UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, ex rel. MARC SILVER, et al.,	:	
Relators,	:	Civil Action No. 11-1326
v.	:	
OMNICARE, INC., et al.,	:	**OPINION**
Defendants.	:	

APPEARANCES:

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HILLMAN, District Judge:

This matter comes before the Court upon Plaintiff-Relator Marc Silver's ("Relator") motion to amend his Third Amended Complaint. (ECF No. 513). PharMerica Corporation ("PharMerica") opposes Relator's motion under futility, undue delay, and unfair prejudice grounds. (ECF No. 520.) The Court has allowed the United States (the "Government") to file a Statement of Interest in support of Relator's Motion, which is limited to addressing PharMerica's futility arguments regarding prescription drug event ("PDE") data, to which PharMerica filed an opposition brief. (ECF No. 531, 535.) The Court has considered Relator, PharMerica, and the Government's arguments and for the reasons below will grant Relator's motion. In addition, the Court, pursuant to Federal Rule of Civil Procedure 54(b), will amend its previous Order dated November 30, 2020, ECF No. 511, to now specify the dismissals were without prejudice.

BACKGROUND

The relevant factual and procedural history of this matter are set forth in the Court's previous Opinions (ECF Nos. 131, 388) and need not be repeated here.

DISCUSSION

A. Subject Matter Jurisdiction

Relator has alleged that PharMerica violated the federal False Claims Act, 31 U.S.C. § 3729, et seq., and the federal Anti-Kickback Statute, 42 U.S.C.A. § 1320a-7b, et seq. Therefore, this Court exercises subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) and exercises supplemental jurisdiction over Silver's related state law claims pursuant to 28 U.S.C. § 1367.

B. Federal Rule of Civil Procedure 54(b) Legal Standard and Analysis

The Court first finds it important to note that in its previous Order the Court granted PharMerica's Motion for Partial Judgment on the Pleadings and ordered that: (1) "Count I and the related conspiracy claims under Count III, insofar as they are based on the alleged submission of false claims to commercial insurance companies under Medicare Part D and under Medicaid Managed Care prior to May 20, 2009 are DISMISSED;" and (2) "Count II in its entirety and the related conspiracy claims under Count III are DISMISSED." (ECF No. 511.) The Court

failed to specify whether the related claims were dismissed with or without prejudice and thus the dismissals are presumed to be with prejudice. Despite this, both parties seem to be in agreement that the applicable legal standard for Relator's motion is Federal Rule of Civil Procedure 15. However, neither party addresses whether the Court must first amend its interlocutory order, which dismissed some, but not all, of Plaintiff's claims with prejudice, before proceeding to the Rule 15 analysis. Without deciding which standard applies in this situation, the Court finds that whether Rule 54(b) or Rule 15 governs the amendment would still be granted.

The Court first notes it is within the Court's inherent powers to reconsider its orders at any time before final judgment. See State Nat'l Ins. Co. v. Cty. of Camden, 824 F.3d 399, 406 (3d Cir. 2016) (citing United States v. Jerry, 487 F.2d 600, 605 (3d Cir. 1973)). Rule 54(b) provides that as to an interlocutory order with ongoing effect, the court retains a good deal of discretion: "[S]o long as [a] district court has jurisdiction over the case, it possesses inherent power over interlocutory orders, and can reconsider them when it is consonant with justice to do so.'" In re Anthanassious, 418 F. App'x 91, 95 (3d Cir. 2011) (quoting United States v. Jerry, 487 F.2d at 605).

That discretionary authority is recognized in Rule 54(b),

which provides, in pertinent part, as follows:

> [A]ny order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities.

Fed. R. Civ, P. 54(b). Thus, until a decision is final, "a trial judge has the discretion to reconsider an issue and should exercise that discretion whenever it appears that a previous ruling, even if unambiguous, might lead to an unjust result." In re Anthanassious, 418 F. App'x at 95 (quoting Swietlowich v. Bucks Cty., 610 F.2d 1157, 1164 (3d Cir. 1979)); see also In re Pharmacy Benefit Managers Antitrust Litig., 582 F.3d 432, 438-39 (3d Cir. 2009).

However, the court must "exercise this authority in a responsible way, both procedurally and substantively" and "[e]ffective trial court management requires a presumption against reconsideration of interlocutory decisions." In re Anthanassious, 418 F. App'x at 95. In discussing the scope of a district court's discretion to reconsider an interlocutory decision, the Third Circuit has held that while "'[a] court has the power to revisit prior decisions of its own or of a coordinate court in any circumstance . . . as a rule courts should be loathe to do so in the absence of extraordinary

circumstances such as where the initial decision was clearly erroneous and would make a manifest injustice.'" In re Pharmacy Benefit Managers, 582 F.3d at 439 (quoting Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 816 (1988)).

The Court finds the unique facts and procedural history of this case warrant reconsideration of the Court's decision to dismiss the relevant claims with prejudice for failure to include the theory of liability Relator relied on his opposition papers to PharMerica's Motion for Partial Judgment on the Pleadings. In 2014, the Court previously denied PharMerica's Motion to Dismiss for failure to properly plead his False Claim Act ("FCA") with the specificity as required under Federal Rule of Civil Procedure 9(b) and for failure to state a claim for conspiracy. United States ex rel. Silver v. Omnicare, Inc., No. 11-1326, 2014 U.S. Dist. LEXIS 136800 (D.N.J. Sept. 29, 2014). In its most recent Opinion, the Court ultimately found the law of the case doctrine did not warrant the denial of PharMerica's Motion for Partial Judgment on the Pleadings. United States ex rel. Silver v. Omnicare, Inc., No. 11-1326, 2020 U.S. Dist. LEXIS 223590, at *7-10 (D.N.J. Nov. 30, 2020).

However, given its previous finding that PharMerica satisfied 9(b) and stated a conspiracy claims as well as the basis for granting PharMerica's Motion for Partial Judgment on the Pleadings, the Court concludes it should have at least

dismissed the relevant claims without prejudice and allowed the Relator to move to amend his complaint to properly include his PDE and enrollee encounter data theories. The Court finds it is consonant with justice to reconsider its previous decision to grant the dismissals with prejudice and that if the Court does not reconsider this portion of the Opinion, then it would create a manifest injustice which could lead to an unjust result.

Thus, the Court will exercise its inherent powers and amend its interlocutory order that previously ordered (1) "Count I and the related conspiracy claims under Count III, insofar as they are based on the alleged submission of false claims to commercial insurance companies under Medicare Part D and under Medicaid Managed Care prior to May 20, 2009 are DISMISSED;" and (2) "Count II in its entirety and the related conspiracy claims under Count III are DISMISSED." (ECF No. 511.) The Court will amend such Order to instead state: (1) Count I and the related conspiracy claims under Count III, insofar as they are based on the alleged submission of false claims to commercial insurance companies under Medicare Part D and under Medicaid Managed Care prior to May 20, 2009 are DISMISSED WITHOUT PREJUDICE; and (2) Count II in its entirety and the related conspiracy claims under Count III are DISMISSED WITHOUT PREJUDICE.

C. Motion to Amend Legal Standard

Rule 15(a)(2) authorizes a party to amend its pleadings

"only with the opposing party's written consent or the court's leave." Rule 15(a)(2) further "requires that leave to amend the pleadings be granted freely 'when justice so requires.'" Long v. Wilson, 393 F.3d 390, 400 (3d Cir. 2004) (citing Fed. R. Civ. P. 15(a)) ("We have held that motions to amend pleadings should be liberally granted."). In Foman v. Davis, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962), the Supreme Court articulated the policy of "freely" granting leave to amend. See also Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000). More specifically, the Supreme Court explained that:

> [i]n the absence of any apparent or declared reason—such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.—the leave sought should, as the rules require, be "freely given."

Foman v. Davis, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed. 2d 222 (1962). "Futility 'means that the complaint, as amended, would fail to state a claim upon which relief could be granted.'" Great Western Mining & Mineral Co. v. Fox Rothschild, LLP, 615 F.3d 159, 175 (3d Cir. 2010) (citing In re Merck & Co. Sec., Derivative, & ERISA Litig., 493 F.3d 393, 400 (3d Cir. 2007)). "The standard for assessing futility is the 'same standard of legal sufficiency as applies under Federal Rule of Civil Procedure 12(b)(6),'" meaning that all pleaded

allegations are taken as true and viewed in a light most favorable to plaintiff. Id. (citing Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000); Winer Family Trust v. Queen, 503 F.3d 319, 330-31 (3d Cir. 2007)).

The Third Circuit has contemplated that the standard for denial of amendment is high, stating "[g]enerally, Rule 15 motions should be granted." United States ex rel. Customs Fraud Investigations, LLC. V. Victaulic Co., 839 F. 3d 242, 249 (3d Cir. 2016). "The Third Circuit dictates that amendments should 'be granted freely,' stating a preference for decisions made 'on the merits rather than on technicalities.'" Ragner Tech. Corp. v. Berardi, 324 F. Supp. 3d 491, 518 (D.N.J. 2018) (quoting Dole v. Arco Chem. Co., 921 F.2d 484, 486-87 (3d Cir. 1990)).

D. Analysis

a. Undue Delay

PharMerica argues there is no reason for Relator's delay in moving to amend his complaint earlier in this matter to cure the deficiencies the Court highlighted in its recent Opinion regarding PharMerica's Motion for Partial Judgment on the Pleadings. (ECF No. 520 at 9.) In response, Relator argues he did not engage in any undue delay in seeking this amendment because the Court "previously upheld Relator's Third Amended Complaint in September 2014, and it found that the Complaint properly stated a claim against PharMerica" under the FCA. (ECF

No. 523 at 2.) For this reason, the Relator argues it was not until the Court's most recent Opinion that the "Relator had any reason to move to amend his Complaint." (Id.) This Court agrees with Relator.

As explained above, the procedural history of this case presents a unique situation. While the Court recognizes several years have passed before Plaintiff has sought to amend his Complaint to include the allegations in his proposed Fourth Amended Complaint ("FAC"), the Court finds this is not a situation where Plaintiff has "offered no cogent reason for the delay in seeking the amendment." CMR D.N. Corp. v. City of Philadelphia, 703 F.3d 612, 629 (3d Cir. 2013). The Court agrees its previous rejection of PharMerica's Motion to Dismiss for failure to satisfy 9(b) and conclusion that the complaint stated a conspiracy claim provided Relator with a cogent reason for not seeking the most recent amendment. Accordingly, the Court does not find undue delay.

b. Unfair Prejudice

"[S]ubstantial or undue prejudice to the non-moving party is a sufficient ground for denial of leave to amend." Cureton v. Nat'l Collegiate Athletic Ass'n, 252 F.3d 267, 273 (3d Cir. 2001) (citing Lorenz v. CSX Corp., 1 F.3d 1406, 1414 (3d Cir. 1993)). "In determining whether amendment of a complaint will cause undue prejudice, the Court must 'focus on the hardship to

the defendants if the amendment were permitted.'" Stolinski v. Pennypacker, No. 7-3174, 2011 U.S. Dist. LEXIS 166153, at *21 (D.N.J. June 23, 2011) (citing Cureton, 252 F.3d at 273 (citing Adams v. Gould, Inc., 739 F.2d 858, 868 (3d Cir. 1984))). Consequently, undue prejudice suffices to deny leave to amend, where "if amendment were permitted, the [defendant] would be prejudiced by having to engage in burdensome new discovery and significant new trial preparation." Cureton, 252 F.3d at 274 (finding that district court did not abuse its discretion in denying motion to amend where the district court determined that the "'proposed amendment would essentially force the [defendant] to begin litigating this case again.'").

However, "incidental prejudice to the opponent is not a sufficient basis for denial of an amendment; such prejudice becomes 'undue' when the opponent shows it would be 'unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered[.]'" Faiella v. Sunbelt Rentals, Inc., No. 18-11383, 2019 U.S. Dist. LEXIS 130325, at *8 (D.N.J. Aug. 5, 2019) (citing Harrison Beverage Co. v. Dribeck Importers, Inc., 133 F.R.D. 463, 468 (D.N.J. 1990) (citing Heyl & Patterson Int'l, Inc. v. F.D. Rich Housing of the Virgin Islands, Inc., 663 F.2d 419, 425 (3d Cir. 1981) (denying in part motion to amend to add affirmative defenses where discovery was complete and amendment to add the defenses would cause discovery

to be reopened and a postponement of trial))).

PharMerica argues it will suffer undue prejudice because the parties will need to engage in additional discovery regarding Relator's new theory and PharMerica will likely need to seek "additional discovery directed to the government, including document requests and depositions of government representatives to explain the purpose of PDE and how the government uses them." (ECF No. 520 at 14-16.) PharMerica's undue prejudice argument also seems to be connected to the "undue delay" Relator has allegedly engaged in by asserting a new theory years after discovery has commenced. (ECF No. 520 at 17.)

Although this Court does agree with PharMerica that the proposed amendments are not merely additions regarding factual allegations, as argued by Relator, and are instead connected to a new theory, the Court has already found Relator did not engage in any undue delay as there appears to be a cogent reason Relator failed to move to amend the complaint years ago. Further, there has been no showing that PharMerica has been deprived of the ability to offer facts or evidence it would have offered, and PharMerica has not sufficiently articulated prejudice that would warrant denial of a motion to amend.

Moreover, as Relator highlights the "very facts and arguments made by PharMerica in its recent Motion for partial

Judgment on the Pleadings could have been made years ago when it filed its prior motion to dismiss in December 2013 (ECF No. 106-2), or at any earlier stage of this litigation." (ECF No. 513-1 at 8.) Relator contends that not allowing Relator to amend his complaint now raises the possibility of piecemeal litigation that would "result in a substantial waste of the Court's and the parties' time and resources" whereas granting "leave for this amendment would avoid this waste of resources, and allow all of Relator's claims to proceed now and be decided on the merits." (Id.)

The Court finds it is difficult to accept PharMerica's unfair prejudice arguments that seem to overlap with its undue delay arguments when PharMerica was actually able to raise the exact arguments from its Motion for Partial Judgment on the Pleadings early on in the litigation. It was not until years after the Court ruled Plaintiff had satisfied the 9(b) requirements and stated a claim for conspiracy and after years of discovery that PharMerica chose to move for dismissal for failure to satisfy the presentment and double falsity requirements of the FCA claims. For the foregoing reasons, the court finds PharMerica has failed to articulate prejudice that would warrant denial of a motion to amend especially where such motions should be granted liberally.

c. Futility

In determining whether a proposed amendment is futile, the Court "applies the same standard of legal sufficiency as applies under Rule 12(b)(6)." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997) (citations omitted). An amended complaint is futile if, as amended, it "would fail to state a claim upon which relief could be granted." Id. The Court "determines futility by taking all pleaded allegations as true and viewing them in the light most favorable to [the moving party]." Great W. Mining & Mineral Co., 615 F.3d at 175. "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) (internal quotation marks omitted).

PharMerica argues that Relator's FAC is futile because (1) Relator cannot satisfy the presentment element of pre-FERA claims under Count I and III of the FAC given PharMerica neither presented nor caused to be presented any Medicare Part D or Medicaid Managed Care claims to an officer or employee of the United States; (2) nor can Relator establish the double falsity element of his claims under Count II and Count III of the FAC. In support of these positions, PharMerica argues the following: (1) PDE data are not "claims" under the FCA because "PDE records are transaction summaries that do not include any request or

demand for payment;" (2) PDEs may not "be rendered false by the payment of kickbacks from a pharmacy to its customers in violation of the Anti-Kickback Statute ("AKS");" and (3) Relator and the Government's reliance on "*Spay*[1] and the cases that cite it for the broad proposition that PDE are claims . . . is misplaced" and that Southern District of New York rejected the Government's argument that "*accurate* PDE data allegedly 'tainted' by kickbacks cannot state a claim under the FCA." (ECF No. 520 at 18-22; ECF No. 535 at 2, 4.)

For similar reasons, PharMerica argues that Relator's amendments regarding Medicaid are also futile. (ECF No. 520 at 22) ("The same analysis holds for relator's amendments addressed to Medicaid Managed Care. The encounter data that Medicaid Managed Care Organizations ("MCOs") submit to state Medicaid Agencies is identical in concept, if not content, to PDE records. The MCOs must compile this data and certify its accuracy in order to receive their capitated payments, which also are based solely on enrollment. 42 C.F.R. § 438.604. Thus, like PDE data, encounter data are not claims under any version of the FCA.").

In response, Relator argues "[i]n a case directly on point where PharMerica was a party, U.S. ex. rel Buth v. PharMerica

[1] United States ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125(E.D. Pa. 2014).

Corp., 2014 WL 4355342 (E.D. Wis. Sept. 3, 2014), the District Court found that there is a direct causal chain between PharMerica submitting false electronic claims to the Part D Sponsor and the Part D Sponsor submitting PDE records to CMS, which are claims for purposes of the FCA." (ECF No. 523 at 4.) Relator also directs this Court's attention to the Spay decision where the Eastern District of Pennsylvania held "[g]iven such guidance, the PDE records submitted by Defendants to CMS are clearly claims for payment." (ECF No. 523 at 14 n.14 (quoting United States ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 168 (E.D. Pa. 2014)).

In the Government's Statement of Interest, the Government argues "[c]onsistent with the statute, regulations, and explicit instructions from CMS courts have affirmed that a PDE is a claim under the FCA." (ECF No. 531 at 7.) The Government further argues PharMerica "seeks to discredit *Buth* by pointing out that its holding on PDEE has not been cited in any subsequent decision" and that "[t]he absence of citation merely reflects the unremarkability of the proposition that a PDE is a claim for purposes of the FCA." (Id.) The Government then highlights that "the Third Circuit addressed the use of false prescriber identifies on PDEs and treated PDEs as claims under the FCA" and that "[i]f Pharmerica were correct that a PDE is not a claim, the Third Circuit presumably would have dismissed the case on

that threshold basis rather than proceeding to address the more involved question of whether the false information in the PDE was material to the agency's payment decision." (Id. at 7-8 (citing United States ex rel. Spay v. CVS Caremark Corp., 875 F.3d 746 (3d Cir. 2017)). The Government additionally argues that "[p]aying kickbacks in connection with prescriptions to Part D beneficiaries renders the claims for such prescriptions false under the FCA." (Id. at 8-11.)

This Court first addresses the issue of whether PDEs and the enrollee encounter data are claims under the FCA. Under the FCA, a "claim" is a "request or demand . . . for money or property." 31 U.S.C. § 3729(b)(2)(A). "Notably, however, 'this definition encompasses only requests or demands for money or property; pursuant to the principle of *expressio unius est exclusio alterius*, excluded from this definition are mere false statements or representations which ultimately lead to a request or demand for money or property.'" United States ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 167 (E.D. Pa. 2012) (quoting United States ex rel. Atkinson v. Pa. Shipbuilding Co., 255 F. Supp. 2d 351, 365 (E.D. Pa. 2002)).

In Spay, the defendant made a similar argument as the one advanced now by PharMerica that "although the PDE data supplied information to CMS, it did not request or demand payment and, thus, is not a claim for payment on which FCA liability can be

based." Id. at 167. The Court ultimately rejected this argument and held "the PDE records submitted by Defendants to CMS are clearly claims for payment." Id. at 168. The Court highlighted that the "PDE data is the only record submitted from PDMs or Part D sponsors that triggers CMS's payment obligation to the Part D Sponsor" and clarified that "[t]he mere fact that CMS refers to PDE submissions as 'data' and not 'claims' does not change what they PDE submissions are in the Medicare Part D scheme—claims on which CMS makes payment." Id. The Court explained that "[a]ny effort by Defendants to argue to the contrary constitutes mere linguistic maneuvering." Id. The Court held the "PDE Record is, standing alone, the demand for money from CMS" and that the cited authorities "clarif[ied] that CMS will only determine and issue further payment upon the receipt of the PDE records." Id.

Following Spay, several courts have held that PDEs are claims for payment on which FCA liability may be based. United States ex rel. Bassan v. Omnicare, Inc., No. 15-4179, 2021 U.S. Dist. LEXIS 52323, at *9 (S.D.N.Y. Mar. 19, 2021); United States ex rel. Mohajer, No. 17-4176, 2021 U.S. Dist. LEXIS 46672, *10 (S.D.N.Y. Mar. 12, 2021); United States ex rel. Buth v. Pharmerica Corp., No. 09-720, 2014 U.S. Dist. LEXIS 122719, *17-18 (E.D. Wis. Sept. 3, 2014). Relying on these cases and their reasoning, this Court agrees PDEs are claims for payment on

which FCA liability may be based. As the Government points out, if PharMerica were correct that PDEs are not claims for payment, the "Third Circuit presumably would have dismissed the case on that threshold basis rather than proceeding to address the more involved question of whether the false information in the PDE was material to the agency's payment decision." (ECF No. 531 at 8.)

For similar reasons, the Court agrees the enrollee encounter data that Medicaid MCOs submit to state Medicaid Agencies are also claims for payment on which FCA liability may be based. As PharMerica even concedes "[t]he same analysis holds for relator's amendments addressed to Medicaid Managed Care. The encounter data that Medicaid Managed Care Organizations ("MCOs") submit to state Medicaid Agencies is identical in concept, if not content, to PDE records." (ECF No. 520 at 22.) The FAC explains that "[w]hen a pharmacy like the Pharmacy Defendants dispenses a drug for these individuals, the pharmacy submits electronic claim information pertaining to the drug to the MCO for reimbursement" and the MCOs "then use that electronic claim information to generate 'enrollee encounter data.'" (FAC ¶40.) The FAC further includes allegations that "[f]ederal regulations require that, as a condition for receiving federal funds, MCOs must submit enrollee encounter data . . . to the state where the MCO operates" and "[a]s a

condition for receiving federal funds for an MCO's expenditures, the states must provide enrollee encounter data they receive from an MCO to CMS, which then 'will assess a State's submission to determine if it complies with current criteria for accuracy and completeness.'" (FAC ¶¶40-42.) Moreover, courts have held "[r]equests for reimbursements submitted to Medicaid qualify as 'claims' under the FCA." United States ex rel. Bassan v. Omnicare, Inc., No. 15-4179, 2021 U.S. Dist. LEXIS 52323, at *10 (citing United States ex rel. Kester v. Novartis Pharms. Corp., 23 F. Supp. 3d 242, 260-61 (S.D.N.Y. 2014)). Accordingly, for the foregoing reasons, this Court concludes PDEs and enrollee encounter data may be a claim for payment upon which FCA liability may be based.

Second, this Court agrees PDEs and enrollee encounter data tainted by kickbacks may constitute false claims under the FCA. This Court has already concluded that PDEs and enrollee encounter data are claims for payment for upon which FCA liability may be based and for this reason reject PharMerica's argument that this Court should agree with the Teva decision where the Court held accurate PDE claims tainted by kickback do not state a claim for violation of the FCA. A claim is "legally false" when the claimant misrepresents that he or she has complied with "statutory, regulatory, or contractual requirement[s]." United States ex rel. Greenfield v. Medco

Health Sols., Inc., 880 F.3d 89, 94 (3d Cir. 2018). "[A] claim that includes items and services resulting from a violation of [the anti-kickback statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Id. at 95. The Eastern District of Pennsylvania has held "once a claim is tainted by an AKS violation, it is automatically legally 'false' under the FCA." United States ex rel. Gohil v. Sanofi U.S. Servs., No. 2-2964, 2020 U.S. Dist. LEXIS 211100, at *18 (E.D. Pa. Nov. 12, 2020) (citing Greenfield, 810 F.3d at 95)).

Relator alleges that each of the claims submitted to the Government were "accompanied by an express or implied certification that the transaction was not in violation of federal or federal or state statutes, regulations, or program rules" and that "[e]ach of those certifications was false, because each claim for payment was tainted by the kickback arrangement detailed in this Complaint." (FAC ¶234.) "[C]ourts have long held that" "compliance with the AKS is a precondition to the payment of Medicare and Medicaid claims." United States ex rel. Kester v. Novartis Pharms. Corp., 41 F. Supp. 3d 323, 330 (S.D.N.Y. 2014) (citing US. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 394 (1st Cir. 2011); US. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 313 (3d Cir. 2011); New York v. Amgen Inc., 652 F.3d 103, 111-13 (1st Cir. 2011); McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.,

423 F.3d 1256, 1260 (11th Cir. 2005); U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004); Hericks v. Lincare Inc., No. 07-387, 2014 U.S. Dist. LEXIS 39706 (E.D. Pa. Mar. 25, 2014); U.S. ex rel. Parikh v. Citizens Med. Ctr., 977 F. Supp. 2d 654, 662-63 (S.D. Tex. 2013); U.S. ex rel. Osheroff v. Tenet Healthcare Corp., No. 09-22253, 2013 U.S. Dist. LEXIS 44235 (S.D. Fla. Mar. 27, 2013); U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., 565 F. Supp. 2d 153, 159 (D.D.C. 2008); U.S. ex rel. Fry v. The Health Alliance of Greater Cincinnati, No. 03-167, 2008 U.S. Dist. LEXIS 102411 (S.D. Ohio, Dec. 18, 2008); U.S. v. Rogan, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006); U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28, 32 (D.D.C. 2003); U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998)). The AKS itself states that it applies to any "Federal health care program." 42 U.S.C. 1320a-7bf.

This Court finds that PharMerica's position that a PDE or enrollee encounter data submission may only constitute a "false claim" where they are either factually false or the payment requests and attendant certifications are rendered false by the allegedly tainted record is unavailing. As the foregoing demonstrates, a claim may be false for FCA purposes when tainted by a kickback scheme. PharMerica does not contest that the FAC pleads a kickback scheme and this is likely so given the Court

has previously held that the Relator has alleged "that PharMerica executed a scheme to defraud the government and paid kickbacks to [skilled nursing facilities]." United States ex rel. Silver v. Omnicare, Inc., No. 11-1326, 2014 U.S. Dist. LEXIS 136800, at *16 (D.N.J. Sept. 29, 2014).

Finally, to the extent PharMerica is reviving its argument in support of its Motion for Partial Judgment on the Pleadings that Relator's pre-FERA claims relating to Medicare Part D and Managed Medicaid and the related conspiracy claims fail because Relator does not allege PharMerica "ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government" as opposed to by a private entity, this Court rejects such argument. (ECF No. 479-1 at 23-27.)

In Spay, which declined to apply the FERA amendments and after concluding PDEs are "clearly claims for payment," the Eastern District of Pennsylvania analyzed Allison Engine and explained that the "Third Circuit has gone on to interpret the Allison Engine holding, noting that '[w]ithout question, Allison Engine categorically precludes liability under the FCA when fraudulent claims induce private entities to disburse federal funds over which the private entity has complete control.'" Spay, 913 F. Supp. 2d at 170 (quoting United States Dept. Of Transp., ex rel. Arnold v. CMC Eng'g, 564 F.3d 673, 678 (3d Cir.

2009)). The Court held "[i]n other words, if the federal government provides money in a lump sum to a grantee, and is thereafter uninvolved in the disbursement of the funds, the FCA does not apply. However, the Court left open the possibility that, if the federal government is somehow involved in the grantee's disbursement of federal money, FCA liability may exist." Id. (quoting CMC Eng'g, 564 F.3d at 678). Thus, "a plaintiff asserting a claim under §§ 3729(a)(2) and (a)(3) must allege that the defendant intended to use the false record or statement to be paid by the government, not by any other party." Id. (quoting CMC Eng'g, 564 F.3d at 678).

In Spay, the court held that "[u]nder this definition, Plaintiff's FCA claim clearly survives Rule 12(b)(6) scrutiny" and that "Plaintiff has sufficiently pled facts on which to infer that Defendants made claims and submitted PDE data in order to cause the government to pay out Part D funds to MCS, which would ultimately flow to Caremark as the PBM." Id. "Drawing all reasonable inferences" from the allegations in the complaint in favor of Plaintiff, the court found that "Defendants submitted the PDE data directly to CMS, on behalf of MCS, 'to get' such claims paid by CMS" and that it was "irrelevant that MCS, not Defendants, received the initial payment from CMS" because the complaint adequately plead "that Defendants knew and intended that the PDE data would cause CMS

to reimburse MCS for those claims and that MCS would, in turn, reimburse Caremark." Id. The court concluded "[i]n other words, Plaintiff has alleged sufficient facts 'which indicate that [the government] reimbursed [MCS] for actual claims paid—meaning that, even if payments to [Defendants] were filtered through a health plan, the money, or some portion of it, was ultimately paid by the Government.'" Id. (quoting United States v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430, 451 (E.D. Pa. 2004)).

Similar to the plaintiff in Spay, this Court finds Relator survives Rule 12(b)(6) scrutiny and has sufficiently plead PharMerica knew and intended that the PDE data and enrollee encounter data would cause CMS to reimburse the states and Part D Sponsors for those claims and that the states and Part D Sponsors would, in turn, reimburse PharMerica. (FAC ¶¶40-44, 77-80, 249-50.) Accordingly, the Court rejects PharMerica's argument that Relator's pre-FERA claims under Count II and the related ones under Count III must be deemed futile for supposed failure to allege PharMerica "ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government" as opposed to by a private entity. 31 U.S.C. § 3729(a)(2). The Court's position is also further supported by its previous holding that the Relator has alleged "that PharMerica executed a scheme to

defraud the government and paid kickbacks to [skilled nursing facilities]." United States ex rel. Silver v. Omnicare, Inc., No. 11-1326, 2014 U.S. Dist. LEXIS 136800, at *16 (D.N.J. Sept. 29, 2014) (emphasis added).

CONCLUSION

For the reasons stated above, the Court will amend its Order dated November 30, 2020, ECF No. 511, to state: (1) Count I and the related conspiracy claims under Count III, insofar as they are based on the alleged submission of false claims to commercial insurance companies under Medicare Part D and under Medicaid Managed Care prior to May 20, 2009 are DISMISSED WITHOUT PREJUDICE; and (2) Count II in its entirety and the related conspiracy claims under Count III are DISMISSED WITHOUT PREJUDICE. Moreover, the Court will grant Relator's Motion to Amend.

An appropriate Order will be entered.

Date: April 13, 2021
At Camden, New Jersey

s/ Noel L. Hillman
NOEL L. HILLMAN, U.S.D.J.