied certification theory." Id. Under the express certification theory, a claim is false if it expressly certifies compliance with a statute or regulation yet fails to meet the requirements of that statute or regulation. Id. Under the implied certification theory, a claim is false when the

claimant makes no express certification of "compliance with a statute or regulation, but by submitting a claim for payment, implies that it has complied with any preconditions to payment" contained in statutes or regulations. *Id.* at 63, 66.

The district court also held that claims are "materially" false if they have "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property" from the government. *Id.* at 64 (quoting United States ex rel. Longhi v. Lithium Power Techs., Inc., 575 F.3d 458, 470 (5th Cir. 2009)) (internal quotation marks omitted). It held that "materiality is a separate element of a claim under the [FCA]" such that "analysis of whether the claim is false vel non ought not be based on the materiality of the false statement." *Id.* at 63.

Applying this framework, the district court held that Hutcheson's complaint failed to identify a claim that was materially false or fraudulent for purposes of the FCA.⁷ The district court divided its analysis between Hutcheson's allegations concerning claims filed by hospitals and her allegations concerning claims filed by physicians.

As to the hospital claims, the district court held that these claims were not false or fraudulent. It did not address the possibility that the claims were factually false. Under the

⁷ In light of this holding, it did not address whether Hutcheson had pled fraud with sufficient particularity under Rule 9(b).

express certification theory, the district court held that (1) the Hospital Cost Report was not specific enough to create an express certification of compliance with the AKS, and (2) although the Provider Agreement created such a certification, "as written, this certification is specific to the party seeking reimbursement." Id. at 66 & n.13. Under the implied certification theory, it held that the relevant statutes and regulations did not expressly condition Medicare payment on compliance with the AKS, and that a precondition to payment "cannot be hidden in an enrollment form." Id. at 66.

As to the physician claims, the district court held these claims were not materially false or fraudulent. The court held that doctors who, while receiving kickbacks, submitted claims to Medicare for surgeries utilizing Blackstone products, had submitted expressly false certifications of compliance with the AKS. Id. It also held that Hutcheson had sufficiently alleged that Blackstone "knowingly caused the submission of these false claims." Id. Nonetheless, the district court held that the claims were not materially false or fraudulent because they sought reimbursement for the physicians' services, not for their use of the Blackstone devices. Id. at 66-67. The court stated that because Hutcheson had not alleged that the kickbacks induced doctors to submit claims for "medically unnecessary surgeries," the misrepresentations had not influenced the government's payment decisions. Id.

II.

Hutcheson timely appealed and her appeal is supported by the United States. We review de novo the grant of a motion to dismiss under Rule 12(b)(6), accepting as true all well-pleaded facts, analyzing those facts in the light most hospitable to the plaintiff's theory, and drawing all reasonable inferences for the plaintiff. Gagliardi v. Sullivan, 513 F.3d 301, 305 (1st Cir. 2008). A suit will be dismissed if the complaint does not set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." Id. (quoting Centro Medico del Turabo, Inc. v. Feliciano de Melecio, 406 F.3d 1, 6 (1st Cir. 2005)) (internal quotation marks omitted).

This appeal concerns whether Hutcheson's complaint identified a false or fraudulent claim that is material within the meaning of the FCA.⁸ The parties agree that a claim is false or

⁸ Blackstone argues that the district court's dismissal may be affirmed on the independent grounds that (1) the suit is barred by the FCA's public disclosure provision and (2) Hutcheson has failed to adequately plead fraud under Rule 9(b). The district court rejected Blackstone's first argument and did not reach its second argument. We reject both of these arguments.

As to the first argument, it is clear that this action is not barred because Hutcheson was an "original source of the information" under 31 U.S.C. § 3730(e)(4). Blackstone's argument to the contrary primarily concerns whether allegations that either (1) pertained to the time when Hutcheson was not employed by Blackstone, or (2) were added to Hutcheson's amended complaint, thereby failed to meet the "original source" requirements under 31 U.S.C. § 3730(e)(4)(B). Even if those particular allegations are barred, and we do not decide the question, the other allegations

fraudulent if it contains factual misstatements on its face.⁹ They advance different theories as to when a claim is false or fraudulent due to a legal misrepresentation. Hutcheson argues that a claim is false or fraudulent due to legal misrepresentation if it fails to meet a "condition of payment" and there is a "material nexus" between the "wrongful conduct" and "the government's decision to expend funds." Blackstone argues that a claim is false or fraudulent due to legal misrepresentation if it (1) incorrectly certifies compliance with a statute or regulation or (2) fails to meet an express condition of payment stated in a statute or regulation.

We need not weigh the abstract merits of these competing theories. The two theories overlap in significant part: all claims that would be false or fraudulent under Blackstone's theory would

remain. As to these remaining allegations, Blackstone only argues that Hutcheson insufficiently alleged that she "provided the information to the Government before filing" as required by 31 U.S.C. § 3730(e)(4)(B). Hutcheson's complaint stated that she disclosed the allegations to the United States Attorneys' Office for the Middle District of Florida in the "Summer of 2006" "prior to filing." This is more than enough.

As to the second argument, Rule 9(b) is not a proper alternative ground for affirmance. The district court never considered this argument. It is up to the court in the first instance to weigh the adequacy of the complaint for purposes of Rule 9(b) and, if appropriate, to provide "an opportunity to correct [any] pleading deficiencies." United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 115 (1st Cir. 2010).

⁹ The parties describe this state of affairs differently. Hutcheson refers to it as "facial falsity," while Blackstone refers to it as "factual falsity." Both parties contrast this type of falsity with "legal falsity."

also be false or fraudulent under Hutcheson's, but not vice versa. The underlying legal dispute concerns two issues. First, the parties dispute whether a claim may be false or fraudulent for failure to meet an implied legal condition of payment that is found in a source other than a statute or regulation. Second, the parties dispute whether representations made by a submitting entity with respect to its own legal compliance may encompass a legal precondition of payment applicable to non-submitting entities.

III.

Before we turn to these two purely legal issues and the specific pleadings in Hutcheson's complaint, we comment briefly on the conceptual divisions the district court employed. The district court's analysis turned on distinctions between (1) factually false or fraudulent claims and legally false or fraudulent claims, as well as, (2) claims rendered legally false or fraudulent by an "express certification" and claims rendered legally false or fraudulent by an "implied certification." The parties dispute the value of these distinctions, but this dispute is an abstract one. We decline to employ the district court's categories here.

In adopting these two distinctions, the district court did draw on case law from some other circuit courts. In the context of the FCA's lengthy history, which dates back to its enactment during the Civil War, see United States v. Rivera, 55 F.3d 793, 709-10 (1st Cir. 1995), these judicially created formal

categories are of relatively recent vintage. They have not been adopted by the Supreme Court or this court.

The distinction between factually and legally false or fraudulent claims appears to derive from a 2001 decision of the Second Circuit. See Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001) (citing Robert Fabrikant & Glenn E. Solomon, Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry, 51 Ala. L. Rev. 105, 111-12 (1999)). The distinction between express and implied certification appears to have emerged in circuit case law in a series of decisions at roughly the same time. See Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 531-33 (10th Cir. 2000); United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786 n.8 (4th Cir. 1999)).

At least three circuits have since applied these two distinctions in concert. See United States ex rel. Kirk v. Schindler Elevator Corp., 601 F.3d 94, 113-14 (2d Cir. 2010), rev'd on other grounds, 131 S. Ct. 1885 (2011); United States ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1167-69 (10th Cir. 2010); United States ex rel. Quinn v. Omnicare Inc., 382 F.3d 432, 441 (3d Cir. 2004).¹⁰ None of these cases addressed the

¹⁰ Drawing on the opinion below, three district court decisions in this circuit have as well. See United States ex rel. Lisitza v. Johnson & Johnson, Nos. 07-10288-RGS & 05-11518-RGS,

possibility of imposing FCA liability on a defendant who had caused another entity to present a materially false or fraudulent claim for payment to the government.

Courts have created these categories in an effort to clarify how different behaviors can give rise to a false or fraudulent claim. Judicially-created categories sometimes can help carry out a statute's requirements, but they can also create artificial barriers that obscure and distort those requirements. The text of the FCA does not refer to "factually false" or "legally false" claims, nor does it refer to "express certification" or "implied certification." Indeed, it does not refer to "certification" at all. See United States ex rel. Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1172 (9th Cir. 2006) (refusing to give the term "certification" a "paramount and talismanic significance" in part because it does not appear in the text of the FCA). In light of this, and our view that these categories may do more to obscure than clarify the issues before us, we do not employ them here.

IV.

Two purely legal issues are raised on appeal concerning when implied misrepresentations and third-party actions can give

2011 WL 673925, at *10, (D. Mass. 2011); United States ex rel. Rost v. Pfizer, Inc., 736 F. Supp. 2d 367, 375-76 (D. Mass. 2010); United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123, 133 (D. Mass. 2010).

rise to a false or fraudulent claim under the FCA. The district court erroneously adopted a categorical rule with respect to the first of these issues, and appeared to reason within the confines of an erroneous categorical rule with respect to the second.

As to the first issue, the district court held that a claim can only be false or fraudulent for impliedly misrepresenting compliance with a legal condition of payment if that condition is found expressly stated in "the relevant statute or regulations." Hutcheson, 694 F. Supp. 2d at 63. As to the second, the district court held that because the CMS forms only made representations about the submitting entity and because Hutcheson identified no statute or regulation conditioning Medicare payment on AKS compliance, unlawful actions taken by a third party about which the hospital neither knew nor had reason to know could not render the hospital claims in this case false or fraudulent. Id. at 66.

Blackstone defends the categorical rule adopted by the district court in the first holding and advances a categorical rule to defend the second holding. Blackstone argues that (1) a claim can only be false or fraudulent due to an implied legal misrepresentation if it fails to comply with the express requirements of a statute or regulation, and (2) a certification that represents a submitting entity's compliance with certain legal requirements cannot incorporate an implied representation about the conduct of non-submitting entities. We reject both arguments.

A. Implied Conditions of Payment

The district court gave little explanation for its holding that a claim can only be impliedly false or fraudulent for non-compliance with a legal condition of payment if that condition is expressly stated in a statute or regulation. It stated that a claim for payment can be false if submission "implies that [the claim] has complied with any preconditions of payment." Hutcheson, 694 F. Supp. 2d at 62 (citing United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1218 (10th Cir. 2008); United States ex rel. Augustine v. Century Health Sys., Inc., 289 F.3d 409, 415 (6th Cir. 2002); Mikes 274 F.3d at 699). It then agreed with the Mikes decision that liability under the "implied theory" should be restricted "to compliance with expressly stated preconditions of payment found in the relevant statute or regulations." Id. (citing Mikes, 274 F.3d at 700). To be clear, the district court held both that implied conditions of payment can only be found in statutes and regulations, and that these sources must expressly state the obligation. We reject both requirements.

Blackstone defends this holding in two ways. First, it argues that this court should follow case law from beyond this circuit that it asserts applied this rule. In particular, Blackstone relies on the Second Circuit's decision in Mikes, 274 F.3d 687, the Ninth Circuit's decision in Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993 (9th Cir. 2010), and the Tenth

Circuit's decision in Conner, 543 F.3d 1211. Second, Blackstone argues that a rule contrary to the one adopted by the district court would yield broader FCA liability than Congress intended. It argues that such a rule would "encompass all violations of law or regulations" by parties that interact with entities that submit claims for government payment.

Both of these arguments fail. This court is not bound by the case law Blackstone cites, and the text of the FCA does not exhibit an intent to limit liability in this fashion.

Neither party argues that this court or the Supreme Court has expressly spoken to whether a precondition of payment must be explicitly stated in a statute or regulation to give rise to a false or fraudulent claim. Although Hutcheson has invoked the Supreme Court's decision in United States ex rel. Marcus v. Hess, 317 U.S. 537 (1943), and this court's decision in Murray & Sorenson v. United States, 207 F.2d 119 (1st Cir. 1953), she has not argued that these cases speak directly to the issue here. These decisions did not distinguish between factual and legal misrepresentations and so had no reason to address the precise source of the government's expectation that the claims at issue in those cases would be unaffected by collusion, see Hess, 317 U.S. at 544-45, and inside tips, see Murray & Sorenson, 207 F.2d at 123-24.

It is true that the Second Circuit held in Mikes 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." Mikes, 274 F.3d at 700 (first emphasis added). It is also true that the Ninth Circuit used similar, but not identical, language in Ebeid, holding that "[i]mplied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule, or regulation." Ebeid, 616 F.3d at 998; see also United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1267 (9th Cir. 1996) (stating, in more general terms, that "[m]ere regulatory violations do not give rise to a viable FCA violation").

Other courts, however, have found that a claim may be false or fraudulent due to an implied representation of compliance with a precondition of payment that is not expressly stated in a statute or regulation. The Tenth Circuit's decision in Conner, upon which Blackstone mistakenly relies, held that for purposes of "an implied false certification theory, . . . the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment." Conner, 543 F.3d at 1218 (emphasis added). The Tenth Circuit has found claims false or fraudulent because a defendant failed to comply with the terms of underlying contractual provisions. See Shaw, 213 F.3d at 531-32; see also Lemmon, 614 F.3d at 1170 (finding that a defendant's failure to comply with certain regulations whose requirements were incorporated into a

government contract rendered a claim false or fraudulent). The D.C. Circuit also recently held that non-compliance with contract terms may give rise to false or fraudulent claims, even if the contract does not specify that compliance with the contract term is a condition of payment. United States v. Sci. Applications Int'l Corp. (SAIC) 626 F.3d 1257, 1269 (D.C. Cir. 2010).

In SAIC, the court rejected the defendant's argument that legal preconditions of payment must be expressly designated as such to give rise to false or fraudulent claims. Id. at 1268. It held that "nothing in the statute's language specifically requires such a rule" and that adopting one could "foreclose FCA liability in situations that Congress intended to fall within the Act's scope." Id. In response to the defendant's argument that its holding would overextend liability under the FCA, the court stated that this concern does not call for "adopting a circumscribed view of what it means for a claim to be false or fraudulent," but rather calls for "strict enforcement of the Act's materiality and scienter requirements." Id. at 1270. We agree. Like the rule advanced by the defendant in SAIC, the rule advanced by Blackstone that only express statements in statutes and regulations can establish preconditions of payment is not set forth in the text of the FCA.

We are not persuaded, moreover, by the concerns that prompted the Second Circuit to adopt such a rule in Mikes, nor are we persuaded that the Second Circuit would extend that rule to

situations like the one before us.¹¹ The plaintiffs in Mikes alleged that Medicare claims submitted by the defendant health care providers were false or fraudulent because the underlying medical treatment had failed to meet a standard of care. Mikes, 274 F.3d at 696. The court reasoned that to find these claims false or fraudulent would allow the government and relators to supplant private plaintiffs in medical malpractice suits. Id. at 700. The risk of federalization of what have been private party tort actions is not a foregone conclusion of declining to adopt a rule that preconditions of payment must be expressly stated in a statute or regulation; nor is that risk sufficient to justify such a rule.

This is so because other means exist to cabin the breadth of the phrase "false or fraudulent" as used in the FCA. The text of the FCA and our case law make clear that liability cannot arise under the FCA unless a defendant acted knowingly and the claim's defect is material.¹² The knowledge requirement is expressly stated

¹¹ The Second Circuit has since applied the standard in Mikes outside the Medicare context. See United States ex rel. Kirk v. Schindler Elevator Corp., 601 F.3d 94, 115 (2d Cir. 2010), rev'd on other grounds, 131 S. Ct. 1885 (2011). In that decision, however, the court held that the submitted claim failed to comply with a precondition of payment expressly stated in a statute. We are unaware of any decision by the Second Circuit finding that a claim was not false or fraudulent where the claim failed to meet a material contract term. Cf. United States v. Sci. Applications Int'l Corp. (SAIC) 626 F.3d 1257, 1270 (D.C. Cir. 2010).

¹² The parties contest the proper place of this materiality requirement in the analysis under the FCA. Hucheson argues that a claim can only be legally false or fraudulent if the legal defect is material. Blackstone argues, in keeping with the district

in the statute and defined at 31 U.S.C. § 3729(b), and this court has "long held that the FCA is subject to a judicially-imposed requirement that the allegedly false claim or statement be material."¹³ United States ex rel. Loughren v. Unum Grp., 613 F.3d 300, 306-07 (1st Cir. 2010).

B. Non-Submitting Party Conduct

The district court appeared to employ the concept of certification such that a claim can be false or fraudulent only if the submitting entity knew or should have known of the underlying falsehood or fraudulence. Under the express certification theory, the district court held that the certifications in the Provider Agreement and Hospital Cost Report created "no obligation on the part of the signatory to determine whether the entire transaction complied" with the AKS. Hutcheson, 694 F. Supp. 2d at 66. After holding that the relevant statutes and regulations did not

court's opinion, that these are two separate inquiries, such that a claim can be false or fraudulent without being materially so. We decline to resolve this semantic dispute, which has no bearing on the outcome of this case. It is uncontested that only false or fraudulent claims that are materially false or fraudulent can give rise to liability under the FCA.

¹³ In Loughren, we noted that the Supreme Court had recently found a materiality requirement applicable to 31 U.S.C. § 3729(a)(2) & (a)(3). Loughren, 613 F.3d at 307 (citing Allison Engine Co., Inc. v. United States ex rel. Sanders, 128 S. Ct. 2123, 2126, 2130 (2008)). We held that this holding did not disturb "our previous reading of a materiality requirement into the statute more generally," id., and held as well that the FERA amendment to the FCA that incorporated an explicit materiality requirement into the former § 3729(a)(2) did not alter this conclusion, id. at 307 n.8.

establish AKS compliance as a precondition of Medicare payment, the district court concluded its analysis with the statement that "[t]he Amended Complaint contains no allegations that the hospitals themselves received kickbacks, or that they knew or should have known about the kickbacks received by the doctors." Id. at 66.

In its description of the concept of certification, the district court did not explicitly outline such a knowledge requirement for submitting entities. It stated, however, that a claim is legally false "where a party certifies compliance [expressly or impliedly] with a statute or regulation as a condition to government payment," but that party "did not actually comply with the statute or regulation." Id. at 62 (emphasis added) (citing Conner, 543 F.3d at 1217; Quinn, 382 F.3d at 440-41; Siewick, 214 F.3d at 1375-76; Harrison, 176 F.3d at 785-87; United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997); Hopper, 91 F.3d at 1265-66).

Building on this aspect of the district court's analysis, Blackstone argues that when a submitting entity expressly represents its own legal compliance, its representations cannot encompass a pre-condition of payment applicable to non-submitting entities. It again advances two arguments. First, it argues that "no court has held that a hospital's truthful certification" can be rendered false "by the acts of an unrelated third party somewhere in the supply chain." Second, it argues that if unlawful third-

party actions could render a claim false or fraudulent on account of a submitting entity's truthful certification, FCA liability would extend to any prohibited behavior "by participants in a marketplace that involves, at some point in a series of transactions, a government program," and thus beyond the scope intended by Congress.

The categorical limitation Blackstone advances does not appear in the text of the statute and is inconsistent with both the statutory text and binding case law. The FCA imposes liability on any person who "knowingly presents, or causes to be presented" to the government "a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1) (emphasis added), or "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," id. 3729(a)(2) (emphasis added). When the defendant in an FCA action is a non-submitting entity, the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid. The statute makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent.

To the extent that Blackstone seeks to locate its proposed limitation in the concept of certification, we repeat that the text of the FCA does not employ this concept. Blackstone cites

a Ninth Circuit decision for the proposition that "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false certification of compliance which creates liability" Hopper, 91 F.3d at 1266. Blackstone omits, however, that decision's qualification that this statement holds "when certification is a prerequisite to obtaining a government benefit." Id. At any rate, as the Ninth Circuit made clear in a later case, "because the word 'certification' does not appear in 31 U.S.C. § 3729(a)(1) or (a)(2), there is no sense in parsing it with the close attention typically attending an exercise in statutory interpretation. So long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach." Hendow, 461 F.3d at 1172.

The Supreme Court has long held that a non-submitting entity may be liable under the FCA for knowingly causing a submitting entity to submit a false or fraudulent claim, and it has not conditioned this liability on whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct. In Hess, 317 U.S. 537, the Court held that the language of the FCA "indicate[s] a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud." Id. at 544-45. The Court has since reaffirmed this aspect of Hess. More than thirty years later, in United

States v. Bornstein, 423 U.S. 303 (1976), it held a subcontractor liable under the FCA for causing a contractor to submit claims seeking payment for materials that, apparently unbeknownst to the contractor, were labeled incorrectly. Id. at 309-313.

This court has followed suit. In Murray & Sorenson, 207 F.2d 119, we held that the defendant had caused the submission of false or fraudulent claims because the government contract bids it relayed to a submitting entity had been secretly inflated in response to tips about the government's willingness to pay. Id. at 123-24. We have made clear that unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party. See Rivera, 55 F.3d at 710-12 (stating that a "false claim may be presented through an innocent third party" (citing Bornstein, 423 U.S. at 309)); see also Scolnick v. United States, 331 F.2d 598 (1st Cir. 1964) (holding a party liable under the FCA when it submitted a mistakenly issued government check to a bank and the bank submitted the check to the government).

These cases do not hold that a submitting entity's representations concerning its own conduct somehow immunize a non-submitting entity from liability under the "causes" clauses of the FCA. Nor does Blackstone cite any other decision from the Supreme court or this court that says that.

Blackstone attempts to distinguish the cases Hutcheson cites concerning third-party liability under the FCA as inapposite because they dealt with "factually false" rather than "legally false" claims. The decisions do not speak in terms of these newly created categories, which are not in the text of the FCA. Nor would Blackstone's effort to retroactively categorize these cases work even if we accepted its terms, which we do not.

While Bornstein, Rivera, and Scolnick arguably involve misrepresentations of a strictly factual nature,¹⁴ Hess and Murray & Sorenson involve misrepresentations related to a legal status. As we held in Murray & Sorenson, "in Hess there was an implied false representation that the bids were competitive, and in this case there was an implied false representation that the bids were at a figure which the corporate defendant would have submitted in competition instead of at a somewhat higher figure" due to the tip. Murray & Sorenson, 207 F.2d at 124. These claims did not misstate a fact; they implied that the defendants had not engaged in certain illicit behaviors that would disqualify them from payment. Neither decision identified a statute, regulation, or certification as the

¹⁴ This proposition is more contestable with respect to Scolnick than Bornstein and Rivera. The claim for payment at issue in Scolnick did not misrepresent a fact about the mistakenly issued government check. Rather, the claim implicitly represented that the check was valid and thus met the legal conditions of payment.

basis of the legal precondition of payment the respective defendants had failed to meet.¹⁵

None of the cases relied on by Blackstone and the district court, moreover, address when the actions of a non-submitting entity can give rise to a false or fraudulent claim. Each of these cases concerned whether claims submitted by the defendant, rather than claims a defendant caused a third party to submit, were false or fraudulent under the FCA. See, e.g., Conner, 543 F.3d 899 (claim submitted by defendant hospital); Quinn, 382 F.3d 432 (claim submitted by defendant pharmacies); Siewick, 214 F.3d 1372 (claim submitted by defendant corporation); Thompson, 125 F.3d 899 (claim submitted by defendant health care provider); Hopper, 91 F.3d 1261 (claim submitted by defendant school district). We cannot adopt Blackstone's categorical rule, which is at odds with the holdings of controlling decisions of both this court and the Supreme Court.

Blackstone cannot evade this conclusion by arguing that in the absence of the rule it proposes FCA liability will stretch

¹⁵ At oral argument, Blackstone introduced an additional argument that the claims in Hess and Murray & Sorenson were false because the submitting entity had "passed along" a false certification by the defendants, who had not submitted claims themselves. However, neither decision gave this rationale for finding the claims at issue false or fraudulent. Nor is it clear that this description fits the facts in either case; neither decision speaks in detail of the materials the defendants gave to the submitting entities.

too broadly to non-submitting entities.¹⁶ First, we cannot rewrite statutes. Second, the policy concerns are overblown. Only persons who knowingly submit or cause the submission of a false or fraudulent claim can be held liable for violating the FCA. The term "causes" is hardly boundless; it has been richly developed as a constraint in various areas of the law. See, e.g., W. Page Keeton et al., Prosser and Keeton on Torts § 41-44 (5th ed. 1984) (discussing causation in tort law). And contrary to Blackstone's argument, as the Supreme Court has held, in enacting the FCA "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" Cook Cnty., Illinois v. United States ex rel.

¹⁶ At oral argument, Blackstone raised a related argument that if claims that contain legal misrepresentations unbeknownst to the submitting entity could be false or fraudulent, submitting hospitals would be required to return these payments as "overpayments" under a provision of the new Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010). See 42 U.S.C. § 1320a-7k(d).

Blackstone and the United States dispute the extent to which enforcement of this requirement would be subject to the government's discretion. The United States contends that it may choose to pursue the architects of a kickback scheme rather than penalize innocent submitting hospitals. Blackstone argues that regardless of such a decision by the government, private relators can sue innocent submitting hospitals under the PPACA. See id. § 1320-7k(d) (3) (citing 31 U.S.C. § 3729(b)(3)).

This dispute is tangential to the question at hand, and we do not discuss it further. As Blackstone acknowledges, the Supreme Court has held that claims may be false or fraudulent even when the submitting entity was unaware of the underlying falsehood or fraudulence. This argument amounts to the assertion that these holdings only apply to so-called factually false claims and not to so-called legally false claims. As we have noted, the text of the FCA and the relevant case law makes no such distinction.

Chandler, 538 U.S. 119, 129 (2003) (quoting United States v. Neifert-White Co., 390 U.S. 228, 232 (1968)).

v.

Having rejected Blackstone's efforts to narrow the text of the statute and thereby justify dismissal of the case, we turn to the question of whether Hutcheson's complaint identified a materially false or fraudulent claim. Hutcheson and Blackstone disagree as to whether the language and legislative history of the AKS, as well as a recent amendment to the statute in the Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), establish that AKS compliance is, without more, a precondition of Medicare payment.¹⁷ We need not address this dispute, as we hold that the Provider Agreement and Hospital Cost Report forms identified in Hutcheson's complaint are sufficient to support her claim.

As we explain below, the claims presented to the government in this case, as alleged, represented that there had been compliance with a material precondition of payment that had not been met. We do not categorize this representation as one of law or fact, nor do we categorize it as either express or implied. We also do not address whether this representation constituted a

¹⁷ The amendment in question states that a "claim that includes items or services resulting from a violation of" the AKS "constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g).

"certification" within the meaning of case law from beyond this circuit. These formal categories, as we have discussed, are nowhere mentioned in the statute. We first address whether the claims at issue here misrepresented compliance with a precondition of payment so as to be false or fraudulent and then address whether those misrepresentations were material.

A. Misrepresentation

Hutcheson argues that the Provider Agreement and Hospital Cost Report forms make clear that compliance with the AKS is a precondition of Medicare payment. In addition to raising the categorical arguments rejected above, Blackstone argues that the Provider Agreement and Hospital Cost Report forms did not identify this precondition with sufficient specificity to render the claims at issue in this case false or fraudulent. As to the hospital claims, Blackstone argues that these forms did not create an express or implied representation that anyone other than the submitting hospital had complied with the AKS. As to the physician claims, Blackstone argues that while the Provider Agreement represented physician compliance with the AKS, this representation only extended to claims that would not have been made in the absence of kickbacks.

The Provider Agreement, drafted by CMS, requires that hospitals and physicians acknowledge that they "understand that payment of a claim by Medicare is conditioned upon the claim and

the underlying transaction complying with [Medicare's] laws, regulations and programs instruction." (Emphasis added.) The Agreement specifically identifies "the Federal anti-kickback statute" as one of only two enumerated examples of the relevant "laws, regulations, and program instructions." This language makes clear that the federal Medicare program will not pay claims if the underlying transaction that gave rise to the claim violated the AKS. The Agreement makes no exception for instances in which that "underlying transaction" violated the AKS because of the actions of a third party like Blackstone.

The Hospital Cost Report, also drafted by CMS, further underscores that hospitals submitting claims represent compliance with the AKS. The form states that "if services identified in this report [were] provided or procured through the payment directly or indirectly of a kickback . . . fines and/or imprisonment may result." It also requires that the hospital's representative sign a statement certifying that he or she is "familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations."¹⁸ This makes it abundantly clear that AKS compliance is a precondition of Medicare

¹⁸ Blackstone focuses on the first sentence of this certification, which is qualified by the phrase, "[t]o the best of my knowledge." The second statement, however, is accompanied by no such qualification.

payment and makes no exceptions for violations caused by third parties like Blackstone.

These two documents are more than specific enough to make clear that the claims submitted by hospitals represented that any underlying transactions had not involved third party kickbacks prohibited by the AKS. Blackstone advances a formalistic reading of the documents to avoid the conclusion that these forms recognize this precondition of Medicare payment. It also seeks to divert attention from this clear language by focusing on whether the hospitals knew of the underlying kickbacks, a fact that has no bearing on Blackstone's potential liability under the FCA. The reading Blackstone proposes would not only strain the language of the documents; it would systematically excuse from FCA liability non-submitting entities who cause the submission of claims that fail to meet that stated precondition.

The Provider Agreement is also sufficiently clear to establish that the claims submitted by physicians represented that the underlying transactions did not involve kickbacks to physicians prohibited by the AKS. The physicians agreed that payment from Medicare is conditioned on compliance with the AKS, yet allegedly accepted kickbacks in violation of the AKS. Blackstone argues that the physician claims nonetheless were not false or fraudulent because the claims were for services that would have been provided in the absence of the alleged AKS violations. This argument does

not address the complaint's allegation that under the express terms of the Agreement, the "underlying transaction" violated the AKS and therefore that the resulting claims were ineligible for payment.¹⁹ Instead, it addresses whether these claims were materially false or fraudulent, which we address separately.

These allegations of misrepresentation, we hold, are sufficient to state a claim that the hospital and physician claims for payment at issue here were false or fraudulent. This holding is consistent with those of other courts that have found claims false or fraudulent for non-compliance with a contract term. See SAIC, 626 F.3d at 1269; Shaw, 213 F.3d at 531-32; see also Lemmon, 614 F.3d at 1170. To be clear, we are not creating a rule that non-compliance with a contractual condition is any more necessary to establish that a claim is false or fraudulent than non-compliance with an express statute or regulation, or an express misrepresentation on a form submitted with payment. We now turn to the question of whether the claims in this case failed to comply with a material condition of payment for purposes of the FCA.

B. Materiality

¹⁹ Blackstone argues that "a hospital's purchase of a device used in an inpatient surgical procedure is not a transaction that underlies or is a part of the physician's request for payment for physician services." This argument, however, does not address whether a physician's receipt of kickbacks is a transaction underlying that physician's provision of services associated with the products involved in the kickback scheme.

Blackstone makes two arguments that the hospital and physician misrepresentations were not material. As to the hospital claims, Blackstone argues that a payment mechanism rendered any AKS non-compliance irrelevant to the payment of claims. Hospitals, it argues, classify patients within "diagnosis-related groups" (DRGs) and receive a set payment for treating patients in a group regardless of the particular services provided.²⁰ As to the physician claims, Blackstone reiterates the argument it advanced that these claims did not misrepresent AKS compliance. It argues that the physicians submitted claims for their services conducting medically necessary surgeries, not for the devices allegedly used because of Blackstone's kickbacks.

In Loughren, this court held that a false statement is material if it has "a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed." Loughren, 613 F.3d at 307 (alteration in original) (quoting Neder v. United States, 527 U.S. 1, 16 (1999)) (internal quotation marks omitted). Although Loughren was decided after the district court's decision, this standard is not

²⁰ Blackstone has not expressly cast this argument as one concerned with materiality. Rather, it has argued that a claim related to a "diagnosis-related group" cannot be false or fraudulent because the claim does not address the particular services used in the treatment of a patient. To the extent this argument concerns whether a sufficiently specific misrepresentation occurred, we reject it for the same reasons we rejected Blackstone's other arguments concerning the specificity of hospital misrepresentations.

relevantly different from the one the district court employed. See Hutcheson, 694 F. Supp. 2d at 64. Express contractual language may "constitute dispositive evidence of materiality," but materiality may be established in other ways, "such as through testimony demonstrating that both parties to the contract understood that payment was conditional on compliance with the requirement at issue." SAIC, 626 F.3d at 1269.

We cannot say that, as a matter of law, the alleged misrepresentations in the hospital and physician claims were not capable of influencing Medicare's decision to pay the claims. See Ocasio-Hernández v. Fortuño-Burset, No. 09-2207, 2011 WL 1228768, at *14 (1st Cir. Apr. 1, 2011) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 554, 556 (2007)). The intricacies of the DRG system do not alter the clear language of the Provider Agreement and the Hospital Cost Report forms. Nor does the fact that the physician claims sought payment for services rather than devices somehow render the fact that the physicians accepted kickbacks irrelevant under the language of the Provider Agreement.

If kickbacks affected the transaction underlying a claim, as Huteson alleges, the claim failed to meet a condition of payment. Blackstone's argument that Medicare would excuse these violations because of a bureaucratic mechanism or because of an implicit medical necessity requirement impermissibly cabins what the government may consider material. Neither the Provider

Agreement nor the Hospital Cost Report forms speak of such exceptions recognized by Medicare. We find Hutcheson's allegations sufficient to show, for purposes of this motion to dismiss, that the kickbacks were capable of influencing Medicare's decision as to whether to pay the hospital and physician claims.

VI.

For the foregoing reasons, we reverse the district court's dismissal of Hutcheson's complaint under Rule 12(b) (6) for failing to identify a materially false or fraudulent claim within the meaning of the FCA, and we remand for further proceedings consistent with this opinion.

So ordered.