IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA ex rel. FOX RX, INC., **Plaintiff,** **v.** **OMNICARE, INC. and NEIGHBORCARE, INC.,** **Defendants.**	**1:11-cv-00962-WSD**

OPINION AND ORDER

This matter is before the Court on Defendants Omnicare, Inc. and NeighborCare, Inc.'s Motion to Dismiss Pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b) [33] ("Motion to Dismiss"). Also before the Court is Relator Fox Rx, Inc.'s Motion for Oral Argument on Defendants' Motion to Dismiss [53] ("Motion for Oral Argument").

I. BACKGROUND

Relator Fox Rx, Inc. ("Relator") initiated this *qui tam* action under the False Claims Act ("FCA"). Relator filed its Second Amended Complaint ("Complaint") in this action on August 4, 2011, against Defendants Omnicare, Inc. and

NeighborCare, Inc. ("Defendants"). (See generally 2d Am. Compl. [14].) The United States declined to intervene.

A. Medicare Part D[1]

This FCA action involves allegedly "false claims" submitted to the government under Medicare Part D ("Part D"). Part D is the federally funded prescription drug benefit program available to Medicare participants who voluntarily enroll. The program is administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency within the Department of Health and Human Services. CMS provides drug coverage to Part D enrollee beneficiaries through private Part D Plans ("PDP") offered and administered by private PDP sponsors authorized by CMS.

To participate in Part D, beneficiaries enroll in a PDP of their choice. Beneficiaries pay premiums to their PDP sponsors. Their PDP coverage is limited by certain deductibles, co-payments, and benefit caps. Beneficiaries have their prescriptions filled at private pharmacies, which are generally within a PDP's contract network. The pharmacies submit their PDP bills for payment by the PDP sponsor, or the PDP sponsor's subcontractor, which pays the prescription costs not

[1] This brief background to Medicare Part D is not a complete overview of the program or its intricacies. It is offered simply to provide general context for the allegations in the Complaint.

paid directly by the beneficiary. CMS ultimately reimburses the PDP sponsor for varying portions of the prescription costs. See generally Omnicare, Inc. v. UnitedHealth Group, Inc., 594 F. Supp. 2d 945, 948–49 (N.D. Ill. 2009) (providing an overview of Medicare Part D).

B. Complaint Allegations

The Complaint alleges that Defendants are specialty pharmacies providing services to long-term care facilities ("LTCFs"), such as nursing homes, throughout the United States. (2d Am. Compl. intro., at 2, ¶ 3.) Defendants provide two relevant services: (1) they act as a "dispensing pharmacy" by filling prescriptions for LTCF residents and (2) they act as a "consulting pharmacy" by providing "consulting pharmacy services" to LTCFs, which LTCFs are required to obtain under federal regulations. (Id. intro., at 2, ¶¶ 45–47.) In their dispensing pharmacy role, Defendants' customers include beneficiaries of Part D. (E.g., id. intro., at 2, ¶ 33.) In their consulting pharmacy role, Defendants acquire specific knowledge of the medical records and drug regimens of LTCF residents who are Part D beneficiaries. (Id. ¶¶ 55–56.)

In an eight (8)-count Complaint, Relator alleges that, since 2006, Defendants have engaged in four (4) separate schemes to defraud the Part D program by seeking reimbursement for "thousands" of prescriptions, filled on behalf of Part D

beneficiaries, that are not covered or are not reimbursable by Part D. (See id. ¶¶ 33, 48, 67, 80, 91.)

1. *"Off-Label" AAP (Counts I and II)*

In Counts I and II, Relator alleges that, in "thousands" of cases "from 2006 to the present," Defendants filled and sought reimbursement for prescriptions for eight (8) atypical antipsychotic drugs ("AAP") prescribed to Part D beneficiaries suffering from dementia. (Id. ¶¶ 37, 48.) Relator alleges that the prescription of AAP to dementia patients constitutes an "off-label" use of such drugs—that is, a use not authorized by the Food and Drug Administration or supported in the authorized medical literature—and is therefore not for a "medically accepted indication." (Id. ¶¶ 34–41.) Relator alleges that, for a drug to be reimbursable under Part D, it must be for a "medically accepted indication." (Id. ¶ 44.) Relator further alleges that Part D does not cover, or pay for, "off-label" drugs, which are not for a "medically accepted indication," such as the AAP medication alleged. (See id.) Relator thus alleges that Defendants are liable under the FCA because they (i) submitted "false claims" for reimbursement for "off-label" AAP prescriptions because they were not for a "medically accepted indication" (as alleged in Count I) and (ii) made "records or statements" related to reimbursement requests for such "off-label" AAP prescriptions (as alleged in Count II). (Id.

¶¶ 97–109.) In support of Counts I and II, Relator attaches several spreadsheets purporting to detail "examples" of the "off-label" AAP prescriptions filled by Defendants. (See id. Exs. A–C4.) These spreadsheets apparently seek to illustrate the claims alleged in Counts I and II.

2. *Prescription Splitting (Counts III and IV)*

In Counts III and IV, Relator alleges that, in "thousands of cases" since January 1, 2006, Defendants only partially filled Part D beneficiaries' prescriptions, requiring the beneficiaries to seek multiple refills for the same prescription. (Id. ¶¶ 65–69.) This practice, which Relator refers to as "prescription splitting," enabled Defendants, Relator alleges, to charge multiple dispensing fees, rather than the single dispensing fee to which Relator claims Defendants only were entitled. (Id.) Relator alleges that Part D does not cover, or pay for, multiple dispensing fees resulting from the "split prescriptions" alleged. (Id. ¶¶ 114, 120.) Relator specifically alleges that Defendants violated the FCA by (i) submitting "false claims" in the form of requests for reimbursement for multiple dispensing fees based on "split prescriptions" (as alleged in Count III) and (ii) making "records or statements" related to reimbursement of these "split prescriptions" (as alleged in Count IV). (Id. ¶¶ 110–122.) In support of Counts III and IV, Relator attaches two spreadsheets purporting to detail "examples" of "prescription

splitting" by Defendants. (See id. Exs. D–E.) These spreadsheets also apparently seek to illustrate the claims alleged in Counts III and IV.

3. *Failure to Obtain "Prior Authorization" (Counts V and VI)*

In Counts V and VI, Relator alleges that, in "over five thousand cases in 2009 and 2010" and other cases since January 1, 2006, Defendants filled and sought reimbursement for AAP prescriptions filled (a) without first obtaining from the beneficiaries' PDP sponsors authorization to fill the prescriptions, as required by the sponsors' CMS-approved formularies, and (b) after authorization was denied. (Id. ¶¶ 80–81.) Relator further alleges that Medicare Part D does not cover AAP prescriptions filled without prior authorization from the PDP sponsor where "prior authorization" is required under the PDP formulary. (Id. ¶¶ 73–79, 127, 133.) Relator thus alleges that Defendants violated the FCA by (i) submitting "false claims" in the form of requests for reimbursement for AAP prescriptions filled without prior authorization for beneficiaries whose PDP formularies required prior authorization for AAP (as alleged in Count V) and (ii) making "records or statements" related to these unauthorized requests (as alleged in Count VI). (Id. ¶¶ 123–135.) In support of Counts V and VI, Relator attaches a spreadsheet, apparently as an illustration, purporting to detail "examples" of AAP prescriptions filled by Defendants without required prior authorization. (See id. Ex. F.)

4. *Failure to Charge "Co-Payments" (Counts VII and VIII)*

In Counts VII and VIII, Relator alleges that, in "over three thousand cases in 2009 and 2010," Defendants filled and sought reimbursement for prescriptions after waiving, or without charging, Part D beneficiaries' required co-payments (i.e., the amount of each prescription, as specified in the PDP formulary, that the beneficiary is responsible for paying directly to the dispensing pharmacy). (Id. ¶ 91.) Relator alleges that, except in limited circumstances not applicable here, Part D does not cover, or pay for, prescriptions unless the beneficiaries are charged and have paid their required co-payments. (Id. ¶¶ 140, 147.) Relator alleges that Defendants waived the co-payments to induce the beneficiaries to purchase prescriptions under their PDP, which Relator alleges is a violation of the Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. (Id. ¶¶ 11–12, 89, 141, 148.) Relator alleges that Medicare Part D does not cover, or pay for, prescriptions that violate the Medicare Anti-Kickback Statute. (Id. ¶¶ 141, 148.) Relator thus alleges that Defendants violated the FCA by (i) submitting "false claims" in the form of requests for reimbursement for prescriptions filled after wrongfully waiving co-payments in violation of the Medicare Anti-Kickback Statute (as alleged in Count VII) and (ii) making "records or statements" related to reimbursement requests for prescriptions filled without co-payments and in

violation of the Anti-Kickback Statute (as alleged in Count VIII). (Id. ¶¶ 136–150.) In support of Counts VII and VIII, Relator attaches an illustrating spreadsheet purporting to detail "examples" of prescriptions filled by Defendants without charging required co-payments. (See id. Ex. G.)

C. Procedural History

On December 21, 2011, Defendants filed their Motion to Dismiss. In it, they move for the dismissal of each of the Complaint's counts on the following grounds: that Counts I through VI fail to state a claim under the FCA because the counts fail to allege a cognizable "false claim"; that Counts II, IV, VI, and VIII fail to state a claim under subsection (a)(1)(B) of 31 U.S.C. § 3729 because the counts fail to adequately allege "false records or statements"; and, that all of the counts fail to state a claim because they are not pleaded with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. Defendants filed exhibits to support their Motion to Dismiss.

On January 19, 2012, Relator filed its opposition to the Motion to Dismiss [35]. Relator attached documents and spreadsheets to support its opposition that were not part of the Complaint [35-1 to 35-24]. On February 1, 2012, despite having declined to intervene, the United States filed a "statement of interest" in response to the Motion to Dismiss in which it opposed certain grounds for

dismissal advanced by Defendants [42]. Specifically, the Government argues that reimbursement under Part D is allowed only for "medically accepted indications" of a drug; that Part D's provisions limiting coverage to "medically accepted indications" are not ambiguous; that the determination of whether a use is a "medically accepted indication" requires a fact-intensive, drug-by-drug inquiry not capable of resolution on a motion to dismiss; and that the filling of a prescription and submission of a reimbursement claim is not a prerequisite to an appeal of a PDP sponsor's decision not to authorize coverage for a prescription. The Government does not take a position on the other issues raised in Defendants' Motion to Dismiss or on the adequacy of Relator's pleading. Defendants filed a reply brief [43] on February 6, 2012 and a response to the government's statement of interest [49] on February 21, 2012.[2]

[2] On February 23, 2012, Relator filed its Motion for Oral Argument. In it, Relator requests a hearing on Defendants' Motion to Dismiss because of the "complexity of the issues presented" and to address the numerous exhibits attached to Defendants' Motion. On February 24, 2012, Defendants filed their opposition to the Motion for Oral Argument [54]. Local Rule 7.1E provides that motions "will be decided by the court without oral hearing, unless a hearing is ordered by the court." The Court determines that oral argument is not necessary, and Relator's Motion for Oral Argument is denied.

II. DISCUSSION

A. Legal Standard

On a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court must "assume that the factual allegations in the complaint are true and give the plaintiff[] the benefit of reasonable factual inferences." Wooten v. Quicken Loans, Inc., 626 F.3d 1187, 1196 (11th Cir. 2010), cert. denied, 132 S. Ct. 245 (2011). Although reasonable inferences are made in the plaintiff's favor, "'unwarranted deductions of fact' are not admitted as true." Aldana v. Del Monte Fresh Produce, N.A., 416 F.3d 1242, 1248 (11th Cir. 2005) (quoting S. Fla. Water Mgmt. Dist. v. Montalvo, 84 F.3d 402, 408 n.10 (1996)). Similarly, the Court is not required to accept conclusory allegations and legal conclusions as true. See Am. Dental Ass'n v. Cigna Corp., 605 F.3d 1283, 1290 (11th Cir. 2010) (construing Ashcroft v. Iqbal, 556 U.S. 662 (2009); Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007)).

"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.'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 570)). Mere "labels and conclusions" are insufficient. Twombly, 550 U.S. at 555. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw

the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 556). This requires more than the "mere possibility of misconduct." Am. Dental, 605 F.3d at 1290 (quoting Iqbal, 556 U.S. at 679). The well-pled allegations must "nudge[] their claims across the line from conceivable to plausible." Id. at 1289 (quoting Twombly, 550 U.S. at 570).

Rule 9(b) of the Federal Rules of Civil Procedure requires that a party alleging fraud "must state with particularity the circumstances constituting fraud." To satisfy Rule 9(b), the complaint must set forth "(1) precisely what . . . representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud." Garfield v. NDC Health Corp., 466 F.3d 1255, 1262 (11th Cir. 2006) (quoting Ziemba v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001)). "This means the who, what, when, where, and how . . . ." Id. (quoting Gross v. Medaphis Corp., 977 F. Supp. 1463, 1470 (N.D. Ga. 1997)). Intent and knowledge "may be alleged generally." Fed. R. Civ. P. 9(b).

B. Analysis

Relator argues that, by engaging in the four (4) reimbursement schemes alleged, Defendants are liable under two provisions of the FCA: subsections (a)(1)(A) and (a)(1)(B) of 31 U.S.C. § 3729.[3] Those provisions impose liability on "any person who—(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) (Supp IV. 2010). To state a claim under either provision, a relator must allege a "false claim." Under subsection (a)(1)(B), a relator is required also to allege a "false record or statement." Both provisions are subject to the heightened pleading requirement of Rule 9(b). In their Motion to Dismiss, Defendants argue that Relator fails to plead a "false claim" in Counts I through VI, that Relator fails to plead a "false record or statement" in Counts II,

[3] The FCA was amended in 2009. See Fraud Enforcement and Recovery Act of 2009, Pub L. 111-21 § 4(a), 123 Stat. 1617, 1621–23. The Complaint alleges Defendants' liability only under the post-amendment version of the Act. Defendants contend that the majority of Relator's claims are governed by the pre-amendment version of the Act; however, Defendants also state that the amendments are not material to their Motion to Dismiss. (See Mem. Law Supp. Mot. Dismiss [33-2] at 6 n.4.) For purposes of the Motion to Dismiss, the Court applies the amended version of the FCA.

IV, VI, and VIII, and that Relator fails to plead any of its claims with particularity sufficient to satisfy Rule 9(b).

1. *Failure to Plead a False Claim (Counts I to VI)*

A claim may constitute a "false claim" under the FCA if it is submitted without statutory or regulatory preconditions to payment having been met, or it is submitted despite violations of statutes or regulations that would preclude payment. See McNutt ex rel. United States v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1259–60 (11th Cir. 2005); see also United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305–06 (3d Cir. 2011) (distinguishing "legally false" claims from "factually false" claims and explaining that "legally false" claims include claims made by a claimant "without disclosing that it violated regulations that affected its eligibility for payment"). When the government does not owe a payment because of an underlying violation of a precondition to payment, the claim for that payment is a "false claim." McNutt, 423 F.3d at 1259.

a. "Off-Label" AAP (Counts I and II)

Defendants move for the dismissal of Counts I and II on the ground that seeking reimbursement for AAP prescriptions filled for Part D beneficiaries suffering from dementia cannot constitute a "false claim" under the FCA. Defendants advance four independent grounds for their argument: (i) that a

pharmacy cannot be liable for a "false claim" by filling, and seeking payment for, an "off-label" prescription because pharmacies do not have a duty to determine whether a prescription is "off-label"; (ii) that AAP prescribed to dementia patients are not "off-label"; (iii) that Part D covers "off-label" prescriptions; and (iv) that Part D coverage of "off-label" prescriptions is ambiguous and, therefore, cannot be the basis for liability under the FCA.

(i) *Whether a Pharmacy Can Violate the FCA by Filling "Off-Label" Prescriptions*

Defendants first argue that, as pharmacies, they do not have a duty to determine whether a drug has been prescribed for an "off-label" use, that it is a physician's or other prescriber's duty to determine if a drug is properly prescribed, and, in the absence of a duty to determine if a use is "off-label," Defendants' prescription billing conduct does not violate Part D's reimbursement requirements. The Court agrees that pharmacies do not have a duty to identify "off-label" prescriptions when prescribed. See, e.g., Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4229 (CMS Jan. 28, 2005) (responding to public comments on proposed Part D regulations and "clarify[ing] that pharmacists will not be required to contact each physician to verify whether a prescription is being used for other than a medically accepted indication"). Relator, however, does not allege that Defendants breached the "off-label" use

duty defined by Defendants. Relator does allege that Defendants had actual knowledge that certain prescriptions were "off-label"—knowledge that Defendants gained in their capacity as LTCF consulting pharmacies. Relator alleges further that Defendants filled "off-label" prescriptions and sought reimbursement for them aware that the prescriptions were for an "off-label" indication.[4] Counts I and II are not dismissed on this ground asserted by Defendants.

(ii) *Whether AAP Prescribed to Dementia Patients Are "Off-Label"*

Defendants next argue that the prescription of AAP to dementia patients is not "off-label"—that is, the use of AAP to treat dementia patients is a "medically accepted indication." A use of a drug is a "medically accepted indication" if the use is either "approved under the Federal Food, Drug, and Cosmetic Act" or "supported by one or more citations included or approved for inclusion in any of [certain specified medical] compendia." 42 U.S.C. § 1396r-8(k)(6) (2006), cross-

[4] Citing United States v. Science Applications International Corp., 626 F.3d 1257 (D.C. Cir. 2010), Defendants argue further that the knowledge gained by the "consulting" sides of their businesses cannot be imputed to the "dispensing" sides of their businesses. Science Applications holds that the scienter element of FCA liability cannot be established solely by constructive "collective knowledge" (i.e., knowledge of different elements by different employees without evidence that any one employee had knowledge of all of the elements of liability). 626 F.3d at 1274–77. The Complaint here alleges actual knowledge on the part of Defendants. Thus, the Complaint's allegations, which the Court must accept as true, do not inappropriately rely on constructive "collective knowledge."

referenced in 42 U.S.C. § 1395w-102(e)(4)(A)(ii) (Supp. IV 2010). The specified medical compendia include "the DRUGDEX Information System." Id. § 1396r-8(g)(1)(B)(i).

Defendants contend that "most" of the AAP described in the Complaint are listed "at some point during the timeframe of the Complaint's allegations" in the DRUGDEX for the treatment of dementia patients. To support this argument, Defendants submit, and refer the Court to, two excerpts of the DRUGDEX, which, Defendants contend, "list" two particular AAP for "dementia." On this basis, Defendants argue that AAP prescribed to dementia patients are not "off-label."

Defendants' DRUGDEX evidence is not appropriate for consideration on a motion to dismiss under Rule 12(b)(6). See, e.g., Harper v. Lawrence County, 592 F.3d 1227, 1232 (11th Cir. 2010) (stating that, in ruling on a motion to dismiss, a district court "may not consider matters outside the pleadings"). But even if the Court could consider Defendants' evidence that some AAP were "listed" in the DRUGDEX for some time periods, the evidence does not establish that the use of the eight (8) AAP described in the Complaint for dementia patients is a "medically accepted indication" for all periods covered by the Complaint. See United States ex rel. Rost v. Pfizer, Inc., 253 F.R.D. 11, 16 (D. Mass. 2008) (explaining that a "listing" of a use in the DRUGDEX is not necessarily "support" for the use, as

required under 42 U.S.C. § 1396r-8(k)(6)); United States ex rel. McDermott v. Genentech, Inc., No. 05-147-P-C, 2006 WL 3741920, at *13 (D. Me. Dec. 14, 2006) (Report & Recommendation) (recommending dismissal of an "off-label" FCA claim, in part, because the contested use of the single drug at issue was "recognized" in the DRUGDEX during the entire period of time covered by the complaint), adopted, No. 2:05-cv-147, 2007 WL 2128410 (D. Me. July 24, 2007). The Court concludes that Counts I and II are not required to be dismissed on this ground asserted by Defendants.

(iii) *Whether Part D Covers "Off-Label" Drugs*

Part D covers only drugs satisfying the Social Security Act's definition of "covered Part D drug." That definition provides, in pertinent part, as follows:

> Except as provided in this subsection, for purposes of this part, the term "covered part D drug" means—
>
> (A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r-8(k)(2) of this title . . .
>
> . . .
>
> *and such term includes . . . any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).*

42 U.S.C. § 1395-102(e)(1) (2006 & Supp. IV 2010) (emphasis added).

Defendants argue that the last clause of the quoted definition (the "includes" clause), emphasized above, creates only a floor to coverage—that is, that Part D must at least cover drugs for a "medically accepted indication" and that Part D may

cover AAP prescribed for "off-label" uses. Relator and the United States argue that the "includes" clause creates a ceiling to coverage—that is, that Part D covers only drugs for a "medically accepted indication."[5]

In interpreting a statute, the Court begins with "the language of the statute itself" and "read[s] the statute to give full effect to each of its provisions." United States v. DBB, Inc., 180 F.3d 1277, 1281 (11th Cir. 1999). "It is a cardinal principle of statutory construction that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.'" Nunnally v. Equifax Info. Servs., LLC, 451 F.3d 768, 773 (11th Cir. 2006) (quoting TRW, Inc. v. Andrews, 534 U.S. 19, 31 (2001)). The Court must not "look at one word or term in isolation," but must instead "look to the entire statutory context." DBB, 180 F.3d at 1281. This means that, "[i]n addition to the 'particular statutory language at issue,' federal courts also must consider 'the language and design of the statute as a whole' to determine 'the plain meaning of the statute.'" Tello v. Dean Witter Reynolds, Inc., 410 F.3d 1275, 1278 (11th Cir. 2005) (quoting K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1988)).

[5] The parties do not dispute that AAP otherwise fall within the definition of "covered part D drug."

The statutory definition here may be inartfully drafted, but under the relevant canons of construction its meaning is clear: to be a "covered Part D drug," the drug must be used for a "medically accepted indication." The definition begins by stating that a covered drug is "a drug that may be dispensed only upon a prescription and that is described in [42 U.S.C. § 1396r-8(k)(2)(A)(i)–(iii)]." 42 U.S.C. § 1395-102(e)(1)(A). This portion of the definition, the parties agree, encompasses all of the AAP described in the Complaint. It does not contain any limitation based on how the drug is used or the reason the drug is prescribed. Both "on-label" and "off-label" AAP fall within the first portion of the definition.

The "includes" clause follows the first portion of the definition. See id. Although the "word 'includes' is usually a term of enlargement, and not of limitation," see Argosy Ltd. v. Hennigan, 404 F.2d 14, 20 (5th Cir. 1968), this is not invariably so. See, e.g., Adams v. Dole, 927 F.2d 771, 776–77 (4th Cir. 1991); see also Samantar v. Yousuf, 130 S. Ct. 2278, 2287–88 (2010) (recognizing that "use of the word 'include' can signal that the list that follows is meant to be illustrative rather than exhaustive" but holding that the statute under consideration was not susceptible to broad interpretation). The Court's primary duty in construing the "includes" clause is to give the clause meaning. See,e.g., Kozak v. Hillsborough County, Fla., 644 F.3d 1347, 1349–50 (11th Cir. 2011) ("[O]ne of

the most basic interpretive canons [is] that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . ." (quoting Corley v. United States, 556 U.S. 303, 314 (2009)) (alterations in original)). For the "includes" clause to have meaning, it must alter the first provision of the definition, which it follows. Relator's and the Government's interpretation does just that: the "includes" clause limits the expansive scope of the first provision to "medically accepted indications" of drugs. Defendants' interpretation, by contrast, renders the "includes" clause superfluous because, under that interpretation, "off-label" AAP would be equally covered with or without the "includes" clause.[6] The Court concludes that Part D does not cover "off-label" AAP or AAP for a use that is not a "medically accepted indication." See Kilmer v. Leavitt, 609 F. Supp. 2d 750, 753–54 (S.D. Ohio 2009) (holding that the plain language of the "covered Part D drug"

[6] Defendants argue that the "includes" clause's effect is to set a floor so that PDP sponsors cannot deny coverage for drugs used for a "medically accepted indication." But Defendants do not explain how a PDP sponsor may exclude coverage for "covered Part D drugs." Instead, Defendants point to provisions of the Medicaid program that allow states to exclude coverage for drugs under the Medicaid program. Although Part D's definition of "medically accepted indication" incorporates the Medicaid program's definition, Defendants do not cite, and the Court is not aware of, any authority that extends the coverage flexibility available to states under Medicaid to PDP sponsors under Part D.

definition shows that the "includes" clause limits the definition to drugs used for a "medically accepted indication").[7]

The Court reaches its conclusion based on the plain language of the statutory definition and, therefore, does not find ambiguity in the definition. See Med. Transp. Mgmt. Corp. v. Comm'r, 506 F.3d 1364, 1368 (11th Cir. 2007) ("The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." (quoting Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997))). If the statute were ambiguous, however, extrinsic aids to its construction would lead the Court to the same conclusion. See Lowery v. Ala. Power Co., 483 F.3d 1184, 1205 (11th Cir. 2007) ("When ambiguity in a statute renders congressional intent unclear, . . . it is appropriate to resort to extrinsic aids . . . ."). The Court would be obliged to defer to a "permissible" interpretation of the statute given by the CMS. See Chevron, U.S.A., Inc. v. NRDC, 467 U.S.

[7] The Court notes that one district court opinion—Layzer v. Leavitt, 770 F. Supp. 2d 579 (S.D.N.Y. 2011)—reaches the opposite conclusion to that reached here and in Kilmer. In Layzer, the court relied primarily on a general Social Security Act provision stating that the term "includes," when used in a definition, "shall not be deemed to exclude other things otherwise within the meaning of the term defined." See 770 F. Supp. 2d at 584 (citing 42 U.S.C. § 1301(b) (2006)). Because the context of the statutory definition here requires that the "includes" clause have meaning, the Court respectfully disagrees with the holding in Layzer.

837, (1984); United States ex rel. Walker v. R&F Props. of Lake Cnty., Inc., 433 F3d 1349, 1357 (11th Cir. 2005). That agency, in promulgating Part D regulations, has expressly defined Part D drugs to include *only* drugs used for a "medically accepted indication." See 42 C.F.R. § 423.100 (2011) (defining "Part D drug"). CMS's interpretation is "permissible," and therefore commands the Court's deference, because it is not directly at odds with any statutory provision and reasonably construes the "includes" clause to have specific meaning. Vidiksis v. EPA, 612 F.3d 1150, 1156 (11th Cir. 2010) (holding that a "reasonable" construction, not directly odds with a statutory provision, was a "permissible" construction).[8] Counts I and II are not required to be dismissed on the ground that the "includes" clause does not require a covered Part D drug to be for a "medically accepted indication."

[8] The Court notes that Congressional action since the enactment of Part D further confirms the limiting construction of the "includes" clause. In 2010 and in 2011, bills were introduced in, but not ultimately passed by, the House of Representatives that would have given the Department of Health and Human Services the ability to broaden the scope of what constitutes a "medically accepted indication" and, therefore, *expand* coverage under Part D. See Part D Off-Label Prescription Parity Act, H.R. 1055, 112th Cong. (2011); Part D Off-Label Prescription Parity Act, H.R. 5732, 111th Cong. (2010).

(iv) *Whether Coverage for "Off-Label" AAP Is Ambiguous so as to Preclude FCA Liability*

Finally, Defendants argue that, even if Part D does not cover "off-label" AAP, the question of "off-label" coverage is ambiguous, precluding FCA liability for filling "off-label" AAP prescriptions. That is, Defendants claim that it is ambiguous whether or not "off-label" AAP are included under Part D and this ambiguity precludes Defendants from being held liable under the FCA. The Court already has found that coverage for "off-label" AAP is not ambiguous. Even if it was ambiguous, the ambiguity alone would not shield claimants from FCA liability. To the extent it is relevant at all, an ambiguity in a condition of payment is relevant only to the claimant's knowledge of falsity. See Walker, 433 F.3d at 1356–58 (holding that an ambiguity in a condition of payment does not negate a "false claim" as a matter of law but could create an issue of fact as to the defendant's knowledge); see also United States v. Bourseau, 531 F.3d 1159, 1164 n.2 (9th Cir. 2008) (explaining that the reasonableness of an interpretation may be relevant to the knowledge requirement in the FCA but not the falsity requirement). In this case, an ambiguity in Part D's coverage of "off-label" drugs could serve as evidence relevant to Defendants' knowledge of falsity, but it does not serve to discredit Relator's *prima facie* allegation of a false claim. Counts I and II are not required to be dismissed on the basis of an ambiguity.

b. Prescription Splitting (Counts III and IV)

Defendants next move for the dismissal of Counts III and IV on the ground that the practice of "prescription splitting"—filling a single prescription over time by dispensing only a portion at a time in order to bill for more dispensing fees—does not give rise to a "false claim." Defendants argue that there is not any statute or regulation that prohibits Part D reimbursement for "split prescriptions."

Relator relies on the definition of "dispensing fees" contained in Part D regulations to support the allegation that "prescription splitting" is impermissible under Part D. The "dispensing fee" definition provides that a dispensing fee may include "reasonable costs" associated with various actions in filling a prescription and that a fee "should take into consideration the number of dispensing events in a billing cycle." 42 C.F.R. § 423.100 (defining "dispensing fees"). This definition does not prohibit prescription splitting, and it does not proscribe engaging in prescription splitting or render single prescription fulfillment a precondition to Part D reimbursement. Relator does not reasonably explain how the definition allows Medicare not to reimburse "split prescriptions," and the definition cannot convert into a false claim a request for reimbursement based on "split prescriptions." See McNutt, 423 F.3d at 1259 (holding that a "false claim" is a claim that the government does not owe); see also United States ex rel. Conner v. Salina Reg'l

Health Ctr., 543 F.3d 1211, 1218 (10th Cir. 2008) (explaining that, when the violation of a statute or regulation forms the basis of a "false claim," the statute or regulation must "make compliance a prerequisite to the government's payment").

Relator also relies on a provision of the Prescription Drug Benefit Manual ("Manual") published by CMS, which lists "prescription splitting" as an example of "pharmacy fraud, waste, and abuse." See CMS, Prescription Drug Benefit Manual ch. 9, § 70.1.3 (2006), 2006 WL 6125641. As with the regulatory definition cited by Relator, the Manual does not state that "split prescriptions" are not reimbursable or that *not* engaging in prescription splitting is a precondition to payment. See McNutt, 423 F.3d at 1259; Conner, 543 F.3d at 1218. The Manual is insufficient to establish that claims for "split prescriptions" are "false claims." The Court concludes that Relator's allegation of "prescription splitting" does not state a "false claim" by Defendants, and Counts III and IV must be dismissed.

c. AAP Prescriptions Without "Prior Authorization" (Counts V and VI)

Defendants move for the dismissal of Counts V and VI on the ground that filling a Part D beneficiary's AAP prescription without obtaining "prior authorization" does not give rise to a "false claim." Defendants argue specifically that no statute or regulation prohibits Part D reimbursement for prescriptions filled without the pharmacy having obtained "prior authorization."

In response, Relator points to three Part D regulations: 42 C.F.R. §§ 423.153, 423.272, and 423.566. Section 423.153 requires Part D sponsors to include in their plans "a reasonable and appropriate drug utilization management program," including "incentives to reduce costs when medically appropriate." 42 C.F.R. § 423.153(b) (2011) (amended June 1, 2012). Section 423.272 describes the process by which CMS reviews and approves Part D sponsors' plans, including the plans' formularies and "utilization management programs." Id. § 423.153. Section 423.566 requires Part D sponsors to have procedures for making "coverage determinations" and defines "coverage determinations" to include denials of coverage for drugs not listed on a plan's formulary. Id. § 423.566(a)–(b).

The regulations cited by Relator do not make "prior authorization" a condition of payment for any type of drug. At most, these regulations authorize a Part D sponsor to impose "prior authorization" requirements in its formulary and to deny coverage for drugs not satisfying the requirements of the formulary. The Court concludes that the failure of a pharmacy to obtain "prior authorization" to fill a prescription does not violate a condition of government payment. See McNutt, 423 F.3d at 1259; Conner, 543 F.3d at 1218. Counts V and VI do not state a "false claim" by Defendants and must be dismissed.

2. *Failure to Plead a "False Record or Statement" (Counts II, IV, VI, and VIII)*

For each of the four schemes alleged in the Complaint, Relator alleges that Defendants are liable under two provisions of the FCA: subsections (a)(1)(A) and (a)(1)(B) of 31 U.S.C. § 3729. Subsection (a)(1)(A) imposes liability on a defendant who "presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Subsection (a)(1)(B) imposes liability on a defendant who "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)(B). Defendants argue that Counts II, IV, VI, and VIII fail to plead liability under subsection (a)(1)(B).

Defendants contend, and the Court agrees, that, to state a claim under subsection (a)(1)(B), a complaint must allege both a "false claim" and a "false record or statement." Defendants then argue that this "double falsity" requirement means that the "false record or statement" must be wholly distinct from the "false claim." With this, the Court disagrees.

The critical difference between subsections (a)(1)(A) and (a)(1)(B) is not two "falsities" but the presentment of a claim by the defendant. Liability attaches under subsection (a)(1)(A) when the defendant presents a false claim for payment. Liability attaches under subsection (a)(1)(B) when any person—whether the

defendant or someone else—presents a false claim (so long as the false claim is connected to the defendant's false record or statement). See Hopper v. Solvay Pharm., Inc., 588 F.3d 1318, 1325–27 (11th Cir. 2009). Thus, subsection (a)(1)(B) allows for liability of a defendant who makes a false record or statement that forms the basis of a false claim, even if the defendant who made the false record or statement did not itself present the false claim. See United States ex rel. Harris v. Bernard, 275 F. Supp. 2d 1, 6 (D.D.C. 2003) (holding that the submission of a claim form could constitute the submission of a "false claim" under the predecessor to subsection (a)(1)(A) and could also constitute the making of a "false record" under the predecessor to subsection (a)(1)(B)).[9]

Count II of the Complaint alleges that Defendants made false records or statements—in the form of documents "relating to the dispensing of" off-label AAP that were submitted to Part D plan sponsors—and that the false records or

[9] In many instances, and maybe even most, the same conduct can give rise to FCA liability under both subsections (a)(1)(A) and (a)(1)(B). See generally John T. Boese, Civil False Claims and Qui Tam Actions § 2.01[B] (2012). The government or a relator may ultimately have only one recovery for a "false claim," but the government or relator is free to plead both theories in the complaint. See Harris, 275 F. Supp. at 6 (citing id.) ("[A]lthough a court can only hold a defendant liable under either section 3729(a)(1) or (a)(2), Rule 8(e)(2) permits the government to plead both sections in the alternative."). To the extent that the claims under subsections (a)(1)(A) and (a)(1)(B) as alleged here are redundant or overlapping, the redundancy can be addressed, if required, later in these proceedings.

statements formed the basis of "false claims"—claims for reimbursement for off-label AAP—that were submitted to the government. This allegation pleads a claim under subsection (a)(1)(B). The Court denies Defendants' motion to dismiss Count II for failure to plead a "false record or statement."

Count VIII of the Complaint alleges generally that Defendants "knowingly made, used, or caused to made or used, a false record or statement material to a false or fraudulent claim." Unlike the allegations in Count II, however, Count VIII does not otherwise identify or describe any actual false record or statement. The Complaint's mere recitation of the elements of subsection (a)(1)(B), without any factual support, is insufficient to plead a claim. See Am. Dental, 605 F.3d at 1289 ("[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." (quoting Twombly, 550 U.S. at 555)). The Court dismisses Count VIII.[10]

3. *Failure to Plead with Particularity Required by Rule 9(b)*

FCA claims must be pleaded with particularity under Rule 9(b) of the Federal Rules of Civil Procedure. See Hopper, 588 F.3d at 1324; United States ex

[10] The Court dismisses Counts IV and VI because the counts fail to plead a "false claim." The Court does not reach the question of whether these counts also fail to plead a "false record or statement."

rel. Atkins v. McInteer, 470 F.3d 1350, 1357 (11th Cir. 2006); United States ex rel. Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1308–10 (11th Cir. 2002). "Particularity means that 'a plaintiff must plead facts as to time, place, and substance of the defendant's alleged fraud, specifically the details of the defendant['s] allegedly fraudulent acts, when they occurred, and who engaged in them.'" Atkins, 470 F.3d at 1357 (alteration in original) (quoting Clausen, 290 F.3d at 1310) (internal quotation marks omitted). Defendants argue that Relator's allegations fail to satisfy this standard.

Because the submission of a false claim to the government is the "*sine qua non* of a False Claims Act violation," a relator must allege not only a fraudulent scheme with particularity but also must allege with particularity the facts of a submission of a false claim based on the scheme. See Clausen, 290 F.3d at 1311; see also Atkins, 470 F.3d at 1357 ("Rule 9(b)'s directive that 'the circumstances constituting fraud or mistake shall be stated with particularity' does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." (quoting id.)). This is true for FCA claims

asserted under subsection (a)(1)(A) and subsection (a)(1)(B) of 31 U.S.C. § 3729. See Hopper, 588 F.3d at 1325, 1327.[11]

In Counts I and II, Relator alleges that Defendants sought reimbursement for filling "off-label" AAP. The Complaint itself does not offer any factual detail of any particular AAP prescription and claim for reimbursement, and Relator refers the Court to several spreadsheets attached to the Complaint.[12] The spreadsheets provide detail of certain prescriptions filled by Defendants, including redacted patient information, drugs dispensed, date filled, and an indication of why the particular prescription is "off-label." At most, however, the spreadsheets show the details of the *filling* of "off-label" AAP prescriptions by Defendants. The

[11] In Hopper, the court construed the former subsection (a)(2), the predecessor to the current subsection (a)(1)(B). 588 F.3d at 1327–28 & n.3. Former subsection (a)(2) did not include a claim "presentment" or "submission" element; however it included an actual "payment" element. Id. at 1327. Accordingly, the court held that Rule 9(b) required that the "payment" element be pleaded with particularity. Id. The current subsection (a)(1)(B) does not have the "payment" element but does have a "submission" element. See 37 U.S.C. § 3729(a)(1)(B) (imposing liability on any person who "knowingly makes . . . a false record or statement material to a false or fraudulent claim); id. § 3729(b)(2) (defining "claim" as a "request or demand" that is either "presented to" a government employee or "made to" a government grantee). Thus, the "submission" element of a subsection (a)(1)(B) claim must be pleaded with particularity.

[12] Relator also filed, and refers to, several additional spreadsheets attached to its opposition brief. As noted above, on a motion to dismiss, the Court does not consider matters outside of the pleadings and, therefore, does not consider these spreadsheets. See Harper, 592 F.3d at 1232.

spreadsheets offer no information on the alleged subsequent *submission* of reimbursement claims for Defendants' having filled those prescriptions. Accordingly, Counts I and II on their face fail to satisfy Rule 9(b) and are dismissed.[13]

In Count VII, Relator alleges that Defendants sought reimbursement for prescriptions filled after waiving or not charging beneficiaries' co-payments. As with Counts I and II, Relator supplemented Count VII with a spreadsheet attached to the Complaint.[14] The spreadsheet details certain prescriptions, but it does not provide any detail or information on the submission of reimbursement claims for those prescriptions. Count VII suffers the same Rule 9(b) deficiency as Counts I and II, and it must be dismissed.[15]

In its opposition to Defendants' Motion to Dismiss, Relator requests leave to amend its Complaint to correct Rule 9(b) pleading deficiencies. The Court

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[13] The Court notes further that, in connection with Count II, alleging a "false record or statement," neither the Complaint nor its attachments offer any detail of the alleged records or statements.

[14] Again, Relator filed, and refers to, an additional spreadsheet attached to its opposition brief. For reasons discussed above, the Court does not consider this spreadsheet. See Harper, 592 F.3d at 1232.

[15] The Court dismisses Counts III, IV, V, VI, and VIII for failure to state a claim. The Court does not reach the issue of whether these counts are pleaded in conformity with Rule 9(b).

normally grants a plaintiff the opportunity to amend before dismissing claims in a complaint for pleading defects. Accordingly, the Court grants Relator the opportunity to file an amended complaint within twenty (20) days of this Order to address the pleading shortcomings identified in Counts I, II, and VII.

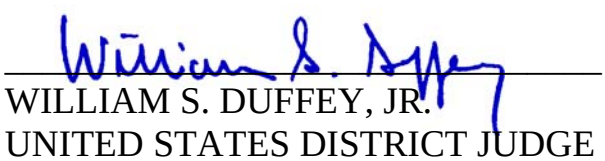
III. CONCLUSION

Accordingly, for the foregoing reasons,

IT IS HEREBY ORDERED that Defendants' Motion to Dismiss [33] is **GRANTED IN PART AND DENIED IN PART**. Counts III, IV, V, VI, and VIII of the Second Amended Complaint are **DISMISSED** for failure to state a claim. Counts I, II, and VII of the Second Amended Complaint are **DISMISSED WITHOUT PREJUDICE** for failure to have been pleaded with particularity. Relator may file an amended complaint within twenty (20) days of entry of this Order to re-plead Counts I, II, and VII.

IT IS FURTHER ORDERED that Relator's Motion for Oral Argument [53] is **DENIED**.

SO ORDERED this 29th day of August 2012.



WILLIAM S. DUFFEY, JR.
UNITED STATES DISTRICT JUDGE