PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

03-2187

UNITED STATES OF AMERICA, ex rel.;
THOMAS G. QUINN, BRINGING THIS CAUSE OF ACTION ON BEHALF OF
THE UNITED STATES OF AMERICA

v.

OMNICARE INC.;
POMPTON NURSING HOME SUPPLIERS, INC.,
(A WHOLLY-OWNED SUBSIDIARY OF OMNICARE, INC.);
ALAN TRASTER, INDIVIDUALLY AND IN HIS CAPACITIES AS AN OFFICER OF OMNICARE, INC. AND POMPTON NURSING HOME SUPPLIERS AND VARIOUS JOHN DOE COMPANIES WHO PROCESS MEDICATIONS RETURNED FROM PATIENTS AT LONG-TERM CARE FACILITIES LOCATED IN THE STATE OF NEW JERSEY PURSUANT TO THEIR CONTRACTUAL RELATIONS WITH NEW JERSEY MEDICAID/PAAD PROGRAMS;
CHERRY HILL PHARMACY, LTC,
(A WHOLLY-OWNED SUBSIDIARY OF OMNICARE, INC.);
WINSLOW'S PHARMACY,
(A WHOLLY-OWNED SUBSIDIARY OF OMNICARE, INC.);
BACH'S PHARMACY EAST

Thomas G. Quinn,

Appellant

Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 98-cv-02031)
District Judge: Honorable Dickinson R. Debevoise

Argued on December 16, 2003

Before: ROTH, MCKEE and ROSENN, Circuit Judges

(Opinion filed : September 1, 2004)

Harvey S. Mars, Esquire **(Argued)**
Leibowitz & Mars
322 West 48th Street
New York, NY 10036

Counsel for Appellant

Harry R. Silver, Esquire **(Argued)**
Patton Boggs
2550 M. Street, N.W.
Washington, D.C. 20037

James A. Robertson, Esquire
Kalison, McBride, Jackson & Murphy

645 Martinsville Road
P.O. Box 814
Liberty Corner, NJ 07938

Peter S. Pearlman, Esquire
Jessica V. Henry, Esquire
Cohn, Lifland, Pearlman, Herrmann & Knopf
Park 80 Plaza West - One
Saddle Brook, NJ 07663

E. John Steren, Esquire
Ober, Kaler, Grimes and Shriver
1401 H. Street, N.W.
Suite 500
Washington, D.C. 20005

Counsel for Appellees

O P I N I O N OF THE COURT

ROTH, Circuit Judge:

Omnicare, Inc., a Medicaid-provider pharmacy, and various of its subsidiaries, including Pompton Nursing Home Suppliers (Pompton), were charged by Thomas Quinn with submitting false claims in violation of the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*[1] Quinn bases his allegations on the fact that Medicaid pays for medications that the defendant pharmacies dispense to Medicaid beneficiaries but, if a medication is subsequently returned to a defendant pharmacy for resale, the pharmacy credits Medicaid with only 50% of what Medicaid had paid the pharmacy for the medication. We find that the lack of legal authority, requiring Medicaid-provider pharmacies to credit Medicaid when a medication is returned for resale, is disturbing. We conclude, however, that there can be no FCA liability in the absence of such authority. In addition, Quinn's failure to present evidence of the actual submission of a single false claim to Medicaid is fatal to this *qui tam* action.

I. FACTUAL BACKGROUND

Pompton is a Medicaid-provider pharmacy that provides medications to individuals residing in long-term care facilities. Long-term care facilities, which include nursing homes, provide care to patients who participate in medical insurance programs, including Medicaid.

---

[1] The complaint also named Alan Traster; Bach's Pharmacy, East; Cherry Hill Pharmacy and Winslow's Pharmacy as defendants. Pompton and Bach's Pharmacy, East are the same entities. Cherry Hill Pharmacy and Winslow's Pharmacy are also subsidiaries of Omnicare. The District Court, in analyzing Quinn's claims, focused solely on Pompton's recycling and crediting practices because Quinn worked at Pompton and did not advance a theory of FCA liability against any other Omnicare subsidiary that was not advanced against Pompton. For the same reason, we too will focus solely on Pompton's recycling and crediting practices.

Approximately sixty percent of the medications that Pompton dispenses are paid for by New Jersey Medicaid.[2] The remainder are paid for by the patients themselves or by private insurers. After a Medicaid-provider pharmacy has supplied a medication to a Medicaid patient, the pharmacy submits a claim to Medicaid. Medicaid then pays the pharmacy for the medication. Instructions for filing Medicaid claims are set forth in New Jersey Medicaid's Pharmacy Services Fiscal Agent Billing Supplement (FABS). FABS instructs provider pharmacies to submit Medicaid pharmacy claims on the MC-6 form. The MC-6 claim form contains a "Provider Certification" which the provider must sign:

> I certify that the services covered by this claim were personally rendered by me or under my direct supervision . . . and that the services covered by this claim and the amount charged thereof are in accordance with the regulations of the New Jersey Health Services Program[3]; and that no part of the net amount payable under this claim has been paid; and that payment of such amount will be accepted as payment in full without additional charge to the patient or to others on his behalf . . .. I understand that . . . any false claims, statements or documents, or concealment of a material fact, may be prosecuted under applicable federal or State law, or both.

On some occasions, the medications, for which Pompton has submitted a claim and received full reimbursement from Medicaid, are returned.[4] New Jersey pharmacy regulations allow Medicaid provider pharmacies to recycle returned unit dose packaged medications if they have been stored properly and the seal and control number remain intact. See N.J.A.C. § 13:39-9.15.[5] When Pompton receives returned medications for recycling, it is Pompton's practice to send Medicaid a

---

[2] Medicaid services are financed by the state governments and the federal government. In New Jersey, the Division of Medical Assistance and Health Services (DMAHS) administers the program.

[3] The New Jersey Health Services Program is Medicaid. *See* N.J. STAT. ANN. § 30:4D-3.

[4] A change in the patient's medication, the death of a patient, or the transfer of a patient out of a long-term care facility are common reasons why medications are returned.

[5] Recycling involves restocking and redispensing the returned medications. Unit dose packaging means single tablets contained in sealed blister packs.

check for 50% of the cost of the returned medications.[6] Pompton justifies retaining the other 50% to cover the expense of restocking and redispensing the medications.

The *qui tam* plaintiff, Thomas Quinn, was Pompton's regional comptroller. Quinn alleges that it was Pompton's practice, when medications were returned, to push out the individual tablets and capsules from their sealed packages and place them in separate containers for subsequent use. Quinn claims that he observed workers in the return department removing pills from their original sealed containers by pushing them through their packaging and that he saw the workers create new packages for the pills by re-sealing the packages with irons. Quinn asserts that Pompton eventually redispensed the returned medications.

After Quinn learned that another recently acquired Omnicare subsidiary in Illinois had settled FCA claims because it had represented to Medicaid that medications were destroyed when they in fact had been returned and redispensed, he became concerned about Pompton's Medicaid recycling and crediting practices. He expressed his concern to Alan Traster, the president of Pompton, who told Quinn that Pompton was not required to credit New Jersey Medicaid for returned medications. Quinn memorialized his concerns in a memo to Traster. Quinn was dismissed by Pompton a few days later on August 22, 1997.

II. PROCEDURAL HISTORY

Quinn filed a complaint under seal against Pompton in the United States District Court for the District of New Jersey. Quinn brought the action under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.*,[7] under New Jersey's Conscientious Employee Protection Act (CEPA), N.J.S.A. § 34:19-3, and under New Jersey common law. Quinn claimed that Pompton violated §§ 3729(a)(1), (2), and (7) of the FCA because it (1) failed "to submit adjustments in order to partially void claims (submitted on required MC-6 claim forms) where the medications supplied pursuant to those claims were ultimately returned," (2) sold "Medicaid the same medication twice," (3) submitted "Medicaid claims for pharmaceuticals that

[6] Pompton "inadvertently" credited New Jersey Medicaid only 25% between November 1996 and September 1997.

[7] The FCA allows a private citizen, called a relator, to bring an action in the name of the United States, and the government may intervene if it so chooses. *See* 31 U.S.C. §§ 3730(b)(1), (2). In this case, the government did not intervene. The FCA permits the relator to bring the action in the absence of the government's intervention. Quinn is entitled to collect at least 25 percent but not more than 30 percent of the proceeds of the action or settlement. *See id*. §§ 3730(b)(4)(B), (d)(2).

were removed from unit dose packaging in the recycling process, in violation of New Jersey Board of Pharmacy Regulations", and (4) returned "credits to Medicaid for less than 100% of the amount initially claimed for returned medications." *United States ex rel. Quinn v. Omnicare, Inc.*, No. 98-2031 (DRD), slip op. at 9-10 (D.N.J. filed March 28, 2003). Quinn claimed that his dismissal violated the anti-retaliation provisions of the FCA and CEPA. Quinn also brought a claim for unjust enrichment.

On cross-motions for summary judgment, the District Court granted summary judgment to Pompton on Quinn's FCA claims and his unjust enrichment claim. The court declined to exercise supplemental jurisdiction over Quinn's CEPA claim and dismissed it for lack of subject matter jurisdiction.

Quinn appeals the adverse disposition of his FCA claims.[8]

III. JURISDICTION AND STANDARD OF REVIEW

The District Court had jurisdiction pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a). We have appellate jurisdiction pursuant to 28 U.S.C. § 1291.

We exercise plenary review over the District Court's decision granting summary judgment and will use the same test applied below. *Belitskus v. Pizzingrilli*, 343 F.3d 632, 639 (3d Cir. 2003). A district court may grant summary judgment when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The moving party bears the burden to show an absence of any genuine issues of material fact. "[I]nferences to be drawn from the underlying facts contained in the evidential sources . . . must be viewed in the light most favorable" to the non-moving party. *Hollinger v. Wagner Mining Equipment Co.*, 667 F.2d 402, 405 (3d Cir. 1981). "[I]f a disputed fact exists which might affect the outcome of the suit under the controlling substantive law," summary judgment is not appropriate. *Belitskus*, 343 F.3d at 639 (citation omitted). Any doubt a court has about the existence of a genuine issue of material fact should be resolved in the non-moving party's favor. *Continental Ins. Co. v. Bodie*, 682 F.2d 436, 438 (3d Cir. 1982). Summary judgment is appropriate when there is no genuine issue of material fact to be resolved at trial. *Gruenke v. Seip*, 225 F.3d 290, 298 (3d Cir. 2000).

IV. DISCUSSION

A. The Submission of the Initial Medicaid Claim

The FCA imposes liability on any person who

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim

[8] Quinn does not appeal the District Court's entry of summary judgment on his FCA retaliation 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). A person acts "knowingly" when he "(1) has 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, and no proof of specific intent to defraud is required." 31 U.S.C. § 3729(b).

Each time Pompton submits a claim for payment on the MC-6 form, it certifies that "the services covered by this claim were . . . rendered . . . and . . . the services covered by this claim and the amount charged thereof are in accordance with . . . [Medicaid] regulations . . .." Quinn alleges that Pompton's initial claims are false due to its failure to adjust them when medications are returned for recycling.

There are several regulatory provisions which do require the voiding or adjustment of claims under certain circumstances. Section 10:49-8.3 of the New Jersey Administrative Code requires "[a]djustments following payment of claims" when "a claim is incorrectly paid and the provider receives an overpayment or underpayment" or when a claim is "paid in error." Situations that may cause underpayment or overpayment include a payment by a private insurance company after Medicaid has paid for the medication, a billing error, or a computer error in processing the claim. A claim is "paid in error" when it is paid and it should not have been paid. *See* N.J.A.C. § 10:49-8.3(b). In addition, N.J.A.C. §10:51-1.25(j)(2) requires "[p]harmacies . . . to initiate claim reversal for those services in which a claim was generated and adjudicated to payment . . . and the service was not subsequently provided to a . . . beneficiary."

FABS instructs the pharmacy to fill out an "Adjustment Request" form when a claim is underpaid, overpaid, or paid in error. In the case of a claim that is paid in error, the pharmacy voids the entire claim and Medicaid deducts the voided amount from the next payment. The provider indicates on the "Adjustment Request" form the reason for the adjustment or void. One of the reasons listed is "service not provided." None of these regulations, however, instruct pharmacies on how to credit or adjust a claim for medications after those medications have been returned for recycling.

Nevertheless, Quinn contends that Pompton violates §§ 3729(a)(1) and (2) of the FCA by failing to void or adjust claims for medications after these medications have been returned for redispensing. Quinn argues that the initial claims become false when medications have been returned because the claims then become claims for services that were not provided to the intended beneficiaries. Quinn asserts that, after the return of the medications, unless Pompton reverses the

claims as required by N.J.A.C. § 10:51-1.25, the certification on the initial MC-6 form is a false one.

The District Court rejected Quinn's argument because there is no language in the MC-6 form, its instructions, or Medicaid regulations that states that medications cannot be returned. *Quinn*, slip op. at 11. The court noted that, even though N.J.A.C. § 10:51-1.25(j)(2) requires reversal when "services are not provided," the regulation does not further state that "services are not provided" when medications are dispensed and subsequently returned. *Id*. at 11-12.

We agree that there is no regulatory requirement of the reversal of a claim once a medication has been returned. As the District Court held, if there is no requirement to adjust the claim, there is no liability for a failure to do so.

However, even more fundamentally, Quinn's allegation is that the initial claim is rendered false by the return. The fallacy of this argument lies in the fact that the return of a medication, which at the outset has been dispensed to the Medicaid beneficiary, does not render the initial claim false or fraudulent. In order to prove FCA liability under §§ 3729(a)(1) and (2), Quinn 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." *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3 176, 182 (3d Cir. 2001). There is no question that the MC-6 forms Pompton submits to Medicaid are claims under the FCA.[9] The only question is whether a claim, which is not "false" or "fraudulent" when initially submitted, can later be rendered so if the medication is returned.

There is FCA liability when a "provider knowingly asks the Government to pay amounts it does not owe." *United States ex rel. Clausen v. Lab. Corp. of America*, 290 F.3d 1301, 1311 (11th Cir. 2002). The FCA reaches "all fraudulent attempts to cause the Government to pay out sums of money." *Harrison v. Westinghouse Savannah River*, 176 F.3d 776, 788 (4th Cir. 1999). The terms "false" and "fraudulent" are not defined in the FCA. The terms, however, do have independent meanings:

> A common definition of "fraud" is an intentional

---

[9] "Claim" is defined as:

> [A]ny request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(c).

> misrepresentation, concealment, or nondisclosure for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right." "False" can mean "not true," "deceitful," or "tending to mislead." The juxtaposition of the word "false" with the word "fraudulent," plus the meanings of the words comprising the phrase "false claim," suggest an improper claim is aimed at extracting money the government otherwise would not have paid.

Mikes v. Straus, 274 F.3d 687, 695 (2nd Cir. 2001) (citations omitted).

Under these standards, it is clear that, when Pompton submits the initial claim form, it is not intentionally making any misrepresentation. To the contrary, it is merely asking for reimbursement for medication which it has dispensed and for which it is entitled to payment. When Pompton submits the initial claim for payment, it has no way of knowing if a medication will be returned. Pompton has not then "knowingly" presented a "false or fraudulent claim" at the time of the original claim submission. Nor can the changed circumstances, caused by the later return of the medication, render the initial claim false or fraudulent.

Quinn contends, however, that, in order to impose FCA liability, it is not necessary that the claim have been false when it was originally submitted. We reject this argument. The FCA aims to impose liability for a broad range of conduct, including "each and every claim submitted . . . which was *originally* obtained by means of false statements or other corrupt or fraudulent conduct." S.Rep.No. 99-345 at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (emphasis added). Pompton's claims were not *originally* false – they did not misrepresent the dispensing of the medication or the cost of what was dispensed.

We conclude that we would be exceeding the intent of Congress in defining false claims if we were to permit the transforming of a valid claim into a false claim by the occurrence of a subsequent fortuitous event which is not itself the basis of any required adjustment.

For the above reasons, we hold that Pompton is not liable under the FCA for the submission of the initial Medicaid claims or for the failure to adjust an initial claim when a medication is returned.

B.The Successive Claim for a Recycled Medication

In Quinn's second allegation, he contends that, when a returned medication is resold, Pompton is making a claim for an amount that has, at least in part, already been paid. The MC-6 form requires Pompton to certify that "no part of the net amount payable under this claim has been paid." Quinn asserts that Pompton submits a false claim to Medicaid when Pompton

sells a medication to a Medicaid patient for the second time. Quinn alleges that by only partially crediting Medicaid for a returned medication and then submitting a new claim for the full cost of the same medication, Pompton violates §§ 3739(a)(1) and (2) of the FCA because Pompton has claimed more than the actual cost of the medication and has falsely represented on the second claim form that there has been no previous payment for the medication.

The District Court rejected this argument. The court refused to find FCA liability under Quinn's theory that Pompton must have resold returned medications to Medicaid by virtue of the large volume of Medicaid business it conducts. *Quinn*, slip op. at 12. The court, relying on *Clausen*, 290 F.2d 1311, to support the theory that the actual submission of a false claim must be proved, noted that Quinn did not point to a single instance when the same medication was in fact the subject of two claims.[10] The District Court held that, without evidence of the actual submission of a false claim, there was no genuine issue of material fact.

Quinn argues that there is a material question of fact whether Pompton submitted duplicate Medicaid claims for the same medication, given that Pompton recycles returned medications and approximately 60% of Pompton's sales are to Medicaid. Pompton responds that, at the summary judgment stage, Quinn has the "burden to establish, in at least one instance, that a given pharmaceutical had been paid for by Medicaid, returned to the pharmacy, and then redispensed and rebilled to Medicaid." We agree and conclude that Quinn has not met this burden.

In *Clausen*, the court held that a False Claims Act plaintiff cannot "merely . . . describe a private scheme in detail but then . . . allege simply and without any stated reason for his belief that claims requesting illegal payments must have submitted, were likely submitted or should have been submitted to the Government." 290 F.3d at 1311. Clausen alleged that the defendant medical testing company was overbilling the government by performing unauthorized, unnecessary, and excessive testing. The court affirmed the dismissal of Clausen's claim because he never provided a single false claim was actually submitted. *Id.* at 1312.

---

[10]Quinn asserts that the District Court erred by relying on *Clausen*. Whereas the dismissal in *Clausen* was pursuant to Federal Rule of Civil Procedure 9(b) for failure to plead fraud with particularity, Quinn points out that the District Court held that his complaint satisfied Rule 9(b)'s requirements. The present case differs from *Clausen*, however, because *Clausen* was dismissed on the pleadings for failure to satisfy the pleading requirements of Fed. R. Civ. P. Rule 9(b). While Quinn survived this first step, he then succumbed at the summary judgment stage for failure to establish a necessary element of FCA liability.

Similarly, in *United States ex rel. Alfatooni v. Kitsap Physicians Service*, the Ninth Circuit Court of Appeals held that the plaintiff's failure to present an actual false claim submitted to the government was fatal to the action. 314 F.3d 995 (9th Cir. 2002). Alfatooni, relying on the volume of bills submitted to the Government each year, made the same argument Quinn makes here – that false claims must have been submitted. The court held that an FCA plaintiff must come to court with a "claim in hand" and "generalized, speculative suppositions" will not suffice. *Id.* at 1002-03. The court contrasted *United States v. Krizek*, 192 F.3d 1024 (D.C.Cir. 1999), in which the court "presumed that the defendants would be liable under the False Claims Act for submitting psychiatric bills that totaled more than twenty four hours for a given day." *Alfatooni*, 314 F.3d at 1003 (citing *Krizek*, 192 F.3d at 1026-27). The court in *Alfatooni* noted that in *Krizek*, "[t]he government *had the Medicare/Medicaid claims in hand*," *id*. (citing *Krizek*, 192 F.3d at 1027-28), even though it could not prove exactly which of the "claims in hand" actually was fraudulent.

The same reasoning applies here. Pompton admits that approximately 60 percent of its business is Medicaid and that it accepts returned medications for recycling. However, as Alfatooni failed to do, Quinn also did not come forward with a single claim that Pompton actually submitted to Medicaid which covered a medication for which Pompton had previously submitted a claim. Discovery was complete at the time Pompton moved for summary judgment, and Quinn did not ask the District Court for extended discovery pursuant to Federal Rule of Civil Procedure 56(f). Quinn failed to link Pompton's recycling and crediting practices to the actual submission of a false claim. Without proof of an actual claim, there is no issue of material fact to be decided by a jury. Quinn's theory that the claims "must have been" submitted cannot survive a motion for summary judgment.

Furthermore, we agree with the District Court that, even assuming that Pompton is submitting successive claims for the same medications, there can be no FCA liability because New Jersey regulations entitle Pompton to recycle and redispense returned medications. Section 13:39-9.15(a)(2) of the New Jersey Administrative Code, entitled "Disposal of unused medications," allows unused unit dose packaged medication, that "has been stored in a medication room or secure area in the institution . . . [with the] seal and control number . . . intact" to be "recycled and redispensed." The regulation does not, however, require pharmacies to credit Medicaid for the "recycled and redispensed" medications. Because Pompton can legally recycle returned medications, the initial sale and the subsequent sale of a returned medication are properly viewed as separate transactions. As the District Court held, these transactions are "not duplicative in any sense that would make them inconsistent with the full-payment representation on the MC-6." *Quinn*, slip op. at 13. Under this separate transaction

theory, Pompton does not make a false representation on the second claim form even though it does not state that Medicaid has already paid, at least in part, for a redispensed medication.

In so concluding, we recognize that the second claim would be submitted to Medicaid for payment for the *same* medication. When Pompton submits the second claim, it knows that the medication, which is the subject of that claim, was already dispensed once and returned. Pompton also knows that Medicaid has already paid 50% of the cost of the medication. However, because New Jersey regulations allow Pompton to recycle returned medications and because no regulation requires Pompton and other Medicaid pharmacies to credit Medicaid for the returns, we conclude that we cannot impose FCA liability based on the submission of the second claim.

C.The Recycling of Repackaged Medications

The MC-6 form requires Pompton to certify that the "services covered by this claim and the amount charged thereof are in accordance with . . . [Medicaid] regulations . . .." Quinn argues that Pompton violated §§ 3729(a)(1) and (2) of the New Jersey Administrative Code when it submitted claims to Medicaid because the certification on the claim constituted an implied false certification that the returned medication was recycled in accordance with "regulations."

The "certification theory" of FCA liability is based on a false representation of compliance with a contract term, statute, or regulation – when payment is conditioned on compliance with that requirement. *See, e.g., United States ex rel. Siewick v. Jamieson Sci & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000).[11] We have not yet adopted this theory of FCA liability. However, other Courts of Appeals have. The Second Circuit noted in *Mikes* that it was joining the "Fourth, Fifth, Ninth, and District of Columbia Circuits in ruling that a claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment." 274 F.3d at 697 (citations omitted).

In *Mikes*, the court limited the applicability of the implied false certification theory to cases where "the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." 274 F.3d at 699. The court limited FCA liability, premised on a legally false certification, to those situations where a party certifies compliance with an underlying statute or regulation as a condition of payment because the FCA aims to impose liability only where a certification of compliance influences the

[11] Legally false certification is different than factually false certification, "which involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Mikes*, 274 F.3d at 697.

government's decision to pay. *Id*. at 697 (noting that the FCA "does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions").[12] Under this approach, when an underlying regulation expressly prohibits payment upon non-compliance with its terms, the submission of a claim implicitly certifies compliance with that regulation.

District courts in the Third Circuit, including the court in this case, have cited *Mikes* in support of the concept of false certification liability. *See In re Genesis Health Ventures, Inc.*, 272 B.R. 558, 569-70 (Bankr. D. Del. 2002)[13]; *United States ex rel. Cooper v. Gentiva Health Servs, Inc.*, No. 01-508, slip op. at 2-3, 2003 WL 22495607, (W.D.Pa. Nov. 4, 2003); *United States ex rel. Watson v. Connecticut Gen'l Life Ins. Co.*, No. 98-6698, 2003 WL 303142, at * 10 (E.D.Pa. Feb. 11, 2003).

In support of imposing liability under this theory, Quinn relies on § 13:39-9.15(a)(2) of the New Jersey Administrative Code, Board of Pharmacy Regulations, which provides: "If a unit dose packaged medication has been stored in a medication room or secure area in the institution and the medication seal and control number are intact, the medication may be recycled and redispensed." Medicaid regulations require pharmacies to comply with Board of Pharmacy Regulations in order to participate in the Medicaid program. *See* N.J.A.C. § 10:51-1.2(d) (expressly incorporating the requirements of N.J.A.C. § 13:39).

The District Court held that failure to comply with the Board of Pharmacy regulations may disqualify a provider from participation in the program, but compliance with the regulations is not a condition to payment by Medicaid. *Quinn*, slip op. at 14-15. Quinn contends, however, that a finding of FCA liability, based on implied false certification theory, should not be limited to situations where

---

[12] The Second Circuit declined to follow the broader approach taken in *Ab-Tech Construction, Inc. v. United States*, 31 Fed. Cl. 429 (Fed. Cl. 1994), *aff'd without opinion*, 57 F.3d 1084 (Fed. Cir. 1995), where "the Court of Federal Claims held that the defendants' submission of payment vouchers, although containing no express representation, implicitly certified their continued adherence to the eligibility requirements of a federal small business statutory program." *Mikes*, 274 F.3d at 699 (citing *Ab-Tech*, 31 Fed. Cl. at 434). The *Mikes* court reasoned that "[t]he *Ab-Tech* rationale . . . does not fit comfortably into the health care context because the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations – but rather only those regulations that are a precondition to payment . . .." 274 F.3d at 699.

[13] The decision of the Bankruptcy Court in *Genesis Health Ventures* was affirmed by the District Court, _____. This case is currently on appeal to this Court.

the underlying regulation or statute expressly states that compliance is a condition of payment. Quinn argues that there should be FCA liability when non-compliance with the underlying regulations would disqualify the provider from participation and that there should be FCA liability here because the improper recycling of medications would disqualify Pompton from participation in the Medicaid program.[14]

Here, the MC-6 form requires providers to certify that the pharmaceutical services comply with Medicaid regulations. The Medicaid regulations expressly incorporate compliance with the Board of Pharmacy Regulations, including N.J.A.C. § 13:39-9.15, as a condition to participation in the program. If a provider does not comply with the Medicaid regulations, by reason of not complying with the incorporated Board of Pharmacy regulations, not only will the provider be ineligible to participate in the Medicaid program, but Medicaid may seek to recover the money it paid to the provider for services covered by the claims. *See* N.J.A.C. § 10:49-9.8(c).

Quinn's arguments are compelling. Even though § 13:39-9.15 does not expressly condition payment on compliance with its terms, it hardly can be said that non-compliance with its terms is "irrelevant to the government's disbursement decisions." *Mikes*, 274 F.3d at 697. However, even if Pompton does not qualify for Medicaid reimbursement if it dispenses an improperly recycled medication to a Medicaid patient, we cannot say that, in this case, Pompton has made any false certifications in connection with a Medicaid claim. The reason we come to this conclusion is because of the impossibility of proving from the numbers alone that a claim was made by Pompton to Medicaid for an improperly recycled medication.

If 100% of the medications that Pompton dispensed were paid for by Medicaid, then *a fortiori*, any claim for an improperly recycled medication would be paid for by Medicaid. If that claim was made on Form MC-6, it would be

---

[14] The United States filed a brief as amicus curiae in the appeal of the Bankruptcy Court's decision in *Genesis Health Ventures*, 272 B.R. 558. The government refers to the 1986 Senate Report, which states that "claims 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 (emphasis added). The report also states that 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, specifications, statute or regulation." *Id*. The government argues that Congress intended eligibility for program participation and compliance with contract terms, specifications, statutes or regulations to be conditions which must be met in order for claims to be true under the FCA.

inevitable that Pompton had violated N.J.A.C. § 3729(a)(1) and (2), and Medicaid would be paying Pompton on the basis of a false certification. Such a situation would be similar to the one in *Krizek*, 192 F.3d 1024, where we know that a false claim had to have been made when 25 or more hours were being charged to Medicaid for a 24 hour day.

In the present case, however, Quinn cannot demonstrate either that an improperly recycled medication was paid for by Medicaid or that it was paid for by one of the other sources of payment for the medications that Pompton dispensed. Although we might hypothesize that 60 % of the improperly recycled medications were paid for by Medicaid, it is impossible to rule out the chance that they were paid for by non-Medicaid sources.[15] For this reason, we agree with the District Court that "even assuming that the MC-6 certified compliance with Board of Pharmacy regulations as a condition of payment, Plaintiff has not pointed to sales inconsistent with the certification." *Quinn*, slip op. at 14. As with our discussion on successive claims, Quinn did not provide the District Court with a single instance where Pompton submitted a claim for payment for medications recycled in violation of § 13:39-9.15.[16] For that reason, Quinn's false certification claim fails.

D. The Failure to Give Medicaid 100% Credit for Returned Medications

[15] We could even hypothesize that if improperly recycled medications comprised more that 40% of the medications that Pompton dispensed, it would be inevitable that a falsely certified claim had been made to Medicaid, the source of 60% of Pompton's receipts. There are, however, insufficient facts in the record to support even this more generous hypothesis.

[16] We do find, however, that there would be enough evidence in the record to create a genuine issue of material fact as to whether Pompton was recycling unit dose packaged medications in violation of N.J.A.C. § 13:39-9.15. Quinn witnessed Pompton's employees recycling medications by removing pills from their sealed packaging, placing the pills in large containers, and then resealing the pills in new packages using an iron. The attorney for Pompton admitted to the District Court at the summary judgment hearing that returned medications were repackaged. *See* Transcript of Proceedings dated November 25, 2002 at A7. This alone, however, is insufficient to withstand Pompton's motion for summary judgment. Quinn submits that every sale has a proportion of recycled inventory because recycled medications are returned to inventory. Since at least 60% of Pompton's sales are to Medicaid patients, Quinn argues that at least 60% of the improperly recycled medications must have been paid for by Medicaid. As we discuss *supra*, however, this "must have been" theory of liability cannot serve as a basis for FCA liability.

The reverse false claim provision of the FCA imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7). To make a prima facie case of liability under § 3729(a)(7), the plaintiff must prove that the defendant did not pay back to the government money or property that it was obligated to return. The District Court held that Pompton was not liable under the reverse false claim provision because it found that Pompton is under no legal obligation to credit Medicaid for returned medications. A prerequisite for liability under this theory is a legal obligation to credit Medicaid 100% for returned medications. The District Court noted that there is no federal or New Jersey Medicaid statute or regulation which specifically requires that Pompton do so. *Id.*, at 15-16.

Quinn asserts that Pompton's failure to give 100 % credit to Medicaid violated § 3729(a)(7) of the FCA. Quinn argues that § 8:39-29.4(j) of the New Jersey Administrative Code imposes a legal obligation on Pompton to credit Medicaid for returned pharmaceuticals. That section provides:

> Where allowable by law, the facility shall generate a crediting mechanism for medications dispensed in a unit-of-use drug distribution system, or other system that allows for the re-use of medications. The crediting system shall be monitored by the provider pharmacist and a facility representative.

Pompton maintains that § 8:39-29.4(j) does not impose an obligation to credit Medicaid because Pompton is not a "facility." Quinn responds that § 8:39-29.4(j) does require Pompton to credit Medicaid for returned medications because the definition of "facility" includes pharmacies. Quinn argues that this section requires Pompton to credit Medicaid 100% because "credit" means "full credit," and "[i]f something less than full credit was acceptable to the State, then the regulation would have said so."

As the District Court noted, "[i]t is debatable whether . . . [N.J.A.C. § 8:39-29-4(j)] even governs the conduct of Medicaid pharmacies." Section 8:39-29-4(j) is a regulation promulgated by the Department of Health and Senior Services, not Medicaid. The regulation appears under Chapter 39, which is titled "Standards for Licensure of Long-Term Care Facilities." This alone suggests that nursing homes, as opposed to pharmacies, are required to create a "crediting mechanism."

The term "facility" is defined as "a facility or distinct part of a facility licensed by the New Jersey State Department of Health and Senior Services as a long-term care facility." N.J.A.C. § 8:39-1.2. Pompton is not a "facility" within this definition because it is not licensed as a long-term care facility. Furthermore, it does not make sense for Pompton, a pharmacy, to be considered a "facility" within the regulation's definition when, if

it were considered a "facility," it would, in addition, have to maintain a pharmacy. *See id.* § 8:39-29.1 (facilities "shall have a consultant pharmacist and either a provider pharmacist, or if the facility has an in-house pharmacy, a director of pharmaceutical services").

Although Pompton is not a "facility," the second sentence of the regulation requires Pompton, because it is a provider pharmacist, to monitor the facility's crediting system. *See id.* § 8:39-29.4(j). Therefore, Pompton, acting as a long-term care facility's mandatory pharmacy provider, does have an obligation under this regulation to "observe, watch, or check" the crediting mechanism put in place by the long-term care facility. *See id.* § 8:39-1.2. This obligation to monitor, however, does not expressly include an obligation to credit Medicaid for returned medications.

Quinn cites two passages in the New Jersey Register in support of his argument that Pompton has an obligation to credit Medicaid for returned medications. The first passage states:

> The Department anticipates significant cost savings will accrue as a result of N.J.A.C. § 8:39-29.4(j) . . . The rule discontinues the current requirement to destroy all unused medications . . . [T]he product is returnable and can be dispensed again by the retail pharmacy. Although no statewide dollar impact is available, literally thousands of dollars of medications are destroyed by many facilities monthly. Both private pay consumers and the State Medicaid program will benefit from this proposed rule.

26 N.J.R. 1776 (Monday, May 2, 1994). The other passage states:

> The economic impact of this amendment should result in savings to residents and families and third party payors such as Medicaid. These savings will occur as a result of drugs which will be returned to the pharmacy for credit. Drugs which have been . . . returned to the pharmacy will be credited to that resident . . . The overall savings to residents, families and Medicaid may exceed $200,000.

29 N.J.R. 4415(a) (Monday, October 20, 1997). These two passages do lend support for Quinn's argument that state officials expected N.J.A.C. § 8:38-29.4(j) to result in savings for Medicaid as a result of crediting. It nevertheless is not clear who has an obligation to credit and how much credit is required to be given.

Even if the regulation imposed upon Pompton an obligation to credit Medicaid, as the District Court noted, "it does not impose upon them a requirement that they credit Medicaid any specific amount for returned medications." *Quinn*, slip op. at 16. Quinn argues that credit means 100%. We conclude, however, that, in light of the absence of a clear obligation to credit Medicaid and the absence of any Medicaid or other regulation requiring provider pharmacies to credit at a specific rate, we can not impose FCA liability on

Pompton.[17]

Quinn also argues that Pompton, by deducting 50% to cover the costs of recycling, violates N.J.A.C. § 10:49-14.5. This Medicaid regulation provides: "A provider shall not pay nor require payment of an administrative charge or service fee . . . for services for which reimbursement is included as part of the Medicaid . . . fee." The District Court rejected Quinn's argument, noting that it "assumes that such a restocking fee pays for a service 'for which reimbursement is included' in other Medicaid payments . . .." *Id.*

Quinn argues that the capitation payment Medicaid pays to Pompton for medications dispensed to Medicaid beneficiaries is understood to include the costs associated with returns. N.J.A.C. § 10:51-2.7, titled "Prescription dispensing fee (capitation)" provides, in relevant part:

> (a) The New Jersey Medicaid and NJ KidCare programs capitate the dispensing fee for each prescription for beneficiaries in Medicaid-approved nursing facilities . . . Additional dispensing fees (add-ons) per prescription shall be given to pharmacy providers who provide the following levels of services:
>
> 1. Twenty-Four Hour Unit Dose Service: Pharmacies . . . dispensing medication in a dispensing system in which a 24-hour supply of unit dose oral medication . . . is delivered for each beneficiary daily, shall be reimbursed the cost of all reimbursable medication plus a fee of $0.656 per beneficiary day.

Edward Vaccaro, Assistant Director of the Office of Health Service Administration within DMAHS, explained in his depositions that "[t]he capitation . . . attempts to compensate the pharmacy for different costs associated with delivery systems, which is why the 24-hour unit dose is the higher capitation . . .." He also stated that "[c]apitation is intended to reimburse providers of long-term care pharmacy services for the costs associated with the dispensing of drugs . . . [and] [i]n the case of long-term care, I would consider recycling to be part of dispensing." Because only unit dose drugs may be recycled, it may be fairly understood *by Vaccaro* that the capitation fee covers the costs of redispensing the returned drugs. However, as Vaccaro admitted, there is no regulation that explicitly bars the collection of a

[17] Edward Vaccaro, a New Jersey Medicaid representative, stated during his deposition that the regulations at issue in this case require pharmacies to provide credit for returned medications at 100%. Quinn asks us to accord this statement deference as an agency interpretation. However, the statement, offered in a litigation setting, was not the product of a rulemaking or an official agency interpretation. Thus, regardless of any deference that may be due a state agency's interpretation of its own regulations, we are not persuaded that the statement represents an official agency position on this matter.

restocking and redispensing fee. Furthermore, § 10:51-2.7 does not indicate that the cost of restocking and redispensing returned medications is included in the capitation payment. Therefore, Pompton is not charging "an administrative charge or service fee . . . for services for which reimbursement is included as part of the Medicaid . . . fee." N.J.A.C. § 10:49-14.5.

Finally, Quinn argues that Pompton acknowledges an obligation to fully credit Medicaid by submitting reimbursement checks to Medicaid. Nevertheless, in order for there to be liability under § 3729(a)(7) of the FCA, a misrepresentation must be made to "conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7). Even if Pompton's payments are implicit representations that they are giving full credit, without a clear obligation to credit Medicaid, these representations are not made to avoid or decrease a legal obligation. As the District Court noted, "[e]ven if the relevant regulations could be construed to contain such an obligation, the lack of clear legal authority might preclude any finding that Defendants breached the obligation with the requisite level of knowledge." *Quinn*, slip op. at 19, n.16.

We conclude, therefore, that the failure to credit 100% of the cost of the medication is not a basis for FCA liability.[18]

V. CONCLUSION

For the foregoing reasons, we will affirm the District Court's grant of summary judgment against Thomas Quinn. In doing so, we are constrained by the lack of a regulation requiring that credit be given for recycled medications. We believe that Congress and/or the New Jersey legislature might serve Medicaid well if this lack of regulation were corrected.

[18] Quinn also appears to make a worthless services claim in his reply brief. He did not pursue, and the District Court did not rule on, this claim below. Therefore, we will not address it.