

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 10-2747

UNITED STATES EX REL. CHARLES WILKINS;
DARYL WILLIS,

Appellants

v.

UNITED HEALTH GROUP, INCORPORATED;
AMERICHoice;
AMERICHoice OF NEW JERSEY, INC.

On Appeal from the United States District Court
for the District of New Jersey
(D.C. Civ. No. 1-08-cv-03425)
Honorable Robert B. Kugler, District Judge

Argued March 24, 2011

BEFORE: FUENTES, SMITH, and GREENBERG,
Circuit Judges

(Filed: June 30, 2011)

Ross Begelman, Esq. (argued)
Marc M. Orlow, Esq.
Begelman, Orlow & Melletz
411 Route 70 East, Suite 245
Cherry Hill, NJ 08034

Attorneys for appellants

Michael C. Theis, Esq. (argued)
Jaasi J. Munanka, Esq.
Hogan Lovells US
1200 Seventeenth Street, Suite 1500
Denver, CO 80202

William P. Deni, Jr., Esq.
Bruce A. Levy, Esq.
Ellen Lubensky, Esq.
Gibbons
One Gateway Center
Newark, NJ 07102-5310

Attorneys for appellees

Tony West , Esq.
Assistant Attorney General
Paul J. Fishman, Esq.
United States Attorney

Douglas N. Letter, Esq.
Teal Luthy Miller, Esq. (argued)
Attorneys, Appellate Staff
Civil Division, Room 7234
U.S. Department of Justice
950 Pennsylvania Ave., N.W.,
Washington, DC 20530-0001

Attorneys for amicus curiae United States

OPINION OF THE COURT

GREENBERG, Circuit Judge.

I. INTRODUCTION

This matter comes on before this Court on an appeal from an order the District Court entered on May 13, 2010, granting the motion of appellees United Health Group, AmeriChoice, and AmeriChoice-New Jersey (collectively “appellees”) under Federal Rule of Civil Procedure 12(b)(6) to dismiss Charles Wilkins’ and Daryl Willis’ (collectively “appellants”) qui tam action¹ based on the False Claims Act (“FCA”), 31 U.S.C. §

¹ Private individuals can bring qui tam actions on behalf of the Government in exchange for their right to retain some portion of any resulting damages award. See Schindler Elevator Corp. v. U.S. ex rel. Kirk, 131 S.Ct. 1885, 1889 (2011); Vt. Agency of

3729, for failure to state a claim on which relief may be granted. Appellants have alleged that appellees, through their participation in federally funded health insurance programs, certified that they were in compliance with all healthcare laws and regulations even though they knowingly violated several Medicare marketing regulations, resulting in their submission of false claims for payment to the federal government. Appellants further alleged that AmeriChoice-NJ violated the FCA by illegally providing kickbacks in violation of the Medicare Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b, to a New Jersey medical clinic to induce the clinic to switch its patients to AmeriChoice-NJ’s Medicare and Medicaid programs. Moreover, appellants have alleged that AmeriChoice-NJ agents violated the AKS by enticing doctors to provide the names of patients eligible for Medicare and Medicaid programs. Thus, this action involves two distinct types of claims with which we will deal separately.

In addition to involving two distinct types of claims, the action implicates the two medical programs to which we already have referred, Medicare, a federally subsidized health insurance program for the elderly and certain disabled persons, see 42 U.S.C. § 1395c and d, and Medicaid, a cooperative federal-state public assistance program pursuant to which the federal government makes matching funds available to pay for certain medical services furnished to needy individuals, see 42 U.S.C. § 1396. Some elderly poor are “dual eligible” under both

Natural Res. v. U.S. ex rel. Stevens, 529 U.S. 765, 769-70, 120 S.Ct. 1858, 1860-61 (2000).

programs.² Though appellants mention both programs in their complaint, this case is essentially a Medicare case arising, as the District Court indicated at the outset of its opinion, “out of alleged fraudulent claims to Medicare.” United States ex rel. Wilkins v. United Health Group, Inc., Civ. No. 08-3425, 2010 U.S. Dist. LEXIS 47080, at *1 (D.N.J. May 13, 2010) (“Wilkins”).

The District Court held that appellants’ allegations failed to state a plausible claim for relief under the FCA for two reasons: (1) appellants failed to identify a single false claim that appellees submitted to the Government, and (2) the marketing regulations that appellants claimed appellees violated were not relevant to the Government’s decision to pay appellees’ Medicare claims. In addition, the Court dismissed appellants’ AKS claims because they did not include an allegation that appellees certified that they were in compliance with the AKS or that such compliance was a relevant consideration when the Government processed their Medicare claims. Inasmuch as we agree with the Court’s disposition of appellants’ Medicare marketing regulations claims but disagree with its holding with respect to appellants’ AKS claims, we partially will affirm and

² Appellants state in their brief that dual eligible individuals receive their prescription drug coverage from Medicaid, but amicus curiae United States seems to describe Medicaid’s responsibility more broadly with respect to dual eligible individuals. We are not concerned, however, with the division between Medicare and Medicaid of responsibility for benefits for dual eligible individuals on this appeal and thus will not address that point.

partially will reverse the Court's May 13, 2010 order and we will remand the case to the District Court for further proceedings.

II. FACTS AND PROCEDURAL HISTORY

In view of the procedural posture of this case, we set forth the facts as appellants have alleged them, and decide the appeal on the basis of those allegations and, in doing so, will construe the complaint in the light most favorable to appellants. See Lexington Nat. Ins. Corp. v. Ranger Ins. Co., 326 F.3d 416, 417 (3d Cir. 2003).

United Health provides access to health care services and resources and AmeriChoice and AmeriChoice-NJ are United Health subsidiaries offering Medicare Advantage ("MA") plans.³ Under MA plans, AmeriChoice and AmeriChoice-NJ provide individuals enrolled in Medicare with health care

³ Medicare Advantage, otherwise known as Medicare "Part C," authorizes qualified individuals to opt out of traditional fee-for-service coverage under Medicare Parts A and B and enroll in privately-run managed care plans that provide coverage for both inpatient and outpatient services. 42 U.S.C. §§ 1395w-21, 1395w-28. United Health also offers qualified individuals coverage under Medicare Part D which is a voluntary prescription drug benefit program. See 42 U.S.C. § 1395w-101 et seq.

services and submit claims to the Government for reimbursement based on the number of patients enrolled in their Medicare programs.⁴ Organizations which provide services under Medicare do so pursuant to contracts with the Centers for Medicare and Medicaid Services (“CMS”), a division of the Department of Health and Human Services charged with administering the Medicare and Medicaid programs. See 42 C.F.R. § 422.503(a). Each month, as participants offering MA plans, appellees certify to CMS that they continue to comply with all of the CMS MA guidelines including MA marketing regulations and the AKS.

Wilkins and Willis began employment with United Health Group and AmeriChoice in 2007, Willis as a general manager for Medicare/Medicaid marketing and sales and Wilkins as a sales representative. In April 2008, United Health terminated Wilkins’ employment in reaction to his complaints concerning what he perceived were United Health’s illegal practices which are the basis for this action. Similarly, at some point during 2008, United Health, after demoting Willis for his conduct in making complaints to his supervisors about what he perceived were United Health’s illegal practices, went further

⁴ The Government pays MA plan participants a set amount of money based on the plans’ enrollees’ risk factors and other characteristics rather than paying them a fee for specific services performed. See 42 C.F.R. §§ 422.300 et seq. CMS makes advance monthly payments to participants calculated on the number of enrollees, adjusted to reflect risk and variations in rates within the plan’s service area. See 42 C.F.R. §§ 422.304, 423.315.

and terminated his employment.

On July 10, 2008, appellants filed this qui tam action under seal in the District Court alleging that appellees' sales representatives violated the FCA by offering physicians illegal kickbacks and violating MA marketing rules while accepting payments from government funded health insurance programs. Specifically, appellants alleged that: (1) United Health used marketing flyers that CMS did not approve beforehand; (2) its licensed sales agents engaged in marketing activities in the waiting rooms of clinics and doctors' offices; (3) non-licensed individuals engaged in marketing activities; (4) United Health commonly used an excessive number of sales representatives at presentations in an attempt to "overwhelm the public;" (5) sales representatives asked persons to raise their hands at presentations if they were eligible for both Medicare and Medicaid; (6) marketing personnel chased people in supermarkets to ask them whether they were dual eligible; (7) United Health used brokers to engage in door-to-door solicitation; (8) United Health sales agents gave out prizes at Medicare presentations in excess of \$15 in value contrary to CMS guidelines; (9) AmeriChoice's sales representatives paid \$27,000 to a medical clinic, Reliance Medical Group, to switch certain eligible beneficiaries to its Medicare and Medicaid plans; (10) United Health's sales representatives offered payments to physicians in exchange for the physicians providing appellees with the names of potential new enrollees eligible for Medicare and Medicaid; (11) United Health failed to maintain and

implement a compliance program.⁵ App. at 39-46.

After appellants filed this action the Government investigated their claims, and, during the investigation, in accordance with the FCA's requirements the case remained under seal. On May 26, 2009, after the Government finished its investigation, it notified the parties that it would not intervene in the case. See 31 U.S.C. § 3730(b)(4)(B).⁶ On August 5, 2009, appellants filed an amended complaint which pleaded an FCA claim predicated on the allegations we discuss above and nine claims based on violations of state law.⁷ Notwithstanding the seeming specificity of appellants' complaint, they do not identify any specific claim for payment that United Health made

⁵ Even though this last claim appears to be separate from appellants' claims based on marketing violations and illegal kickback payments, appellants do not make any separate arguments based on appellees' failure to maintain a compliance program.

⁶ The Government did not move to dismiss the action, as it could have done under 31 U.S.C. § 3730(c)(2)(A).

⁷ The state law claims alleged that appellees' actions violated state false claims act provisions of New Jersey, Florida, Indiana, Michigan, Tennessee, Texas, and New York law. In addition, Wilkins and Willis individually alleged that appellees violated the New Jersey Conscientious Employee Protection Act, N.J. Stat. Ann. § 34:19-1 et seq. (West 2000). These state law allegations are not at issue in this appeal.

to the federal Government in violation of the FCA. The complaint, however, does allege that CMS makes advanced monthly payments to United Health for each enrollee in its plans and that United Health certifies each month its “continued compliance with all of the CMS [Medicare Advantage] Guidelines and based on such certification, United Defendants continues [sic] to receive the monthly capitation payment.” Am. Compl. at 10.⁸ Thus appellants contend that appellees, by submitting claims for payment to CMS while failing to comply with the Medicare laws and regulations, including the AKS, presented false claims to the Government in violation of the FCA.

After the Government declined to intervene, appellees moved to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief could be granted and Federal Rule of Civil Procedure 9(b) for failure to plead fraud with particularity.⁹ The District Court granted appellees’ motion for failure to state a claim and therefore did not address appellees’ alternative argument for dismissal that appellants failed to plead their claims with the

⁸ The parties have included the original complaint but not the amended complaint in their joint appendix. We, however, have examined both versions of the complaint, and have considered both in our disposition of this appeal.

⁹ We have held that plaintiffs must plead FCA claims with particularity in accordance with Rule 9(b). See U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., 149 F.3d 227, 234 (3d Cir. 1998).

particularity that Rule 9(b) requires. The Court dismissed the complaint because appellants did not identify “even a single claim for payment to the Government.” Wilkins, 2010 U.S. Dist. LEXIS 47080, at *13. Moreover, the Court held that United Health’s failure to comply with marketing guidelines and regulations that were not relevant to the Government’s decision to issue payment could not be the basis for a recovery for an FCA violation. The Court also rejected appellants’ FCA claims that they based on violations of the AKS, finding that appellants failed to allege that United Health certified compliance with the AKS and also failed to allege that the Government predicated its funding decisions on such a certification. Finally, the Court declined to exercise supplemental jurisdiction over appellants’ state law claims and denied appellants’ request for leave to amend the complaint.

Appellants filed a timely notice of appeal from the District Court’s May 13, 2010 order, challenging the Court’s decision granting appellees’ motion to dismiss and arguing that, in any event, when the Court determined that it would dismiss the complaint it should have done so without prejudice and/or allowed appellants to amend their complaint. The Government, though declining to intervene in the District Court and expressing no opinion on the merits of appellants’ claims, has filed an amicus curiae brief urging us to reverse the District Court’s order to the extent that the Court concluded that an FCA claim cannot survive if the plaintiff does not identify a specific false claim that a defendant submitted for payment and that appellants’ kickback allegations did not state a claim for relief under the FCA.

III. JURISDICTION AND STANDARD OF REVIEW

The District Court had jurisdiction over appellants' FCA claims under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331 and supplemental jurisdiction over appellants' state law claims under 28 U.S.C. § 1367. We have jurisdiction to review the District Court's final order under 28 U.S.C. § 1291.

We exercise plenary review of the District Court's order granting appellees' motion to dismiss for failure to state a claim. See Allen ex rel. Martin v. LaSalle Bank, N.A., 629 F.3d 364, 367 (3d Cir. 2011). As we have indicated, we accept all factual allegations in the complaint as true, construe the complaint in the light most favorable to appellants, and determine whether, under any reasonable reading of the amended complaint, appellants may be entitled to relief. Id. In this determination "[t]he issue is not whether [appellants] will ultimately prevail but whether [they are] entitled to offer evidence to support the claims." See Maio v. Aetna, Inc., 221 F.3d 472, 482 (3d Cir. 2000) (citations and internal quotation marks omitted). We review the District Court's decisions to dismiss the complaint with prejudice and deny appellants' request for leave to amend their complaint for an abuse of discretion. See In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1332 (3d Cir. 2002); Lake v. Arnold, 232 F.3d 360, 373 (3d Cir. 2000).

IV. DISCUSSION

A. The Record on Appeal

Before we discuss the merits of appellants' claims we address a dispute between the parties concerning whether we should consider certain exhibits that appellants have included in the appendix. Though ordinarily the parties on an appeal do not have a dispute over what documents should be in the record, in this case we address this question because appellants have included two documents in the joint appendix, without our leave, that neither party filed in the District Court and that the Court therefore did not consider, i.e., the February 13, 2008 testimony of Kerry Weems, Acting Administrator for CMS, before the Senate Finance Committee on "Selling to Seniors: The Need for Accountability and Oversight of Marketing by Medicare Private Plans, Part 2" and a December 2009 report the United States Government Accountability Office authored on Medicare marketing. See addendum to app. at 1-58. Appellants contend that we should consider these materials as they are a matter of "public record" which "are inextricably intertwined and connected to items that are part of the record" Appellant's br. at 12-13.

Though we do not doubt the authenticity of these documents, nevertheless we will not consider them because the parties did not present them to the District Court and we do not find any indication in the record that the Court considered them on its own initiative. See Fed. R. App. P. 10(a) (stating that record on appeal is composed of original papers and exhibits filed in district court, transcript of proceedings, if any, and a certified copy of docket entries prepared by district court clerk); Fed. R. App. P. 30 (limiting contents of a party's appendix to record before district court). While we recognize that there might be "exceptional circumstances" which could justify our

consideration of these materials even though they were not presented to the District Court, we discern no such circumstances on the appeal. See Acumed LLC v. Advanced Surgical Servs., Inc., 561 F.3d 199, 226 (3d Cir. 2009).

We recognize that appellants argue that we should take judicial notice of the two documents as they are part of the “public record.” Appellant’s reply br. at 2. Although a court of appeals may take judicial notice of a matter of public record not presented to the district court when reviewing the disposition of a motion to dismiss under Rule 12(b)(6), see, e.g., Papasan v. Allain, 478 U.S. 265, 268 n.1, 106 S.Ct. 2932, 2935 n.1 (1986), we think that ordinarily a court of appeals should not take judicial notice of documents on an appeal which were available before the district court decided the case but nevertheless were not tendered to that court, the precise situation here.¹⁰ See Zell v. Jacoby-Bender, Inc., 542 F.2d 34, 38 (7th Cir. 1976) (refusing to take judicial notice of documents filed in companion case to undermine trial court’s findings where to do so would violate rule that appellate court must consider only record before trial court). Therefore, we will make our analysis by considering only the record that the parties made in the District Court for that Court’s consideration of appellees’ motion to dismiss.¹¹

¹⁰ Weems testified before appellants filed this action and the Accountability Office submitted the December 2009 report after appellants filed the action but before the District Court decided the case.

¹¹ We add, however, that even if we expanded the record to

B. The False Claims Act

1. FERA Amendments

At this early point in our discussion we consider a recent amendment to the FCA. On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which amended the FCA and re-designated 31 U.S.C. § 3729(a)(1) as 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(2) as 31 U.S.C. § 3729(a)(1)(B). The pre-FERA version of the FCA, imposed liability on:

[A]ny person who—

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

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

31 U.S.C. § 3729(a)(1)-(2).

include the two documents our result on this appeal would not be different.

The FCA as FERA has amended it, now imposes liability on:

[A]ny person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. § 3729(a)(1).

The FCA defines “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4). For purposes of this case both versions of the FCA define a claim in pertinent part as a “request or demand . . . for money or property that . . . is presented to an officer, employee, or agent of the United States . . .” 31 U.S.C. § 3729(c) (pre-FERA); 31 U.S.C. § 3729(b)(2)(A)(i) (post-FERA). FERA contains a retroactivity provision which applies only to section 3729(a)(1)(B), and provides that that clause “take[s] effect as if enacted on June 7, 2008, and appl[ies] to all claims under [the FCA] that are pending on or after that date.”¹² Pub. L. No. 111-21 § 4(f)(1),

¹² Congress adopted the term “material to,” as well as the retroactivity provision, in response to the Supreme Court’s June 9, 2008 decision in Allison Engine Co. v. U.S. ex rel. Sanders,

123 Stat. at 1625.

Though appellants filed their complaint on July 10, 2008, and their amended complaint on August 5, 2009, they cited to the pre-FERA version of the FCA in both their original and amended complaints. Nevertheless, appellants argued in the District Court that the addition of “material to” in section 3729(a)(1)(B) made it easier to state a claim under the FCA inasmuch as, under the amended version of the FCA, a relator only need show that compliance with the applicable regulations which the defendant allegedly violated would have a tendency to influence the Government’s payment decision. The Court, though assuming that the amendment applied in this case, held that Congress’ addition of a materiality requirement did not change the meaning of the FCA. Appellants do not contend that the Court erred in this conclusion but they do argue that the

553 U.S. 662, 128 S.Ct. 2123 (2008), which Congress viewed the Court as having decided incorrectly. See S. Rep. No. 111-10, at 11 (2009), reprinted in 2009 U.S.C.C.A.N. 430, 437-39 (“To correct the Allison Engine decision . . . in section 3729(a)(2) the words ‘to get’ were removed striking the language the Supreme Court found created an intent requirement for false claims liability under that section. In place of this language, the Committee inserted the words ‘material to’ a false or fraudulent claim.”). In Allison Engine, the Supreme Court held that a plaintiff “must prove that the defendant intended that the false record or statement be material to the Government’s decision to pay or approve the false claim.” 553 U.S. at 665, 128 S.Ct. at 2126.

original complaint “clearly alleged a time period were [sic] claims would be pending on June 7, 2008.” Appellants’ br. at 16 n.17. Appellees argue that the majority of courts considering the applicability of the retroactivity provision have determined that the retroactivity provision does not apply to cases which were pending on June 7, 2008.¹³ Appellees’ br. at 9 n.6 (citing Hopper v. Solvay Pharm., Inc., 588 F.3d 1318, 1327 n.3 (11th Cir. 2009)).¹⁴

We need not decide whether the earlier or amended version of the FCA is applicable because we conclude that appellants’ claims based on appellees’ alleged violation of the Medicare marketing regulations cannot survive appellees’ motion to dismiss under either version of the statute. Moreover, as we explain later, appellants’ claims under the AKS fall only under pre-FERA section 3729(a)(1), which was still in force at the time that appellees submitted their claims for payment to the Government and at the time that appellants filed this suit. Therefore, we will decide this case under the pre-FERA version of section 3729(a)(1).

¹³ This is a puzzling argument inasmuch as this case was not pending on June 7, 2008.

¹⁴ At least one district court has held that FERA’s retroactivity provision violates the Ex Post Facto Clause of the United States Constitution. See U.S. ex rel. Sanders v. Allison Engine Co., 667 F. Supp. 2d 747, 756 (S.D. Ohio 2009). Clearly, we need not consider that possibility.

2. Establishing a Claim Under the FCA

The primary purpose of the FCA “is to indemnify the government-through its restitutionary penalty provisions-against losses caused by a defendant’s fraud.” Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001) (citing U.S. ex rel. Marcus v. Hess, 317 U.S. 537, 549, 551-52, 63 S.Ct. 379, 388 (1943)). A plaintiff, in order to establish a prima facie FCA violation under section 3729(a)(1), must prove that “(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.” U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004) (internal quotation marks omitted); Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 182 (3d Cir. 2001). As we have indicated, a private individual, otherwise known as a relator, may bring a civil action in the name of the United States to enforce this provision of the FCA and may share a percentage of any recovery resulting from the suit. 31 U.S.C. § 3730(b) & (d).

There are two categories of false claims under the FCA: a factually false claim and a legally false claim. U.S. ex rel. Conner v. Salina Reg’l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008). A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment. Id. A legally false FCA claim is based on a “false certification” theory of liability. See Rodriguez v.

Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir. 2008), overruled in part on other grounds by U.S. ex rel. Eisenstein v. City of New York, 129 S.Ct. 2230 (2009). On this appeal, we are concerned only with allegedly legally false claims related to appellees' eligibility to receive payment, as appellants do not contend that appellees did not deliver the services for which they sought payment.

There is a further division of categories of claims as the courts have recognized that there are two types of false certifications, express and implied. See, e.g., Conner, 543 F.3d at 1217. Under the "express false certification" theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds. Rodriguez, 552 F.3d at 303. There is a more expansive version of the express false certification theory called "implied false certification" liability which attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment. Id. Thus, an implied false certification theory of liability is 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." Mikes, 274 F.3d at 699; see also United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010) ("Courts infer implied certifications from silence where certification was a prerequisite to the government action sought." (internal quotation marks and citation omitted)).

The United States Court of Federal Claims seems to have

been the first court to recognize that there can be implied false certification liability under the FCA. See Ab-Tech Constr., Inc. v. United States, 31 Fed. Cl. 429 (Fed. Cl. 1994), aff'd, 57 F.3d 1084 (Fed. Cir. 1995). In Ab-Tech the court held that Ab-Tech's submission of payment vouchers to the Government impliedly certified that Ab-Tech was continuing to adhere to the eligibility requirements of a federal small business program in which it was a participant. Id. at 433-34. Though the vouchers did not contain any express misrepresentations, Ab-Tech's failure to honor the requirements of the program rendered it subject to false certification liability under the FCA. Id. at 434.

While we have held that there can be express false certification liability under the FCA, see U.S. ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009), we have not decided whether there can be implied false certification liability under the FCA. See Rodriguez, 552 F.3d at 303-04.¹⁵ However, other courts of appeals have considered this possibility and a majority of those courts, including those in the Second, Sixth, Ninth, Tenth, Eleventh, and District of Columbia Circuits have recognized that there can be implied false certification liability under the FCA. See Mikes, 274 F.3d at 699-700; U.S. ex rel. Augustine v. Century Health Servs., Inc., 289 F.3d 409, 415 (6th Cir. 2002); Ebeid ex rel. U.S. v.

¹⁵ In Rodriguez we stated that we have “yet to adopt in a holding the false certification theory, either in its express or implied version.” 552 F.3d at 303-04. But, as we have indicated, we later recognized that there can be FCA liability under an express false certification theory and therefore our statement in Rodriguez is no longer true.

Lungwitz, 616 F.3d 993, 996-98 (9th Cir. 2010); Conner, 543 F.3d at 1217-18; McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1259 (11th Cir. 2005); Sci. Applications Int'l Corp., 626 F.3d at 1266, 1269; but see U.S. ex rel. Hutcheson v. Blackstone Med. Inc., ___ F.3d ___, 2011 WL 2150191, at *7 (1st Cir. June 1, 2011) (declining to employ judicially created categories of express and implied false certification); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786 n.8 (4th Cir. 1999) (stating without addressing validity of implied false certification theory under FCA, that its precedent makes the theory “questionable”). We now join with these many courts of appeals in holding that a plaintiff may bring an FCA suit under an implied false certification theory of liability.

We adopt the implied false certification theory for liability for several reasons. First, the implied false certification theory gives effect to Congress’ expressly stated purpose that the FCA should “reach all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services.” S. Rep. No. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274; see also United States v. Neifert-White Co., 390 U.S. 228, 232, 88 S.Ct. 959, 961 (1968) (“[T]he [FCA] was intended to reach all types of fraud, without qualification, that might result in financial loss to the government.”). Moreover, our ruling is consistent with Congress’ stated intent inasmuch as under the implied false certification theory of liability, even in the absence of a false certification of compliance, the Government or qui tam plaintiffs successfully may bring an action that holds a claimant liable for submitting legally false claims to the Government:

[A] false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation [Claims made to Medicare or Medicaid programs] may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program. . . .

S. Rep. No. 99-345, at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274.

In addition, the language and the structure of the FCA support the conclusion that a claim based on an implied false certification “may constitute [an actionable] false or fraudulent claim.” Shaw v. AAA Eng’g & Drafting, Inc., 213 F.3d 519, 531 (10th Cir. 2000) (internal quotation marks omitted). “Under § 3729(a)(2), liability is premised on the presentation of a ‘false record or statement to get a false or fraudulent claim paid or approved.’” Id. On the other hand, section 3729(a)(1) requires only that a claimant present “a ‘false or fraudulent claim for payment or approval’ without the additional element of a ‘false record or statement.’” Id. Therefore, section 3729(a)(1), when compared with section 3729(a)(2), indicates that a plaintiff can bring a claim under the FCA even without evidence that a claimant for Government funds made an express false statement in order to obtain those funds. Id.

As several courts of appeals have held, however, the implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA

allegations arising from the Government's payment of claims under federally funded health care programs. In particular, the Court of Appeals for the Second Circuit in Mikes recognized that the rationale behind Ab-Tech "does not fit comfortably into the health care context because 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" Mikes, 274 F.3d at 699. Moreover, in Rodriguez, although we did not expressly adopt the implied false certification theory, we stated that "[t]o state a claim under [the implied false certification] theory it is necessary to allege not only a receipt of federal funds and a failure to comply with applicable regulations, but also that payment of the federal funds was in some way conditioned on compliance with those regulations." 552 F.3d at 304. Thus, under this theory a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims. See Conner, 543 F.3d at 1219-20 ("If the government would have paid the claims despite knowing that the contractor has failed to comply with certain regulations, then there is no false claim for purposes of the FCA."). Absent this requirement, the FCA could turn "into 'a blunt instrument to enforce compliance with all . . . regulations' rather than 'only those regulations that are a precondition to payment.'" Rodriguez, 552 F.3d at 304 (quoting Mikes, 274 F.3d at 699). With these principles in mind, we now will consider appellants' FCA allegations.

3. Violations of Medicare Marketing Regulations

As we already have indicated, appellants contend that United Health personnel engaged in marketing practices which violated several Medicare marketing regulations, including: (1) using marketing flyers and forms that CMS did not approve; (2) engaging in marketing activities in the waiting rooms of clinics and doctors' offices; (3) allowing non-licensed individuals to engage in marketing activities; (4) using an excessive number of sales representatives at presentations in an attempt to "overwhelm the public;" (5) asking persons to raise their hands at Medicare presentations if they were dual eligible for Medicare and Medicaid; (6) chasing people in supermarkets to ask whether they were dual eligible; (7) using agents to engage in door-to-door solicitation; and (8) giving out prizes at Medicare presentations in excess of \$15 in value.

The District Court held that appellants' allegations that United Health engaged in illegal marketing did not state a claim for relief under either an express or implied false certification theory. According to the Court, these allegations did not state a claim under an express false certification theory inasmuch as appellants failed to plead a single instance of United Health submitting a false claim for payment to the Government: "Without an allegation of a claim, Relators' False Claims Act claim is like a battery without a touching, or a defamation without a statement." Wilkins, 2010 U.S. Dist. LEXIS 47080, at *14. In support of its holding, the Court cited to our opinion in Rodriguez, but appellants and amicus curiae contend that the District Court mischaracterized the holding of Rodriguez, and

we agree.¹⁶

In Rodriguez, we based our holding affirming the district court's Rule 12(b)(6) dismissal of the relators' FCA action on their failure adequately to plead, under an implied false certification theory, that the defendant violated a law or regulation connected to the Government's decision to pay the defendant's claims rather than on the relators' failure to identify a specific claim for payment that the defendant submitted to the Government. 552 F.3d at 304. It is true that to recover under the FCA, we have recognized that ultimately a plaintiff must come forward with at least a "single false [or fraudulent] claim" that the defendants submitted to the Government for payment. U.S. ex rel. Quinn v. Omnicare Inc., 382 F.3d 432, 440 (3d Cir. 2004). Thus, in Quinn we held that the district court correctly granted the defendant's Federal Rule of Civil Procedure 56(f) motion for summary judgment based on the plaintiff's failure to identify a single claim for payment to the Government arising from defendant's alleged Medicare fraud. Id. But to our knowledge we never have held that a plaintiff must identify a specific claim for payment at the pleading stage of the case to state a claim for relief. See Fowler v. UPMC Shadyside, 578 F.3d 203, 213 (3d Cir. 2009) ("It is axiomatic that the standards for dismissing claims under Fed. R. Civ. P. 12(b)(6) and granting judgment under . . . Fed. R. Civ. P. 56 are vastly different.").

¹⁶ The District Court also cited one of our not precedential opinions but we will not discuss that case. See 3d Cir. Internal Operating P. 5.7 ("The court by tradition does not cite to its not precedential opinions as authority.").

In any event, as appellants correctly point out, the question of whether a plaintiff, at the pleading stage, must identify representative examples of specific false claims that a defendant made to the Government in order to plead an FCA claim properly is a requirement under the more particular pleading standards of Rule 9(b). See Ebeid, 616 F.3d at 998-99 (listing cases and noting disagreement among courts of appeals). But here, as we stated above, the District Court explicitly declined to analyze appellants' claims under the pleading requirements of Rule 9(b).

Nevertheless, we see no need to decide whether appellants' marketing claims satisfied the pleading requirements of Rule 9(b), because, despite our rejection of the District Court's reasoning with respect to appellants' claim under an express false certification theory, we will affirm its holding dismissing appellants' claims predicated on the Medicare marketing regulations on the same ground that the Court provided for denying appellants' claims under an implied false certification theory. Thus, we will affirm the District Court's order rejecting appellants' claims predicated on the violation of Medicare marketing regulations because appellants' allegations that appellees violated the regulations do not state a plausible claim for relief under the FCA inasmuch as the Government's payments of appellees' Medicare claims were not conditioned on their compliance with the marketing regulations.

As we stated above, to plead a claim upon which relief could be granted under a false certification theory, either express or implied, a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a

condition of payment from the Government. Rodriguez, 552 F.3d at 304; Mikes, 274 F.3d at 698. In determining whether compliance with a regulation was a condition of payment from the Government, courts have distinguished between regulations which are conditions of participation in the Medicare programs and conditions of Government payment of Medicare funds. Conner, 543 F.3d at 1220; Mikes, 274 F.3d at 697 (“Since the Act is restitutionary and aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced the government’s decision to pay.”). The Court of Appeals for the Tenth Circuit explained the difference between conditions of participation and conditions of payment: “Conditions of participation . . . are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program,” while “[c]onditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment.” Conner, 543 F.3d at 1220.

Appellants assert that 42 C.F.R. § 423.509, pursuant to which CMS may terminate a contract with a Medicare sponsor that fails to comply with the applicable marketing guidelines, demonstrates “[t]he relevancy and materiality of compliance” with the marketing guidelines. Appellants’ br. at 23. Indeed, section 423.509 states that “CMS may at any time terminate a contract if CMS determines that the Part D plan sponsor . . . [s]ubstantially fails to comply with . . . [m]arketing requirements in subpart V of this part.” 42 C.F.R. § 423.509(a)(8)(i); 42 C.F.R. § 422.510(a)(11) (same for MA organization). The same regulation, however, provides that before CMS may issue a

notice of intent to terminate a Medicare contract it will provide a plan sponsor “a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.” 42 C.F.R. § 423.509(c)(1)(i); 42 C.F.R. § 422.510(c)(1)(i). The regulation further provides, in section (c)(2)(iii), an exception for the 30-day correction period if the termination is based on “credible evidence, [that the Plan Sponsor] has committed or participated in false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data.” 42 C.F.R. § 423.509(a)(4); 42 C.F.R. § 422.510(c)(2)(iii) (referring to 42 C.F.R. § 422.510(a)(4)). The regulation also contains an exception to the requirement that a sponsor be allowed a 30-day correction period where CMS’s delay in termination, or the financial difficulties of the Plan Sponsor, pose an imminent and serious risk to the health of the individuals enrolled in the sponsor’s plan. 42 C.F.R. § 423.509(c)(2)(i)-(ii); 42 C.F.R. § 422.510(c)(2)(i)-(ii). Thus, sections 423.509 and 422.510 clearly demonstrate that compliance with the marketing regulations is a condition of participation and not a condition of payment as the regulations draw a line between the type of violations which are correctible and, if corrected, will allow the sponsor to continue as a Medicare program participant and the type of violations which lead to immediate termination of a CMS contract.

Accordingly, the fundamental flaw in appellants’ allegations is that the amended complaint does not cite to any regulation demonstrating that a participant’s compliance with Medicare marketing regulations is a condition for its receipt of payment from the Government. Nor do appellants cite

examples, in case law or otherwise, of the Government seeking recovery of Medicare payments for services that a provider actually performed on the basis that its lack of compliance with marketing regulations rendered those services fraudulent. Appellants offer no evidence beyond a CMS published statement that the guidelines “were developed after careful consideration by CMS of current industry practices, recent advancements in communication technology, and how best to protect the interests of Medicare beneficiaries.” Appellant’s br. at 21; app. at 210. This statement, however, does not indicate that a participant’s compliance with marketing regulations is a condition for Government payment under the federal health care programs. Moreover, we think that it is appropriate for us to presume that the CMS surely develops all of its regulations after careful consideration of these and other relevant factors no matter what it determines should be the consequences of a participant’s non-compliance with the regulations.¹⁷

¹⁷ Similarly, appellants contend that Weems’ statement, which we have determined is not part of the record on which we will decide this appeal, that “protecting people with Medicare from deceptive or harmful practices is among our highest priorities at CMS,” demonstrates the relevancy of the marketing guidelines to the Government’s decision to pay Medicare claims. Appellant’s br. at 21. However, even if we included that statement in the materials that we consider in deciding this appeal, we would regard the statement as demonstrating only that CMS considers the marketing regulations to be very important, but we would not regard the statement as indicating what the consequence of non-compliance should be. After all,

Further, considering that the Government has established an administrative mechanism for managing and correcting Medicare marketing violations which includes remedies for violations other than the withholding of payment otherwise due, it is clear that, although the Government considers substantial compliance with the marketing regulations “a condition of ongoing Medicare participation, it does not require perfect compliance as an absolute condition for receiving Medicare payments for services rendered.” Conner, 543 F.3d at 1221. Furthermore, we think that anyone examining Medicare regulations would conclude that they are so complicated that the best intentioned plan participant could make errors in attempting to comply with them. Moreover, it is ironical that if we allowed appellants, though they are ostensibly acting on behalf of the Government, to bring suit based on United Health’s non-compliance with marketing regulations, we would short-circuit the very remedial process the Government has established to address non-compliance with those regulations. “It would . . . be curious to read the FCA, a statute intended to protect the government’s fiscal interests, to undermine the government’s own regulatory procedures.” Id. at 1222.

Finally, like the District Court in this case and the courts of appeals in Conner and Mikes, we question the wisdom of regarding every violation of a Medicare regulation as a basis for a qui tam suit. Conner, 543 F.3d at 1221; Mikes, 274 F.3d at

as appellees aptly point out, “[p]resumably all regulations and agency guidelines have some importance to the government agency, or there would be no purpose for the agency to promulgate them.” Appellees’ br. at 24.

699-700. Federal agencies are unquestionably better suited than federal courts to ensure compliance with Medicare marketing regulations. In the circumstances, we believe that by permitting qui tam plaintiffs to file suit based on the violation of regulations which may be corrected through an administrative process and which are not related directly to the Government's payment of a claim, courts unwisely would shift the burden of enforcing the Medicare regulations to themselves even though the administration of the vast and complicated Medicare program is best left to the administrators.¹⁸ In this regard, we point out that if we adopted appellants' broad theory of FCA liability, every time a plan participant's agent gave out a prize worth over \$15.00, or asked Medicare participants eligible for Medicaid to raise their hands at a meeting, assuming that these are improper marketing techniques, the agent's conduct could be the basis for a federal court action. We do not think that this is the purpose of 42 C.F.R. § 423.509, 42 C.F.R. § 422.510, the marketing regulations, or the FCA.

In sum, inasmuch as compliance with the Medicare marketing regulations is not a condition for Government payment under the federal health insurance programs, the District Court properly dismissed appellants' FCA claims based on appellees' violations of those regulations for failure to state a claim upon which relief could be granted.

4. The Anti-Kickback Statute

¹⁸ In reaching this conclusion we point out that administrators sometimes address and resolve problems informally using procedures that courts would not employ.

The AKS, in relevant part, provides that

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(2).¹⁹

¹⁹ As part of the comprehensive health care legislation Congress enacted in 2010, it amended the AKS to clarify that “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of

As we stated above, a prima facie claim under the FCA requires that the plaintiff show that “(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.” Schmidt, 386 F.3d at 242. We have held that “[f]alsely certifying compliance with the . . . Anti-Kickback Act[] in connection with a claim submitted to a federally funded insurance program is actionable under the FCA.” Kosenske, 554 F.3d at 94. Further, in Schmidt we stated that “[a] certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program.” 386 F.3d at 243 (citing 42 C.F.R. § 413.24(f)(4)(iv)).

[the FCA].” Patient Protection and Affordable Care Act of 2010 (“PPACA”), Pub. L. No. 111-148 § 6402(f), 124 Stat. 119, 759 (to be codified at 42 U.S.C. § 1320a-7b(g)). But the PPACA was not in effect at the time of the alleged violations at issue in this case or at the time that appellants filed this action, and there is no indication that Congress intended for the PPACA to apply retroactively. See Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 130 S.Ct. 1396, 1400 n.1 (2010) (“The [PPACA] makes no mention of retroactivity, which would be necessary for its application to pending cases given that it eliminates petitioners’ claimed defense to a qui tam suit.”). Therefore we will not consider this amendment in our analysis of appellants’ AKS claims. In the circumstances, though we are aware that there is an ongoing nationwide dispute with respect to the constitutionality of the PPACA, we are not joining in that controversy, at least not at this time.

In dismissing appellants' AKS allegations, the District Court stated that "[r]elators never once alleged that United Health certified compliance with the [AKS], nor did they allege that such compliance was relevant to the Government's funding decisions (if indeed any were made, which Relators failed to allege)." Wilkins, 2010 U.S. Dist. LEXIS 47080, at *18. Appellants argue that "[a] certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare Program," see appellant's br. at 41 (citing 42 C.F.R. § 413.24(f)(4)(iv)), and argue that they specifically referenced that certificate of compliance in the amended complaint by referring to the Medicare Managed Care Manual which states that a plan sponsor ensures compliance with applicable federal laws, including, specifically, the FCA and the AKS.

The Government, as amicus curiae, supports appellants' position by pointing out that Medicare regulations require MA and Prescription Drug Plan ("PDP") organizations to operate under agreements with CMS which include a provision requiring that the organization comply with the AKS. See 42 C.F.R. §§ 422.504(h) ("The MA organization agrees to comply with—(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including... [the AKS]"). United Health responds that the District Court's holding was correct inasmuch as "[n]owhere within the four corners of Relators' Amended Complaint did the Relators allege the nexus between compliance with the AKS and payment to a Medicare Advantage plan contractor. . . ." Appellees' br. at 34.

The issue of whether appellants properly pleaded an FCA claim based on United Health's express false certification of

compliance with the AKS presents a close question. Yet we cannot ignore appellants' pleading in their amended complaint that "[e]ach month . . . United Defendants certify to CMS its continued compliance with all of the CMS MA Guidelines and based on such certification, United Defendants continues [sic] to receive the monthly capitation payments." App. at 31. Moreover, in the next section of the amended complaint, appellants summarized the applicable Medicare regulations and pleaded that an MA Organization may not provide "[a]ny incentive that might have the effect of inducing enrollees to use a particular provider, practitioner or supplier cannot [sic] violate 1128A(a)5 [sic] of the Social Security Act and the corresponding regulations related to the federal anti-kickback statute." Id. at 32. Further, appellants alleged that AmeriChoice paid \$27,000 to the Reliance Medical Group to induce the owners of the clinic to change dual eligible beneficiaries from Horizon Blue and move them to AmeriChoice, and that AmeriChoice agents enticed doctors into receiving additional income if they provided agents with names of the physicians' patients. Arguably, these allegations state a claim for relief under an express false certification theory inasmuch as appellants allege that appellees falsely certified compliance with the AKS in order to receive monthly payments from the Government.

But we need not decide whether the amended complaint states a claim under an express false certification theory because appellants' allegations in the amended complaint clearly state a claim for relief under an implied false certification theory of liability. Under an implied false certification theory, instead of looking at the defendant's representations to the Government,

“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. Accordingly, we conclude that the District Court’s holding that because appellants failed to allege in their complaint that United Health certified its compliance with the AKS their AKS claim must fail is incorrect when we analyze the amended complaint under an implied false certification theory of liability. To plead a claim for relief under an implied certification theory, appellants were required to allege, as they did, that appellees submitted claims for payment to the Government at a time that they knowingly violated a law, rule, or regulation which was a condition for receiving payment from the Government.

We reach our conclusion because appellants’ amended complaint meets the implied false certification standards for liability as they alleged that appellees received payment from the federal health insurance programs despite their knowing violation of the AKS. Moreover, unlike the plaintiffs in Rodriguez, 552 F.3d at 304, appellants alleged that compliance with the AKS was an express condition of payment to which appellees agreed when they entered into an agreement with CMS. See app. at 31-32; 37-38 (stating that “Compliance with CMS MA Guidelines . . . are express conditions of payment” and stating that the AKS is part of the MA Guidelines). We conclude that appellants, in stating a plausible claim for relief at this stage of the proceedings for their complaint to survive a Rule 12(b)(6) motion, need not allege a relationship between the alleged AKS violations and the claims appellees submitted to

the Government.²⁰ Rather, the complaint is sufficient to survive a Rule 12(b)(6) motion to dismiss because appellants have pleaded that appellees knowingly violated the AKS while submitting claims for payment to the Government under the federal health insurance program. See Ebeid, 616 F.3d at 998 (“Implied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim.”).

We disagree with the District Court to the extent that it held that compliance with the AKS was not a condition for payment from the Government under the federal health insurance program. Compliance with the AKS is clearly a condition of payment under Parts C and D of Medicare and appellees do not refer us to any judicial precedent holding otherwise. In fact, the precedents hold the opposite. See, e.g., Kosenske, 554 F.3d at 94 (“Falsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program is actionable under the FCA.”); McNutt, 423 F.3d at 1259-60; Conner, 543 F.3d at 1223 n.8 (listing cases). Indeed, as both amicus curiae and appellants point out, Medicare regulations specifically name the AKS as a statute that is “designed to prevent or ameliorate fraud, waste, and abuse.” 42 C.F.R. §§ 422.504(h), 423.505(h).

²⁰ We emphasize again that we are not reviewing these claims under the particularized pleading standards of Rule 9(b).

We have not overlooked appellees' argument that our holding will transform the FCA into a strict liability statute in which "every participant in the Medicare program impliedly certifies each time it submits a claim for payment to the program that the claim does not arise from some payment arrangement that—however attenuated, immaterial, and unknowing—could be characterized as a violation of the AKS." Appellees' br. at 36. Rather, we consider but reject this argument. First, the AKS does not prohibit all payment arrangements related to federal health care programs as the statute contains several safe harbor provisions allowing such arrangements. See 42 U.S.C. § 1320a-7b(b)(3)(A)-(F). Further, contrary to appellees' argument, a defendant could not be held accountable for an "unknowing" illegal payment arrangement inasmuch as the AKS explicitly requires that for any payment to induce a person to refer an individual for the furnishing of healthcare services to be unlawful it must be made knowingly and willfully.

In order to avoid FCA liability under an implied certification theory, participants making claims to the Government under the federal health care programs have to ensure that they are not violating the federal health care laws which they agreed to follow when they entered into contracts with CMS. As we made clear above, for purposes of the FCA, this compliance does not require perfect adherence to regulations which are not prerequisites to payment from the Government. Compliance, however, does require a participant in a federal health care program to refrain from offering or entering into payment arrangements which violate the AKS, while making claims for payment to the Government under that program. We do not think this is an unreasonable requirement

to impose on federal health care contractors, for as Justice Holmes once wrote: “Men must turn square corners when they deal with the Government.” Rock Island, A. & L. R. Co. v. United States, 254 U.S. 141, 143, 41 S.Ct. 55, 56 (1920). And as the United States as amicus curiae points out, “[t]he Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback.” Amicus curiae br. at 31. Therefore, we hold that appellants, by alleging that appellees violated the AKS while submitting claims for payment to a federal health insurance program, have stated a plausible claim for relief under the FCA.

C. Amendment of the Complaint

Appellants argue that the District Court erred by dismissing the case with prejudice. In this regard, they contend that if the Court found the amended complaint to be deficient, it should have dismissed the case without prejudice. Of course, this argument now is partially moot as we are reversing the District Court’s order with respect to appellants’ AKS claim. But we nevertheless address the contention because the argument remains germane with respect to the marketing claims.

On the merits, we are satisfied that appellants do not provide a convincing argument that the District Court, to the extent that we hold that it correctly dismissed the complaint, abused its discretion by dismissing it with prejudice instead of without prejudice, nor do they explain how if permitted to amend they could cure the deficiencies that we have identified in their complaint. In making this point we observe that when a district court allows plaintiffs the opportunity to amend a complaint so that they can survive a Rule 12(b)(6) motion, it is implicit in the

court's ruling that if the plaintiffs seek to amend the complaint they will do so only in good faith and allege facts that they believe they can prove.²¹ Accordingly, appellants' failure to explain how they could have amended the complaint to cure its deficiencies is a critical omission.

Appellants also argue that the District Court misconstrued their statement in their reply to appellees' motion to dismiss that "[i]n the event that the Court concludes that the Complaint does not meet the standards of Rule 9(b), Relator requests that he be provided the opportunity to amend the Complaint" Appellants' br. at 43. Appellants argue that the amended complaint adequately pleaded the causes of action and that "[t]he request was made only if, and subject to, the Court concluding, after a review of United's [Motion to Dismiss] and the Relator's [sic] opposition, that deficiencies existed." Id. at 44.

Whatever appellants' intentions were in asking the District Court to permit them to amend their complaint, we agree with that Court that the request, without an attached amended complaint, was not the proper method for appellants to seek to amend their complaint. See Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc., 482 F.3d 247, 252 (3d Cir.

²¹ We are not suggesting that appellants have acted or would act in bad faith and have made or would make allegations that they did not believe. In fact, we do not doubt that appellants believe that they can prove the allegations they already have made, and, if permitted to amend their complaint again, would be able to prove their new allegations.

2007) (stating “that a failure to submit a draft amended complaint is fatal to a request for leave to amend”). Therefore, to the extent that appellants requested leave to amend their complaint, the Court did not abuse its discretion by denying their deficient request to amend nor did it abuse its discretion by not granting them leave to amend sua sponte. Id. To the extent, if any, that the Court misunderstood appellants’ request to amend their complaint, that circumstance has no bearing on this appeal. Should appellants on the remand submit another request to amend their complaint in any respect, it will be up to the District Court to decide whether to grant them leave to amend their complaint, and in making that determination to consider the procedural appropriateness and substantive merits of the request. See Fed. R. Civ. P. 15(a).

V. CONCLUSION

For the foregoing reasons, we will affirm the portion of the District Court’s May 13, 2010 order which dismissed appellants’ FCA allegations based on appellees’ violation of Medicare marketing regulations and will reverse the order insofar as it grants appellees’ motion to dismiss appellants’ amended complaint based on its allegations that appellees submitted false claims to the Government by violating the AKS. We will remand the case to the District Court for further proceedings consistent with this opinion. On remand, the District Court should rule on appellees’ Rule 9(b) contention raised in their motion to dismiss with respect to the portion of appellants’ reinstated amended complaint. The parties shall bear their own costs on this appeal.