UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, et al., ex rel. Fox Rx, Inc., Plaintiff, -v- OMNICARE, INC., NEIGHBORCARE, INC., PHARMERICA CORP., and MANAGED HEALTH CARE ASSOC., INC., Defendants.	12cv275 (DLC) OPINION & ORDER

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DENISE COTE, District Judge:

A qui tam relator has brought this action under the federal False Claims Act, 31 U.S.C. § 3729 et seq. ("FCA"), and twenty-one states' and the District of Columbia's false claims statutes against entities that provide or assist others to provide pharmacy services to long-term care facilities ("LTCFs"). The defendants have moved to dismiss the Second Amended Complaint ("SAC") in this action. For the reasons given below, these motions are granted.

BACKGROUND

The following allegations are drawn from the SAC and documents integral to it. In broad strokes, the SAC asserts that the defendants have engaged in two illegal practices. The plaintiff asserts that the defendants (1) failed to substitute generic drugs for brand-name drugs in states that have laws

mandating such substitution, and (2) dispensed drugs after the termination date of a national drug code in states that have laws prohibiting pharmacies from dispensing drugs beyond their shelf-life expiration dates. By engaging in such practices, the plaintiff asserts that the defendants falsely indicated in "submissions" to a federal agency that the drugs they dispensed were "covered" by Medicare, and overcharged Medicare and Medicaid.

I. The Parties

The relator is Fox Rx, Inc., the corporate parent of Fox Insurance, Inc. (together, "Fox"). From 2006 to 2010, Fox sponsored prescription drug plans pursuant to the federal government's Part D prescription drug benefit program.[1] Fox asserts that it, along with the federal government ("Government") and the states, was a victim of the defendants' fraudulent practices.

Fox has sued four defendants: Omnicare, Inc. and NeighborCare, Inc. (together "Omnicare"), PharMerica Corp. ("PharMerica"), and MHA Long Term Care Network ("MHA"). Omnicare and PharMerica (together, "Pharmacy Defendants") provide pharmacy services to LTCFs. Through contracts with LTCFs, they dispense drugs to 1.4 million residents of LTCFs.

[1] In 2010, the Government terminated Fox's contract.

MHA contracts with independent long-term care pharmacies to, inter alia, negotiate reimbursement rates on their behalf and manage Medicare Part D claims. MHA receives an administrative fee per paid prescription. MHA provides its member pharmacists and pharmacies with its RxPertise software, which assists pharmacies in determining insurance plan coverage and covered therapeutic alternatives quickly.

MHA enters into agreements with Pharmacy Benefits Managers ("PBMs") on behalf of the pharmacies in its network that allow the PBMs to provide claims adjudication services when claims are submitted to Medicare and Medicaid for payment. One such agreement, executed by MHA and ProCare PBM, is attached as an exhibit to the SAC. In that document MHA agreed that the "Pharmacy Provider" also had certain obligations. (A "Pharmacy Provider" was defined in that agreement as the "dispenser of drug products and/or services.") Those obligations include the Pharmacy Provider's

> obligation to ensure that any pharmacist who is performing on behalf of the Pharmacy Provider shall use his or her professional judgment when filling prescript orders, and will comply with all legal, professional and ethical obligations applicable to pharmacists under the laws of the jurisdiction in which the prescription service is received.

(Emphasis added.) In addition, the "Pharmacy Provider agrees to inform [prescription drug plan] Part D enrollees at the point of

sale of any differential between the price of the lowest-priced therapeutically equivalent and bio-equivalent generic drug unless the lowest price drug is being purchased in accordance with 42 CFR § 423.132(a)."[2]

II. Federal Programs At Issue

A. Medicare Part D

The SAC asserts that the defendants defrauded the Government's Medicare Part D program. Medicare is a federally funded health insurance program for the elderly and disabled. The federal agency Centers for Medicare & Medicaid Services ("CMS"), which is a component of the Department of Health and Human Services ("HHS"), administers the Government's Medicare and Medicaid programs. 42 U.S.C. §§ 1395, 1396. In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. Pub. L. No. 108-173, 117 Stat. 2066, codified at 42 U.S.C. § 1395w-101 et seq.

[2] The allegations in the body of the SAC regarding this agreement make it seem as if the commitments recited here are being made by MHA as opposed to the Pharmacy Provider. When the attached agreement is examined, however, the agreement's terms make clear that the commitments are being made by Pharmacy Providers and concern acts performed by Pharmacy Providers in dispensing medication. The language quoted above is drawn from the agreement attached to the SAC and not from the body of the SAC.

To provide Part D benefits to enrollees, Medicare enters into contracts with private companies known as Part D sponsors. The sponsors administer prescription drug plans ("PDPs"). Fox was one such sponsor.

The sponsors may contract with pharmacies and pharmacy networks to provide the prescription drugs to Part D beneficiaries who have enrolled in their plans. When a Medicare Part D beneficiary has a prescription filled, the pharmacy presents a claim to the sponsor. The sponsor then notifies CMS of the transaction, including the cost the sponsor incurred in making a payment to the pharmacy.

CMS provides advance monthly payments to sponsors based on a subsidy per enrollee in the sponsor's program and on estimates of the subsidies CMS will be required to pay to the sponsors. At the end of a payment year, CMS reconciles the advance payments it made to the sponsor and the actual costs the sponsor has incurred. To the extent that the sponsor paid out more than it received in advance payments from CMS, CMS may provide the sponsor with additional payments, which are calculated according to a complex regulatory formula. 42 C.F.R. § 423.336 (a)-(b).

Part D sponsors may also enter into contracts with PBMs to create a pharmacy network and to administer their prescription drug programs. PBMs may develop and implement a prescription drug formulary, that is, a list of prescription drugs the

purchase of which will be reimbursed by the sponsor's plan. PBMs may also provide automated processing services to "adjudicate" claims submitted by pharmacies. CMS regulations require that the contracts between sponsors and either PBMs or pharmacies contain language obligating the pharmacy to comply with federal law and CMS instructions.

When pharmacies dispense drugs to a Medicare Part D enrollee, they submit a claim electronically to the enrollee's sponsor, often through a PBM. The claim contains information about the cost of the drug, the dispensing fee, any taxes paid, any payments made by the enrollee, and any rebates received from the drug's manufacturer or distributor. According to the SAC, if the drug was a brand-name "multisource drug," the pharmacy also provides the basis for its decision not to substitute a generic.

CMS has identified thirty-seven data fields related to a Prescription Drug Event ("PDE") that it requires Part D sponsors to submit when making claims to CMS for payment. In instructions published on April 27, 2006, CMS describes in detail the requirements for submitting PDE data ("Instructions").[3] The Instructions explain that "[a]s a

[3] The Instructions, which may be found at www.cms.gov and are cited throughout the SAC, are integral to the SAC and therefore are properly considered here. See L-7 Designs, Inc. v. Old Navy, LLC, 647 F.3d 419, 422 (2d Cir. 2011).

condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions" of the MMA. (Instructions 5.) Not all of the data that sponsors submit to receive payments, however, relate directly to the payments. As the Instructions explain,

> Much of the data, especially dollar fields, will be used primarily for payment. However, some of the other data elements such as pharmacy and prescriber identifiers will be used for validation of the claims as well as for other legislated functions such as quality monitoring, program integrity, and oversight.

(Id. at 5-6.) One of these fields, the "Drug Coverage Status Code," indicates whether the dispensed drug is covered by Medicare Part D and a given PDP. (Id. at 14, 20.) A "C" in this fields indicates coverage. (Id.)

The Instructions describe the origins of the PDE fields of data. CMS

> employ[s] the National Council for Prescription Drug Programs (NCPDP) industry standard whenever possible. Most data elements represent existing NCPDP fields where [CMS] employ[s] the same definition and field values that are currently in use per the NCPDP version 5.1 drug claim standard. CMS has also drafted several new fields for data that are not currently collected on industry drug claims but that are necessary for [CMS] to pay plans in accordance with the new law. All fields are consistent with NCPDP formatting. It is not [CMS's] intent to change NCPDP standards; the NCPDP format is developed independently from CMS.

(Id. at 11.) The Instructions recognize that "the pharmacy industry is highly automated" and that most plans "receive data electronically in NCPDP format." (Id. at 18.)

It is the plan sponsor, however, that is responsible for submission of the PDE data. As explained in the Instructions,

> For each dispensing event, the plan must submit a prescription drug event or PDE record. Most organizations or sponsoring entities will use a pharmacy benefit manager (PBM) or other third party administrator to process incoming claims from pharmacies. Claims typically undergo several rounds of transactions between these parties before the plan finally adjudicates a claim for payment. The PDE is a summary record that documents the final adjudication of a dispensing event.

(Id. at 9.)

B. Medicaid

The SAC also claims that the defendants defrauded the Government's Medicaid program. Medicaid is a cooperative program between the Government and the states that provides health care benefits principally to the indigent and to disabled individuals. To qualify for federal Medicaid funds, a state must comply with minimum federal standards.

The Medicaid statute requires participating states to pay for prescription drugs. Pharmaceutical manufacturers that want their drugs to be eligible for payment by Medicaid are required to enter into a Rebate Agreement with CMS under which they agree to give state Medicaid programs discounts through a quarterly rebate payment that is calculated based on the utilization of

the drug by the state's Medicaid program beneficiaries. This usage is tracked using the drug's unique 11-digit number called the National Drug Code ("NDC"), which is discussed below.

The SAC does not identify any claims submitted to Medicaid relating to defendants' alleged conduct. Instead, the SAC identifies claims submitted to CMS through Medicare Part D for those "also eligible for benefits under the Medicaid program."

III. Substitution of Generic for Brand-Name Drugs

A. DAW Code

According to the SAC, physicians sometimes write prescriptions for drugs by using the name of the branded drug even after its generic equivalent has become available on the market. To explicitly indicate a preference for the brand-name drug, the physician may write "dispense as written" ("DAW") or "brand medically necessary" ("BMN"). The SAC asserts that in several states, state law requires the pharmacist to dispense the generic version of the drug "[i]n the absence of a statement by the prescriber to the pharmacist that the brand-name drug alone must be dispensed."

The Instructions include definitions of "each data element and its specific potential use for CMS's payment process." (Instructions 11.) The field of data in the PDE that is at issue here is Field 17. Field 17 is entitled "Dispense as Written/Product Selection Code" or DAW Code. The Instructions

explain that "[t]his field will indicate the prescriber's instruction regarding substitution of generic equivalents or order to dispense the specific product written." (Id. at 13.)

There are ten numbers, from 0 to 9, that may be entered in Field 17. Entering the number "0" may indicate that no product selection was indicated on the prescription. The NCPDP definition of "0" in Field 17 is: "No Product Selection Indicated." The NCPDP "official" value meaning of DAW Code "0" is: "This is the field default value that is appropriately used for prescriptions where the product selection is not an issue. Examples include prescription written for single source brand products and prescriptions written using the generic name and a generic product is dispensed." According to the Instructions, when filling the DAW Code, "[i]f plans do not have source data to populate these fields, plans will use" a "default value" of "'0-No Product Selection Indicated.'" (Id. at 19.)

The SAC adds the NCPDP definitions for the remaining nine DAW Codes. For instance, "1" indicates that substitution was not allowed by the prescriber, and "8" indicates that substitution of the generic for the branded drug was allowed but the generic drug was not available in the marketplace.

The SAC asserts that the Pharmacy Defendants have utilized a "0" DAW Code when they have chosen not to substitute an available generic. According to the SAC, they have done so even

though state pharmacy laws and their contracts with Part D Sponsors have required the substitution.[4]

B. State Laws Requiring Substitution

Nine states require that pharmacists substitute generic drugs, in certain circumstances, for brand-name drugs.[5] For instance, Florida law provides that "[a] pharmacist who receives a prescription for a brand name drug shall . . . substitute a less expensive, generically equivalent drug product . . . [l]isted in the formulary of generic and brand name drug products" established by that pharmacy, except where otherwise requested by the purchaser or the prescriber. Fla. Stat. § 465.025(2), (5). Minnesota requires substitution with similar exceptions where, "in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug." Minn. Stat. § 151.21 sub. 3. Minnesota's law "does not apply when a pharmacist is dispensing a prescribed drug to persons covered under a managed

[4] The SAC also asserts that the Pharmacy Defendants entered into an Electronic Data Interchange ("EDI") agreement with CMS that certified that any data that it "transmitted to the PDE" would be "accurate and complete" to its "best knowledge, information and belief." Fox has since stipulated that the Pharmacy Defendants never entered into EDI agreements.

[5] See Fla. Stat. § 465.025; Haw. Rev. Stat. § 328-92; Minn. Stat. § 151.21; Nev. Rev. Stat. § 639.2583; N.J. Stat. Ann. § 24:6E-7; N.J. Admin. Code § 10:51-1.11(b)(2); N.Y. Educ. Law § 6816-a; 35 Pa. Cons. Stat. § 960.3; Tenn. Code Ann. § 53-10-205; W. Va. Code § 30-5-12b.

health care plan that maintains a mandatory or closed drug formulary." Id. at sub. 7. New Jersey's law requires substitution where the generic "shall reflect a lower cost to the consumer." N.J. Stat. Ann. § 24:6E-7.

IV. NDC Termination Date

A. National Drug Code (NDC)

A drug's National Drug Code, or NDC, is a unique 11-digit number that identifies the manufacturer and the product, among other things. Manufacturers submit a list of all of their drugs to the U.S. Food and Drug Administration ("FDA") and update that list twice a year. The updates include information about drugs that were previously listed for commercial distribution but whose distribution has been discontinued and the date that distribution ceased. 21 C.F.R. § 207.30(a)(2).

According to the SAC, CMS defines the termination date of an NDC generally as the self-life expiration date of the last batch of a discontinued drug sold by the manufacturer or the date that the FDA or the manufacturer withdraws a drug from the market for health and safety reasons or orders such withdrawal. Fox alleges that "[a]ny claims submitted to Medicare and Medicaid for drugs dispensed after the NDC termination date are invalid and are not reimbursable," but Fox has identified no statute or regulation that bars coverage under Medicare for the dispensation of a drug after its NDC termination date.

The Department of Health and Human Services's Office of the Inspector General issued a report in 2010 noting that "[f]ederal regulations do not specifically prohibit coverage of terminated drugs under the Medicare Part D program" and recommending that CMS issue regulations to do so. (Office of the Inspector General, U.S. Dep't of Health & Human Servs., Review of Terminated Drugs in the Medicare Part D Program 3 (Nov. 2010).[6]) In its response, CMS rejected the report's recommendation and noted that the use of NDC termination dates "is likely flawed, and cannot be relied upon as a proxy for identifying the dispensing of outdated products." (Id. at App'x A.) CMS noted that "these [NDC termination] dates are not infrequently subject to change, in certain cases by more than a year," and "the only authoritative source of data on final product expiration dates at the [NDC] level is data officially submitted by manufacturers to the Food and Drug Administration." (Id.) CMS explained "it is not uncommon for a pharmacy to bill using an NDC for the correct drug product but the incorrect package size" and cited an example where "the billing of [a] terminated NDC most likely

[6] Available at http://oig.hhs.gov/oas/reports/region7/70903130.pdf (last visited August 12, 2014.) The Court takes judicial notice of the fact that CMS, the agency that authored the regulations implementing Medicare Part D, made the statements that follow, as these statements "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2).

represented the pharmac[y's] failure to update the precise NDC in their billing systems to reflect the new package size and not that the pharmacy dispensed outdated drugs." (Id.) CMS emphasized that "it is important to recognize that such discrepancies do not support a finding that outdated drugs were dispensed." (Id.)

B. Drug Expiration Dates

Federal regulations require drug manufacturers or labelers to assign an expiration date to each pharmaceutical product, which must appear on the label. See 21 C.F.R. § 211.137. According to the SAC, the expiration date effectively establishes a shelf-life for the drug. Some states have enacted statutes that prohibit pharmacies from dispensing drugs after their shelf-life expiration dates, including prescriptions dispensed to Medicare Part D beneficiaries.

C. State Laws Prohibiting Dispensing of Expired Drugs

The SAC alleges that thirty-seven states prohibit a pharmacist from dispensing expired drugs. New York, for example, provides that

> Unprofessional conduct in the practice of pharmacy shall include . . . [h]olding for sale, offering for sale, or selling (i) any drug later than the date, if any, marked upon the label as indicative of the date beyond which the contents cannot be expected beyond reasonable doubt to be safe and effective and/or beyond the use date, which shall mean the expiration date of the drug.

N.Y. Comp. Codes R. & Regs. tit. 8, § 29.7(a)(17). Massachusetts law provides that "[a] pharmacist shall not dispense or distribute expired, outdated or otherwise substandard drugs . . . to any person or entity who is not licensed or legally authorized to receive such drugs." 247 Mass. Code Regs. 9.01(10).

V. Procedural History

Fox filed this action on January 12, 2012 on behalf of the United States, the District of Columbia and twenty-one states. Its first amended complaint was unsealed on November 12, 2013. A Pretrial Scheduling Order of January 21, 2014 required that any second amended complaint be filed by February 7, and provided that plaintiff would have no further opportunity to amend. Fox filed the SAC on February 10, 2014. The United States and the other government jurisdictions have declined to intervene in this action.[7]

The SAC contains twenty-five counts. Counts I and II allege false claims for payment to Medicare Part D and Medicaid, respectively, pursuant to 31 U.S.C. § 3729(a)(1)(A). Count III alleges a violation of § 3729(a)(1)(B). The remaining counts in the twenty-five-count complaint plead violations of state law.

[7] The Government submitted express notice that it and all other jurisdictions but the State of Indiana had elected not to intervene in this action. The State of Indiana has not advised the Court that it wishes to intervene in this action.

The defendants moved to dismiss the SAC on February 28, 2014. The motions were fully submitted on May 2.[8]

DISCUSSION

I. Legal Standards

A. Motion to Dismiss

When considering a motion to dismiss under Rule 12(b)(6), a court must accept as true all allegations in the complaint and draw all reasonable inferences in the plaintiffs' favor. Keiler v. Harlequin Enters. Ltd., 751 F.3d 64, 68 (2d Cir. 2014). The claims raised in the SAC require application of both the ordinary and heightened pleading standards in the Federal Rules of Civil Procedure. The ordinary pleading standard is set forth in Rule 8(a), Fed. R. Civ. P., which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Under Rule 8(a), to survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citation omitted). A complaint must do more, however, than offer "naked assertions devoid of further factual enhancement." Id. (citation omitted).

[8] The SAC is a lengthy document and its theories of liability are difficult to discern. As a result, the discussion of the plaintiff's theories of liability has been largely informed by the plaintiff's articulation of its claims in its opposition to the three motions to dismiss.

The court is "not bound to accept as true a legal conclusion couched as a factual allegation." Id. (citation omitted). Accordingly, a court may disregard "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." Id.

Applying the plausibility standard is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. at 679. "Plausibility depends on a host of considerations: the full factual picture presented by the complaint, the particular cause of action and its elements, and the existence of alternative explanations so obvious that they render plaintiff's inferences unreasonable." Fink v. Time Warner Cable, 714 F.3d 739, 741 (2d Cir. 2013) (citation omitted). Although the focus should be on the pleadings in considering a motion to dismiss, the court will deem the complaint to include "any written instrument attached to it as an exhibit, materials incorporated in it by reference, and documents that, although not incorporated by reference, are 'integral' to the complaint." L-7 Designs, 647 F.3d at 422 (citation omitted).

In addition, because Fox's claims allege fraud, they must also meet the heightened pleading standard set out in Rule 9(b). See Gold v. Morrison-Knudsen Co., 68 F.3d 1475, 1477 (2d Cir. 1995) (per curiam). Rule 9(b) requires plaintiffs to "state

with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). In order to comply with Rule 9(b), a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Nakahata v. New York-Presbyterian Healthcare System, Inc., 723 F.3d 192, 197-98 (2d Cir. 2013) (citation omitted). Under Rule 9(b) "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Nonetheless, "plaintiff[s] must allege facts that give rise to a strong inference of fraudulent intent." Nakahata, 723 F.3d at 198 (citation omitted); see also Acito v. IMCERA Group, Inc., 47 F.3d 47, 52 (2d Cir. 1995). The inference "may be established either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Lerner v. Fleet Bank, N.A., 459 F.3d 273, 290-91 (2d Cir. 2006) (citation omitted).

B. False Claims Act

The FCA creates liability when a person

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

> (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).[9] The FCA defines "claim" to include any request for money directed to (i) the United States or (ii) a "contractor, grantee, or other recipient," where the money "is to be spent or used on the Government's behalf or to advance a Government program or interest" and the Government either provides some portion of the money requested or "will reimburse the contractor, grantee, or other recipient for any portion of the money." Id. at § 3729(b)(2)(A). The FCA defines "knowingly" as either possessing actual knowledge or as acting in deliberate ignorance of falsity or action in reckless disregard of falsity, and not to require "proof of specific intent to defraud." Id. at § 3729(b)(1). A false record or statement is "material" to a false or fraudulent claim if it has "a natural tendency to influence, or [is] capable of

[9] The False Claims Act was amended by the Fraud Enforcement and Recovery Act of 2009 ("FERA") to broaden liability by eliminating certain limitations on FCA claims. See Pub. L. 111-21 § 4(a), 123 Stat. 1617, 1621-23. FERA became effective on May 20, 2009, except for the amended subsection (a)(1)(B), which applied "to all claims under the [FCA] that [we]re pending on or after" June 7, 2008. FERA § 4(f), 123 Stat. at 1625. Fox alleges false claims from 2006 through the date this action was filed, January 12, 2012. Because the Court holds that Fox has failed to state a claim under the broader, post-FERA statute, Fox's claims would fare no better under the pre-FERA provisions.

influencing, the payment or receipt of money or property." Id. at § 3729(b)(4).

A certification may be either factually or legally false. A factually false certification is one that involves "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001). A legally false certification is one that relies "upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term." Id. at 696. Noncompliance with regulations that are "irrelevant" to the Government's disbursement decisions, however, do not constitute legally false certifications since the FCA is "aimed at retrieving ill-begotten funds." Id. at 697. "[O]nly where a party certifies compliance with a statute or regulation as a condition to governmental payment" is there a violation of the FCA based on a legally false certification. Id.

Because state and local agencies are best suited to monitor quality of care issues in the health care industry, an impliedly false certification theory of liability is only available "in limited circumstances" in connection with Government health care reimbursement claims. Id. at 700. Thus, a claim of liability based on an implied false certification is viable "only when the underlying statute or regulation upon which the plaintiff relies

expressly states the provider must comply in order to be paid." Id. Statutory or regulatory provisions "establish[ing] conditions of participation" in a federal health care program are to be distinguished from those setting forth "prerequisites to receiving reimbursement." Id. at 701-02. The parties agree that the identical analytical framework applies to the state law claims pleaded by Fox.

The defendants move to dismiss the SAC on the ground that it fails to state a claim. They assert, among other things, that Fox seeks to convert two alleged violations of state regulations of pharmacy practice into FCA violations.

The defendants are correct. The SAC does not identify any federal statute or regulation that conditions reimbursement of Medicare Part D claims on the substitution of a generic drug for its brand name equivalent, on not dispensing drugs beyond the termination date of an NDC, or even on complying with the specific state pharmacy laws recited in the SAC. Fox's claims of legal falsity are addressed first, followed by its assertions of factual falsity concerning the DAW Code and the NDC termination date. Finally, there will be a brief discussion of issues that relate exclusively to defendant MHA.

II. Legal Falsity: Express or Implied Certification

Fox principally relies in this lawsuit on a theory of implied certification and cites four regulations in support of

such a claim. Three of these provisions do not set out conditions for payment of a claim; the fourth requires an express certification of truthfulness, but Fox has failed to adequately allege falsity of this certification. These regulations are addressed in turn.

A. Section 423.153(c)(1)

Fox first cites 42 C.F.R. § 423.153, which in pertinent part addresses steps Part D sponsors must take to establish systems of quality assurance. Among many other requirements, it provides that a

> Part D sponsor must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use that include all of the following --
> (1) Representation that network providers are required to comply with minimum standards for pharmacy practice as established by the States.

Id. at § 423.153(c)(1) (emphasis added).

The phrase "minimum standards for pharmacy practice" does not articulate a sufficiently clear rule to create a condition of reimbursement. See Mikes, 274 F.3d at 700. Nor has Fox explained the linkage of this regulation to CMS's payment of a claim. Section 153(c)(1) appears to describe actions entities must take to qualify as a Part D sponsor, as opposed to establishing the conditions for reimbursement of prescription claims. Id. at 701-02. For both of these reasons, Fox's claims premised on this theory of implied certification are dismissed.

B. Section 423.505(h)(1)

Fox next relies upon 42 C.F.R. § 423.505(h)(1). Section 505, which is entitled "contract provisions," describes the contract between the Part D plan sponsor and CMS, and lists the provisions that must be included in such contracts. Subsection (h)(1) states in pertinent part that a

> Part D plan sponsor agrees to comply with --
> (1) Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act).

Id. at § 423.505(h)(1) (emphasis added).

As was true for the prior regulation, this regulation is too general to support the FCA claims at issue here and does not describe a condition for payment of Part D claims. As a result, the motions to dismiss the SAC to the extent it is premised on a violation of § 505(h)(1) are granted.

C. Section 423.505(i)(3)(iv)

Fox also relies upon 42 C.F.R. § 423.505(i)(3)(iv),[10] which addresses the relationship between the sponsor and downstream entities. Section 505(i) outlines the commitments that a sponsor must obtain from its downstream and related entities, such as an agreement that HHS may audit their books and

[10] In the SAC and their papers, the parties cite to 42 C.F.R. § 423.505(i)(3)(v). After briefing, subparagraph (v) was redesignated (iv).

contracts. Then, in the subsection to which Fox refers, the regulation provides in pertinent part that

> every contract governing Part D sponsors and first tier, downstream, and related entities, must contain the following: . . . (iv) Each and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

Id. at § 423.505(i)(3)(iv) (emphasis added).

Again, this regulation is a component of the regulatory framework rather than a condition of the payment of any claim. It does not define with sufficient precision any duty or create any condition of payment. Moreover, even if this regulation could be read to impose obligations on certain downstream entities in connection with payment, Fox has not plausibly alleged that any of the defendants are the downstream entities to which this regulation is referring. Although Fox pleads that the defendants had "entered into subcontracts with the majority of Medicare Part D Sponsors, including Fox, either directly, or through PBMs," it has recently stipulated that Fox never had a contract with either Pharmacy Defendant. While MHA does not dispute that it had executed a contract with an entity related to Fox, as described below, the obligations concerning the manner in which medication is dispensed were imposed upon the pharmacies in MHA's network, and not on MHA. For each of these

reasons, any claim premised on this implied certification theory must be dismissed as well.

D. Section 423.505(k)(3)

The final regulation on which Fox relies is 42 C.F.R. § 423.505(k)(3), which relates to the certification of claims data by plan sponsors and their contractors. It is entitled "Certification of data that determine payment," and provides in relevant part that the

> CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) . . . are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.

Id. at § 423.505(k)(3) (emphasis added). Section 423.329(b)(3) applies to Part D sponsors such as Fox.

Unlike the preceding regulations, this provision does relate directly to the payment of Part D claims. It requires a certification that the submitted data is accurate, complete and truthful. Fox asserts that the FCA was violated when sponsors, including Fox, submitted PDE data to CMS that contained a false

or fraudulent use of the DAW Code or requested coverage for the dispensation of a drug past the reported NDC termination date.

While Fox has not alleged that the Pharmacy Defendants made such an express certification, that does not bar liability for causing Fox or other sponsors to falsely make such a certification, or for creating a false record material to a sponsor's false claim. Yet, as explained below, Fox has not plausibly pleaded that the claims for payment to which it refers in the SAC contained an inaccurate statement in connection with the use of the DAW Code or NDC termination dates. Accordingly, Fox has not adequately alleged that any certification made, or caused to be made, by the Pharmacy Defendants was false, or that the Pharmacy Defendants made, or caused to be made, any false records or statements material to a false or fraudulent claim.

III. Factual Falsity

Fox contends that the Pharmacy Defendants' use of a DAW code of "0" rendered their submissions to sponsors false where a generic drug was not substituted for a brand-name drug. Similarly, Fox argues that the Pharmacy Defendants' submission of claims to sponsors for drugs dispensed after their NDC termination dates was fraudulent.[11] The facts alleged do not support Fox's claims for the reasons that follow.

[11] Fox also points to the "Drug Coverage Status Code" field of PDE data and argues that the Pharmacy Defendants' use of a "C"

A. Generic Substitution and the DAW Code "0"

In the SAC, Fox asserts that the Pharmacy Defendants submitted factually false claims for reimbursement through the "fraudulent use" of the DAW code of "0." Fox alleges that the code "0" is properly reserved to indicate that there is "no approved generic equivalent available," but that the Pharmacy Defendants used that code when they knew, or were reckless in not knowing, that a cheaper generic form of the drug was "readily available." Fox has not alleged or argued that any federal statute or regulation required the substitution of generic for brand-name drugs, except insofar as Plan D sponsors are to comply with state pharmacy law. According to Fox, some state laws require substitution of the generic drug for the brand-name drug whenever the generic drug is available. The SAC asserts that the Pharmacy Defendants have chosen not to substitute a generic drug under circumstances required by state pharmacy law or by their contracts with Part D sponsors, and that their "illegal" utilization of a "0" DAW Code falsely represented that the branded drugs were "actually covered" by Medicare.

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code, indicating that a PDE was covered by Medicare, was false in these instances. Because, as explained below, coverage was not conditioned on either generic substitution or dispensation before the NDC termination date, Fox's "C" code allegations offer no independent support for Fox's claims.

In opposition to this motion, Fox alters this theory of liability. It disavows any claim that the Pharmacy Defendants wrongfully used DAW Codes to indicate that no generic drugs were available. Instead, it explains its claim as follows:

> It was [Pharmacy Defendants'] knowing dispensation of brand name drugs, when a generic was readily available, and its blanket use of DAW Code "0" (inappropriate unless falling into particular exceptions, not present here), that create the false claim. That indiscriminate use of Code "0" . . . ignored [Pharmacy Defendants'] regulatory and contractual obligations to create and submit a PDE with an accurate and complete DAW code explanation for each drug dispensed.

The Pharmacy Defendants contend that Fox has failed to plead that they submitted factually false claims for reimbursement. They emphasize several undisputed facts. The parties agree that the claims submitted to CMS that are at issue here correctly listed the brand-name drug that was dispensed and for which reimbursement was sought. They also agree that the existence of a generic substitute for the branded drug was publicly available information that any sponsor could examine if it were material to its decision-making. And they agree that there is no federal regulation requiring substitution of a generic for a branded drug.

Whether as pleaded or as explained in opposition to the motions to dismiss, Fox's claim of factual falsity fails. Fox has not alleged sufficient facts from which one could plausibly

infer that the use of DAW Code "0" is false or inaccurate when dispensing a branded drug. CMS permits the DAW Code of "0" to indicate that "No Product Selection [was] Indicated" on the prescription. Thus, if a doctor prescribes a drug for which there are both branded and generic alternatives, and the pharmacist dispenses the branded version, there does not appear to be any literal falsity associated with the pharmacist's use of the DAW Code "0" in the NCPDP data field, or the sponsor's use of the DAW Code "0" in submitting the PDE data. Indeed, CMS empowers PDP sponsors to create drug formularies and to decide which drugs to include on those formularies. Accordingly, sponsors may decide whether to include both the branded drug and the generic version in its formulary and thereby pay for brand name drugs when a generic version is available. See 42 C.F.R. § 423.120(b).

At its heart, Fox's claim is not that there has been any false statement to CMS in the use of DAW Code "0." Fox is asserting something quite different. It is asserting that pharmacists should not have been dispensing branded drugs in those state jurisdictions with statutes mandating use of generic drugs. But, this assertion does not constitute a false statement claim, a violation of the FCA, or a violation of the MMA.

Fox's theory of liability appears to rest on the interplay of the statutes in some state jurisdictions that mandate use of generics and an implied requirement that the DAW Code of "0" may be used when, and only when, no other code applies. In those jurisdictions with statutes requiring the dispensing of generic drugs, Fox reasons that the branded drug may only be lawfully dispensed when the generic is unavailable. On the assumption that the pharmacist is adhering to state law and yet dispensing the branded drug, Fox apparently concludes that that must mean that no generic drug was available to be dispensed. In such circumstances, the pharmacist who dispenses the branded drug should use the DAW Code "8" to indicate that the generic drug was not available in the marketplace and may not use the DAW Code "0" to indicate that the prescribing physician made no selection of a branded or generic drug.

On the other hand, if the pharmacist ignored state law and dispensed branded drugs even when the generic version is available -- which is the crux of Fox's accusation -- the pharmacist should not use the DAW Code "8" to indicate that the generic drug was unavailable. Using an "8" in such circumstances might constitute a false statement. The appropriate code is "0" -- the very code that Fox asserts was utilized here. Thus, even under this construction of Fox's theory of liability, there is no factually false statement made

when the pharmacist (or the sponsor) uses the DAW Code "0". For these reasons, and those set out above, the claims associated with the substitution of a branded drug for a generic version of the drug and the use of the DAW Code "0" are dismissed.

B. NDC Termination Date

Fox has alleged a violation of the FCA premised on a second false statement. Fox asserts that the Pharmacy Defendants have submitted claims for drugs that were dispensed on a date following the NDC termination date for the drug, and has given as an example a drug that was dispensed 730 days after its NDC termination date. Fox asserts that this violates the FCA because certain states prohibit dispensing expired drugs; those state requirements constitute minimum standards of pharmacy practice; and dispensing expired drugs amounts to providing "worthless" services.

It is unnecessary to unravel each of the embedded assumptions in this assertion of illegality. It is assumed for purposes of this discussion that the submission to CMS of a claim for payment of a drug that was dispensed after the drug's expiration date constitutes a violation of the FCA. Despite that assumption, Fox has failed to plead a violation of the FCA.

The SAC does not assert that any Pharmacy Defendant dispensed drugs after the expiration date for the drugs. Instead, the SAC asserts that the Pharmacy Defendants dispensed

drugs after their NDC termination dates and argues in opposition to these motions to dismiss that the NDC termination date should be equated with the drug's expiration date. Because Fox has failed to adequately plead, however, that the termination date of an NDC number and the expiration date of a quantity of manufactured drugs are the same, these claims must be dismissed. As noted above, an NDC is a unique number for every drug. When an NDC number is terminated, that may reflect a simple change in the quantity of pills contained in a given package. In contrast, the expiration date for a batch of drugs is placed on the packaging for the drugs and is commonly understood to reflect the shelf-life of the product contained within that package.[12]

Accordingly, Fox's allegations that the Pharmacy Defendants dispensed drugs after the termination date of the NDCs associated with those drugs do not constitute an adequate

[12] Fox also appears to assert a second implied certification claim arising from a duty to properly use NDCs. Fox argues in opposition to these motions that the defendants are required to comply with the data transmission standards that CMS has adopted, including the use of NDCs, citing 45 C.F.R. § 162 et seq.; that pharmacists may only dispense drugs pursuant to prescriptions that are valid under state law, citing 42 U.S.C. § 1395w-102(e); and that only properly prescribed and recorded drug claims may be submitted to CMS. Without identifying which of the many provisions of Section 162 it is relying upon to assert this false certification claim, Fox has failed to give the defendants fair notice of the alleged violation. Thus, this vaguely worded claim based on an alleged misuse of NDCs must be dismissed.

allegation that the Pharmacy Defendants dispensed expired drugs. For these reasons, Fox's claims related to NDC termination dates are dismissed.

IV. MHA

The claims against MHA merit additional discussion. As described in the SAC, MHA is not a pharmacy. It does not fill prescriptions or make judgments about how they should be filled. It provides services that connect independent pharmacies providing LTCF services with PBMs. It receives a payment for each reimbursed prescription, but is not involved in submitting any claims for reimbursement.

The SAC attempts to plead a claim against MHA premised on MHA's purported failure to abide by its contractual obligation to oversee its network of pharmacies and to ensure that those pharmacies comply with the law. But, in doing so the SAC misdescribes the terms in a form contract that MHA executed with a PBM named ProCare PBM. An examination of the ProCare PBM agreement, which is attached as an exhibit to the SAC, shows that the commitments described within the agreement that are pertinent to Fox's claim are duties imposed on pharmacies and not duties assumed by MHA. In any event, for the reasons already discussed, even if MHA could be held responsible for the action of the pharmacies in its network, Fox has failed to state an FCA claim against those pharmacies.

Fox argues in opposition to this motion that it is premature to dismiss its claims against MHA since MHA has raised nothing more than a factual dispute over the terms of the ProCare PBM agreement, and specifically whether that agreement may be read to define MHA as a "pharmacy provider." Fox points to the prologue to the agreement, which explains that it is an agreement made between ProCare PBM and the undersigned LTC "Pharmacy Provider." The signatory is MHA. Fox argues that by signing the agreement, MHA "expressly assumed certain compliance obligations of its network pharmacies and then failed in those obligations." It argues that this constitutes more than a "simple agency relationship."

Fox cannot avoid the plain and unambiguous meaning of the agreement by pointing to MHA's signature on the agreement. The agreement has a definition of "Pharmacy Provider" that excludes MHA. It is undisputed, and acknowledged in the SAC, that MHA is not a pharmacy and does not dispense medication. The agreement defines the "Pharmacy Provider" as the entity that dispenses drugs. MHA's signature on behalf of its network of pharmacies does not convert MHA into a dispenser of drugs. All of the obligations in the agreement to which Fox points apply solely to the entities that dispense drugs.[13]

[13] MHA's duties vis-à-vis its network of pharmacies are defined in other agreements to which the SAC refers, but which are not

Because MHA is not a pharmacy and did not dispense medication it is not surprising that Fox has also failed to allege the fraud claims against MHA with particularity. The SAC does not allege with particularity any act by MHA that resulted in a branded drug being dispensed instead of a generic, in a pharmacist dispensing a medication beyond its expiration date or even its NDC termination date, or in the submission of any inaccurate information. There is also no allegation from which MHA's fraudulent intent may be inferred. For each of these reasons as well, the claims against MHA must be dismissed.

CONCLUSION

Defendants PharMerica's, MHA's, and Omnicare and NeighborCare's February 28, 2014 motions to dismiss the Second

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attached to the SAC. MHA has submitted copies of those agreements in support of this motion to dismiss. Fox argues that the documents are not integral to the SAC and may not be properly considered on this motion. Yet the SAC describes the legal relationships between MHA, its pharmacies, and PBAs; these documents are the embodiment of those legal relationships. Thus these documents are integral to the SAC and, accordingly, may be considered on this motion. See L-7 Designs, 647 F.3d at 422. Nonetheless, since their examination would simply confirm the analysis already undertaken here, there is no need to consider them.

Amended Complaint are granted. The Clerk of Court shall enter judgment for defendants and close the case.

Dated: New York, New York
August 12, 2014

DENISE COTE
United States District Judge