**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| UNITED STATES OF AMERICA, ex rel. ANTHONY R. SPAY, | : | |
| | : | CIVIL ACTION |
| Plaintiff, | : | |
| v. | : | |
| | : | NO. 09-4672 |
| CVS CAREMARK CORPORATION; CAREMARK Rx, LLC (f/k/a CAREMARK Rx, Inc.); CAREMARK, LLC (f/k/a CAREMARK, INC.); SILVERSCRIPT, LLC (f/k/a SILVERSCRIPT INC.), | : | |
| Defendants. | : | |

**MEMORANDUM**

BUCKWALTER, S.J. December 20, 2012

Currently pending before the Court is the Motion by Defendants CVS Caremark Corporation, Caremark RX, LLC, Caremark, LLC, and Silverscript, LLC (collectively "Defendants") to Dismiss Relator's First Amended Complaint. For the following reasons, the Motion is denied in its entirety.

## I. FACTUAL AND PROCEDURAL BACKGROUND

The present litigation is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made, used, and caused to be made, used, or presented by Defendants. (Am. Compl. ¶ 1.) At this stage of the litigation, the Court takes the facts directly from the Amended Complaint.[1]

[1] See Schrob v. Catterson, 948 F.2d 1402, 1405 (3d Cir. 1991) ("On a motion to dismiss for failure to state a claim, all allegations must be accepted as true and the plaintiff . . . must be

### A. General Background on Medicare and the Medicare Part D Program[2]

Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly and disabled persons. The Department of Health and Human Services ("HHS") administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"). There are four major components to the Medicare program: (1) Part A, the hospital insurance benefits program, 42 U.S.C. §§ 1395c, 1395d; (2) Part B, the supplemental medical insurance benefits program, which generally pays for a percentage of certain medical and other health services, including physician services, 42 U.S.C. §§1395j, 1395k, 1395l; (3) Part C, the Medicare Advantage program, which allows CMS to contract with public and private entities to provide, at a minimum, Medicare Part A and B benefits to certain Medicare beneficiaries, 42 U.S.C. § 1395w-21–28, et seq.; and (4) Part D, the voluntary prescription drug benefit program. 42 U.S.C. § 1395w-101, et seq.

Part D was established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, which set up a voluntary prescription drug

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given the benefit of every favorable inference that can be drawn from those allegations.") The United States Court of Appeals for the Third Circuit has explained that "in deciding motions to dismiss pursuant to Rule 12(b)(6), courts generally may not consider matters extraneous to the pleadings unless it is a matter of public record or is 'integral to or explicitly relied upon in the complaint.'" In re Burlington Coat Factory Secs. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997) (citation omitted).

Notably, however, the factual recitation provided by the Court is merely a summary of Plaintiff's rather significant 382-count pleading. To the extent facts beyond this summary are relevant to the issues at hand, the Court addresses them within the pertinent section of this Memorandum.

[2] In crafting this summary of the Medicare and Medicaid Part D program, the Court relies heavily on the thorough, but concise description provided in the United States' Statement of Interest in Response to Defendants' Motion to Dismiss.

benefits program for Medicare enrollees. Part D became effective January 1, 2006. 42 U.S.C. § 1395w-101(a)(2). An individual may enroll in Part D if he or she lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

Unlike Parts A and B, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D "sponsors" to administer prescription drug plans. Part D benefits are provided by a Part D plan sponsor, which is either a prescription drug plan ("PDP"), a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan ("MA-PD plan), a Program of All-Inclusive Care for the Elderly ("PACE") organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4. The Part D plan sponsor must provide qualified prescription drug coverage which includes "standard prescription drug coverage" or "alternative prescription drug coverage" with at least actuarially equivalent benefits. 42 U.S.C. § 1395w-102; 42 C.F.R. § 423.104(c). The requirements for standard or alternative prescription drug coverage relating to deductibles, benefit structure, initial coverage limits, out-of-pocket expenditures, etc., are set out in the Medicare Statute and its regulations. 42 U.S.C. § 1395w-102(b); 42 C.F.R. § 423.104(d)(3). Plans may also provide supplemental prescription coverage, which can include reductions in cost-sharing (such as deductibles or coinsurance percentages) or covering certain drugs that would qualify as a covered Part D drugs if they were not among the drugs described at 42 U.S.C. § 1396r-8(d)(2), (d)(3) and excluded from the definition of a Part D drug at 42 U.S.C. § 1395w-102(e)(2)(A).

A Part D sponsor submits a bid in the year prior to the calendar year in which Part D

benefits will actually be delivered. Id. § 423.265. The bid contains a per member per month ("PMPM") cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. Id. §§ 423.265, 423.272. From the bids, CMS calculates nationwide and regional benchmarks which represent the average PMPM cost. Id. § 423.279. If the Part D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium. Id. § 423.286. CMS then provides each Part D plan sponsor with advance monthly payments equal to the Part D plan sponsor's standardized bid, risk adjusted for health status, minus the monthly beneficiary premium, estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. § 423.293

When a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes the amount paid to the pharmacy. The PDE is an electronically created document that includes at least thirty-seven fields of information about a specific drug transaction. (Defs.' Mot. Dismiss, Ex. B, Instructions: Requirements for Submitting Prescription Drug Event Data ("CMS Instructions"), April 26, 2006, at 9.) CMS uses the information in the PDE at the end of the payment year to reconcile its advance payments to the sponsor with actual costs the plan sponsor incurred. Id. If a Part D Plan sponsor's actual costs exceed the estimated costs, the plan sponsor may be able to recoup some of its losses through a risk sharing agreement with CMS. Id. at 9–10. If a Part D Plan sponsor's estimated costs exceed its actual costs by a specified amount, payments to the Part D Plan sponsor for the year are reduced and the Plan

sponsor will have to pay back some its estimated payments. Id.

Part D Plan sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans, including subcontracts with pharmacy benefit managers ("PBM") who provide drugs through mail order and pharmacies. As a condition for receiving its monthly payment from CMS, a Part D Plan sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS. 42 C.F.R. § 423.505(k)(1). If the claims data has been generated by a subcontractor of a Part D plan sponsor, such as a PBM, that entity must "similarly certify" that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement. 42 C.F.R. § 452.505(k)(3). Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1). CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

### B. The Parties and Other Relevant Entities

#### 1. The Relator/Plaintiff

Relator/Plaintiff Anthony R. Spay is a licensed physician with approximately thirty-seven years of diversified experience within the pharmacy industry. (Am. Compl. ¶¶ 8–21.) He is not only a licensed pharmacist, but has been involved with pharmacy management, benefits management, long-term care, behavioral health, executive management, prescription drug

fraud/abuse detection, audition, and recovery for many of the nation's largest payers and pharmacy claims processors. (Id.)

**2. The Defendants**

Defendant CVS Caremark Corporation ("CVS Caremark") is the largest provider of prescriptions and related healthcare services in the United States. (Id. ¶ 22.) CVS Caremark participates in the Medicare Part D prescription drug program and has provided Part D Pharmacy Benefits Manager ("PBM") services to its clients' Part D Plans through its subsidiaries, Silverscript, Inc., Caremark LLC, CaremarkPCS, CVS Caremark Part D Services, LLC, and RxAmerica, LLC. (Id. ¶ 33.) Since 2006, CVS Caremark has served as a Medicare Prescription Drug Plan ("PDP") sponsor that contracts with Medicare to provide prescription drug benefits in all fifty states, the District of Columbia, and Puerto Rico through SilverScript Insurance Company ("SSIC") and Accendo Insurance Company ("Accendo"). (Id. ¶ 34.) In addition, CVS Caremark operates thousands of retail pharmacies, as well as mail order and specialty pharmacies that process Part D prescriptions and dispense Part D drugs to Medicare beneficiaries. (Id. ¶ 36.) Since 2006, CVS Caremark, through its subsidiary SSIC, a Medicare Prescription Drug Plan Sponsor, has provided Medicare Part D drug benefits to eligible beneficiaries. (Id. ¶ 37.) Finally, on April 29, 2011, CVS Caremark acquired the Medicare Part D business of Universal American Corp. ("UAM Medicare Part D business"), through which CVS Caremark now provides Medicare prescription drug benefits to more than three million beneficiaries through the community CCRxSM prescription drug plan. (Id. ¶ 39.)

Defendant Caremark Rx, LLC ("Caremark Rx") is one of the largest pharmaceutical services companies in the United States. (Id. ¶¶ 40–41.) Its services are referred to as pharmacy

benefit management ("PBM") services, which, through its subsidiaries, operates mail order, specialty mail order, and retail specialty pharmacy subsidiaries throughout the United States. (Id. ¶¶ 42–43.) CVS Caremark participates in the administration of Medicare (Part D) Drug Benefit through Caremark Rx. (Id. ¶ 45.) It also "assists employer, union, and other health plan clients that qualify for the Medicare Part D retiree drug subsidy by collecting and submitting eligibility and/or drug cost data to the CMS as required under Part D in order for these employer, union, and other health plan clients to obtain Part D retiree drug subsidies." (Id. ¶ 46.)

Since March 22, 2007, Defendant SilverScript, LLC ("Silverscript") has been a wholly-owned subsidiary of Caremark Rx and presently is a wholly-owned subsidiary of CVS Caremark. (Id. ¶ 48.) Since 2006, Defendant Caremark Rx, through Silverscript has provided PBM services to Part D Plan Sponsors throughout the United States. (Id. ¶¶ 49, 52.) Defendant Caremark, LLC is also a wholly-owned subsidiary of CVS Caremark. (Id. ¶ 54.) In 2006 and before the March 2007 CVS-Caremark merger, Defendant Caremark Rx conducted its pharmaceutical services operations through its subsidiaries, including but not limited to, Caremark, Inc. (Now Caremark, LLC) and Caremark PCS. (Id. ¶ 55.)

CVS Caremark also participates in the Medicare Part D Program through the offering of Medicare Part D benefits by its subsidiary, SilverScript Insurance Company, a subsidiary of Silverscript. (Id. ¶ 56.) SilverScript Insurance Company obtained a license from the State of Tennessee to operate as a health insurance company in 2006. (Id. ¶ 57.) It now offers Part D Plans in all fifty states, Washington D.C. and Puerto Rico. (Id. ¶ 59.)

Overall CVS Caremark's net revenues include both Part D Payments received from CMS, as well as payments received from Part D Sponsors related to CVS Caremark's subsidiaries' Part

D PBM services. (Id. ¶ 61.) CVS Caremark's Part D insurance premiums earned by its PDP are set based on the Part D sponsor's annual bid and related contractual arrangements with CMS. (Id. ¶ 62.) In addition to the Part D insurance premiums, CVS Caremark's net revenues include co-payments, deductibles, and co-insurance (collectively, the "Member Co-Payments") related to PDP members' actual prescription claims. (Id. ¶ 63.) Finally, CVS Caremark's net revenues include retiree drug subsidies paid by CMS. (Id. ¶ 64.)

### 3. The "Medical Card System" Entities

Medical Card System, Inc. ("MCS") is the second largest health administration and health insurance company in Puerto Rico where more than 725,000 commercial, Medicare, and Puerto Rico Medicaid ("Reforma") insureds live. (Id. ¶ 66.) MCS provides health plans to more than 1,000 companies and covers over 150,000 employees and family members. (Id.) Among other health services, MCS provides medical plans in Puerto Rico, and Medicare Part D coverage through both PDPs and Medicare Advantage Part D Plans ("MA-PDs"), which are offered through MCS's subsidiary, MCS Life Insurance Company. (Id. ¶ 67.) MCS also provides Part D coverage to employers who offer Part D benefits through employer plans to whom Part D retiree drug subsidies would apply. (Id.) In addition, MCS, through its affiliate, MCS Advantage, Inc., provides managed Medicare coverage. (Id. ¶ 68.) Finally, MCS provides pharmacy benefits to dual eligible Medicare Part D and Medicaid beneficiaries, including members impacted by Low Income Subsidy grants available to Medicare Part D beneficiaries living in the United States territories. (Id. ¶ 69.)

MCS Life Insurance Company ("MCS Life") is a subsidiary of MCS and provides Medicare Part D coverage to plans offered by MCS. (Id. ¶¶ 70–71.) In November 2004, CMS

approved MCS Life's request to offer managed care coverage to Medicare beneficiaries in Puerto Rico. (Id. ¶ 72.) Since January 1, 2006, MCS Life has participated with CMS as a Medicare Part D Plan Sponsor, providing Medicare Part D coverage to plans offered by MCS. (Id. ¶ 73.) From January 1, 2006 through at least September 2007, pursuant to the terms of a contract executed between them ("the Part D Contract"), CVS Caremark and SilverScript provided Medicare Part D PBM services to MCS Life for health insurance plans offered by MCS. (Id. ¶ 74.) In early 2006, MCS Life offered Part D benefits through a number of PDPs and MA-PDs. (Id. ¶ 75.) MCS Life also developed formularies for multiple Part D Plans. (Id. ¶ 76.) Finally, MCS Life also offered Part D benefits to employer plans providing prescription coverage to their retirees. (Id. ¶ 77.)

### C. The Prescription Benefit Management Agreement

In June 2003, Defendant Caremark Rx entered into a Prescription Benefit Management ("PBM") Agreement with MCS, pursuant to which Caremark, Inc. provided PBM services to health insurance plans offered by MCS. (Id. ¶ 235.) The Agreement was amended once in 2004 and again in 2006. (Id.) In early 2006, MCS Life and Defendant SilverScript entered into a Managed Pharmacy Benefit Services Agreement—Medicare Part D, pursuant to which SilverScript provided PBM services to support MCS Life's participation with CMS as a Part D Plan sponsor (the "MCS-SilverScript PBM Agreement" or the "Agreement"). (Id. ¶ 237.) According to the terms of this Agreement, SilverScript agreed "to participate, as a subcontractor to [MCS], in the management of [MCS's] Part D Plan, and [SilverScript] understands that its activities must, to the extent these are communicated to SilverScript, be consistent and comply with [MCS's] contractual obligations to CMS as a Part D Plan Sponsor." (Id. ¶ 238.) Both

parties also agreed to "comply with applicable CMS Laws and Regulations without the need for further notice to and approval from the other party." (Id. ¶ 239.) With regard to the submission of Part D claims data, SilverScript and MCS expressly agreed that "SilverScript shall perform data edit and quality control procedures designed to ensure accurate and complete prescription drug data." (Id. ¶ 241.)

Pursuant to the MCS-SilverScript PBM Agreement, the Caremark Defendants had significant financial incentives for adjudicating Part D claims and dispensing Part D drugs. (Id. ¶ 242.) First, the Caremark Defendants received administrative fees per paid retail or mail order/on-line claim. (Id. ¶ 242.) Second, they collected a dispensing fee only if the prescription was billed and dispensed to the Part D participant through Caremark's retail pharmacy network. (Id. ¶ 243.) The Caremark had additional incentives through their Caremark and CVS-owned mail order and retail pharmacies. (Id. ¶ 244.)

Under the MCS-SilverScript PBM Agreement, the Medicare Part D PBM services to be provided by Defendant's subsidiary also included concurrent Drug Utilization Review ("DUR") services for retail or point of sale ("POS") claims. (Id. ¶ 245.) According to the contract's terms, when a claim was rejected by Caremark's system, but actually represented appropriate therapy in the judgment of the physician or pharmacist, the pharmacist could either dispense the drug at the plan participant's expense or call MCS Life or SilverScript to override the denial edit. (Id. ¶ 246.) Under Caremark's system, however, only those claims processing edits provided by the PBM and selected by the Part D Plan as triggering a denial edit would require further action by the pharmacist to either contact MCS or SilverScript to override the denial or to have the plan participant obtain the prescription outside Part D at their own expense. (Id. ¶ 247.)

The MCS-SilverScript PBM Agreement remained in effect from January 1, 2006 until January 1, 2008, when Catalyst Rx took over as PBM for MCS's Medicare Part D Program. (Id. ¶ 249.) During that time, SilverScript, as a Caremark subsidiary, provided Medicare Part D PBM services to MCS Life for health insurance plans offered by MCS. (Id. ¶ 250.) In turn, for each health insurance benefit plan offered by MCS, MCS Life provided Medicare Part D prescription drug coverage. (Id. ¶ 251.)

**D. The Part D Audit by Pharm/DUR, Inc.**

**1. The Audit**

In February 2007, MCS retained Plaintiff Spay's company, Pharm/DUR, Inc. ("Pharm/DUR") to perform a comprehensive audit of the Medicare Part D retail and mail order pharmacy claims paid by MCS for MCS Life's Part D participants from January 1 through December 31, 2006. (Id. ¶ 254.) This audit was to include both desk audits and on-site audits. (Id. ¶ 255.) The desk audit program was used in instances where the Part D data analysis system identified a specific submission or data trend that was fraudulent or abusive, or where the claim volume of a specific pharmacy was not sufficient to be included for an on-site audit. (Id. ¶ 256.) After using pre-determined edits to identify pharmacies, Pharm/DUR made written requests directly from those pharmacies for documentation of specific components of the Part D claims. (Id.)

In February 2007, Pharm/DUR informed the Caremark Defendants that MCS had retained Pharm/DUR to conduct its audit. (Id. ¶ 257.) At the same time, Pharm/DUR obtained from the Caremark Defendants the paid Part D claims data for the MCS Life Part D participants. (Id.) The pharmacies in the CVS Caremark network serving MCS members were throughout the

United States and Puerto Rico. (Id. ¶ 260.) Pharm/DUR conducted an analysis of all Part D paid claims data for both retail and mail order pharmacy prescriptions submitted by pharmacies to be adjudicated by Defendant Caremark/Silverscript from January 1, 2006 through December 31, 2006. (Id. ¶ 261.)

Following the Part D paid claims data analysis, the next step in the audit process was to perform on-site and desk audits of retail pharmacies and on-site audits of mail order pharmacies. (Id. ¶ 262.) These involved auditors visiting the pharmacies to obtain copies of documents that supported the claims information submitted by the pharmacies and processed by the PBM for specific prescriptions in the review claims data set. (Id. ¶ 263.) The on-site auditor would compare the original hard copy of the prescriptions with the information submitted for payment. (Id. ¶ 263.) Pharm/DUR sent notices to the Caremark network retail pharmacies selected for desk and/or on-site audits. (Id. ¶ 264.)

Thereafter, on August 23, 2007, the Caremark Defendants sent a facsimile on Caremark letterhead to the pharmacies serving MCS members directing them not to cooperate with Pharm/DUR's Part D audit. (Id. ¶ 264.) Specifically, the fax stated, in pertinent part, "Please **DO NOT** release any information to [Pharm/DUR] or to MCS. Pharm/DUR does not have the right or privilege to contact any pharmacy on behalf of MCS, and therefore should not receive any claims, pricing, personal health information, or any confidential proprietary information from you concerning MCS." (Id. (emphasis in original).) Due to a series of obstructive actions of the Caremark Defendants, Pharm/DUR was unable to fully complete the desk or on-site audits of many of the MCS retail pharmacies, or to conduct the audits of mail order facilities as requested by MCS, the Part D Sponsor. (Id. ¶ 266.)

### 2. Pharm/DUR's Audit Findings

Pharm/DUR communicated the results of its audit analysis of paid claims data from MCS's retail and mail order pharmacies ("CVS Network Providers") to both MCS and to the Caremark Defendants through a series of communications, which culminated in Pharm/DUR issuing a December 2007 report (the "Audit Report"). (Id. ¶ 267.) The Audit Report documented the six areas where Pharm/DUR concluded that the Defendants had illegally adjudicated, paid, and submitted to CMS claims for Medicare Part D drugs, including the following:

1. Gender Specific Deviations: fraudulently dispensing of gender-specific drugs: 507 claims, causing improper payments by MCS and reported to CMS totaling $53,608.

2. MAC Pricing: fraudulently failing to apply Maximum Allowable Cost ("MAC") pricing to all MAC drugs: 3,658 claims causing improperly paid by MCS and reported by MCS to CMS totaling $105,141.80.

3. Expired Drugs: fraudulent payment for expired drugs on 11,286 claims causing improperly paid claims by MCS and reported to CMS by Defendant Caremark totaling $399,794.

4. False Prescriber Identities: fraudulent payment for claims where Defendant Caremark as the PBM adjudicated claims even though its network pharmacies failed to report accurate physician identifiers, and instead used "push" numbers on 15,903 claims causing improper payments by MCS and Part D claims reported to CMS totaling $673,494.58.

5. No Prior Authorization: fraudulent adjudication of claims where drugs were dispensed and claims were paid without prior authorization: 15,473 claims improperly paid by MCS and reported by Caremark to CMS totaling $2,842,298.09.

6. Over Limits: fraudulent adjudication of claims processed for quantities of drugs or days supply over the approved limit on 1,875 improper claims paid by MCS and reported by Caremark to CMS totaling $209,209.66.

(Id. ¶ 268.) Pharm/DUR's conclusions were based on the Part D claims data analysis of mail order and retail pharmacies, as well as desk audits of some of the retail pharmacies. (Id. ¶ 269.) Ultimately, Pharm/DUR identified 48,702 Medicare Part D claims which Defendant Caremark had adjudicated and fraudulently paid, with a total cost of $4,283,546.13 to MCS, all of which were submitted to CMS for payment. (Id.)

**E. The Fraud Allegations**

According to the Amended Complaint, the Caremark Defendants' nationwide Part D claims adjudication failed to have the required concurrent Drug Utilization Reviews ("DUR's"), including gender contraindications and review for over-utilization. (Id. ¶ 319.) The Part D customers of the Caremark Defendants were thus permitted to illegally reject the performance of drug-to-sex edits at point of sale or point of sale distribution. (Id. ¶ 319.) Part D Plan sponsors are not entitled to receive Medicare Part D payment for claims based on drugs dispensed without appropriate concurrent DUR's, including for gender-related contraindications and over-utilization. (Id. ¶ 326.)

Moreover, the Amended Complaint alleges that during the relevant time period, Defendants regularly and knowingly submitted false or fraudulent PDE data items to CMS. (Id. ¶ 323.) Further, the CVS Caremark Defendants intentionally and fraudulently thwarted the Sponsor's (MCS's) efforts to conduct an appropriate Part D fraud, waste and abuse program as required by 42 C.F.R. § 505(h)(1). The Caremark Defendants' customers should not have submitted Part D claims data to CMS related to Part D drugs dispensed as a result of the Caremark Defendants' intentional company-wide failure to perform the Part D claims adjudication process as required for compliance with Medicare Part D program requirements.

(Id. ¶ 326.) The payments made to MCS by CMS reflect more than $4 million in Part D claims which should not have been submitted to CMS. (Id. ¶ 335.) By virtue of these alleged false claims, MCS illegally received an overpayment. (Id. ¶ 335.) In turn, the Caremark Defendants' efforts to interfere with MCS's Part D fraud, waste and abuse program resulted in MCS neither reporting the overpayment to CMS nor returning any overpaid funds to CMS. (Id. ¶ 337.)

In addition to the foregoing, Defendants' failures allegedly resulted in CMS improperly paying Part D retiree drug subsidies. Specifically, MCS also offered, in addition to its plans providing standard Medicare Part D benefits, at least ten employer plans providing prescription coverage to their retirees. (Id. ¶ 344.) As MCS supplies health plans to more than 1,000 companies and covers over 150,000 employees and family members, MCS has applied for Part D Retiree Drug Subsidies ("RDS") with regard to those employer plans which offer prescription drug benefits similar to Part D Plans to Medicare-eligible retirees. (Id. ¶ 345.) The claims by MCS for these RDS benefits were "plagued" by the CVS Caremark Defendants' intentional system-wide adjudication fraud and non-compliance with state and Federal laws and Regulations described above with regard to the traditional Part D program. (Id. ¶ 346.) Therefore, any claims for RDS payments made by MCS health plans based upon prescription claims which failed to adhere to applicable Part D requirements led to illegal and unwarranted Part D RDS payments to MCS health plans by CMS. (Id.)

Defendant CVS Caremark also administers claims for other Part D customers nationwide and has processed claims which were included in the costs reported by its other customers with employer Plans in support of requests to CMS for RDS. (Id. ¶ 348.) Defendant Caremark's largest customer during the year ending December 2007 was the Federal Employee Health

Benefits Program ("FEHBP"), which qualifies as a group health plan eligible for RDS subsidies. (Id. ¶ 349.) Any claims submitted by Defendant Caremark's other customers' health plans, including FEHBP, which included prescription drug claims which failed to adhere to Part D requirements caused illegal and unwarranted Medicare Part D RDS payments by CMS to these plans. (Id. ¶ 351.)

Following litigation of contract disputes between MCS and Caremark in 2007 in the United States District Court for the District of Puerto Rico, Civil Action No. 07-1951 ("MCS-Caremark Litigation") (Defs.' Mot Dismiss, Ex. K), Plaintiff Anthony R. Spay initiated this action against Defendants. On August 15, 2011, Plaintiff filed an Amended Complaint alleging violations of the Federal False Claims Act, 31 U.S.C. § 3729(a)(1), (2), and (7). On April 23, 2012, Defendants filed a Motion to Dismiss the Amended Complaint. Plaintiff filed his Response on June 26, 2012, Defendants submitted a Reply Brief on August 3, 2012, and Relator filed a Sur-reply Brief on September 24, 2012. In conjunction with this Motion, Plaintiff moved to strike certain exhibits to Defendants' Motion to Dismiss and Defendants requested that the Court take judicial notice of their exhibits in support of their Motion to Dismiss. Finally, the United States filed a Statement of Interest on September 11, 2012, to which both parties responded. As all of these filings were completed by October 10, 2012, the Motion to Dismiss and related motions are ripe for judicial consideration.

## II. EVIDENTIARY MOTIONS

Prior to reaching the merits of Defendants' Motion to Dismiss, the Court must first consider two evidentiary motions filed in conjunction with the dispositive motion. First, Defendants request judicial notice of certain exhibits in support of their Motion to Dismiss.

Second, Plaintiff moves to strike certain exhibits attached to Defendants' Motion to Dismiss.

### A. Defendants' Request for Judicial Notice of Certain Exhibits in Support of Defendants' Motion to Dismiss

Defendants first request that the Court take judicial notice of Exhibits B through O, attached to the April 20, 2012 Declaration of their counsel, Robert H. Griffith. The Court grants this Motion. Rule 201 of the Federal Rules of Evidence allows a court to take judicial notice of adjudicative facts. Fed. R. Evid. 201(a). Facts that may be judicially noticed are those not subject to reasonable dispute because they are either generally known within a trial court's territorial jurisdiction or can be readily determined from sources whose accuracy cannot reasonably be questioned. Id. at 201(b). Where a party requests judicial notice and supplies the necessary information, a court must take judicial notice. Id. at 201(c)(2). "On a motion to dismiss, courts take judicial notice of documents which are matters of public record such as Securities and Exchange Commission filings, Oran v. Stafford, 226 F.3d 275, 289 (3d Cir. 2000), court-filed documents, Rouse v. II-VI Inc., No. Civ.A.06-566, 2008 WL 398788, at *1 (W.D. Pa. Feb. 11, 2008), and Federal Drug Administration reports published on the FDA website, In re Wellbutrin SR/Zyban Antitrust Litig., 281 F. Supp. 2d 751, 755 n.2 (E.D. Pa. 2003)." McGehean v. AF & L Ins. Co., No. Civ.A.09-1792, 2009 WL 3172763, at *2 (E.D. Pa. Oct. 2, 2009). Such notice serves only to indicate what was in the public realm at the time, not whether the contents of those documents are true. Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt., L.P., 435 F.3d 396, 401 n.15 (3d Cir. 2001); DCIPA, LLC v. Lucile Slater Packer Children's Hosp. at Stanford, No. Civ.A.10-6131, 2011 WL 5141505, at *3 (D. Or. Oct. 20, 2011) ("[T]aking judicial notice of certain documents does not demonstrate the truth of

everything contained in those records, and, as such, the truthfulness and proper interpretation of the document are disputable.").

In the present case, Defendants ask that the Court take judicial notice of fourteen exhibits attached to their pending Motion to Dismiss. Exhibits B through F are documents issued by the Centers for Medicare and Medicaid Services ("CMS"), the entity that administers the federal Medicare and Medicaid programs. Exhibits G through I are reports issued by the Office of the Inspector General for the Department of Health and Human Services. Exhibit J is the Medicare Prescription Drug Benefit Manual, prepared and published by CMS. Finally, Exhibits K through O are documents from prior litigation between MCS and Caremark in the United States District Court for the District of Puerto Rico ("MCS-Caremark Litigation").

Plaintiff does not object to the Court taking judicial notice of these documents. (Pl.'s Resp. Opp'n Req. For Judicial Notice 2.) Indeed, courts regularly take judicial notice of similar documents. See Wellbutrin SR/Zyban, 281 F. Supp. 2d at 755 n.2 (recognizing that courts may take judicial notice of federal government or federal agency documents published on websites or otherwise); McLaughlin v. Volkswagen of Am., Inc., No. Civ.A.00-3295, 2000 WL 1793071, at *3 n.3 (E.D. Pa. 2000) (taking judicial notice of National Highway Traffic Safety Administration's website description of vehicle recall in considering a 12(b)(1) motion); In re Able Labs. Secs. Litig., No. Civ.A.05-2681, 2008 WL 1967509, at *17 n.21 (D.N.J. Mar. 24, 2008) ("[I]n reviewing a motion to dismiss, documents subject to judicial notice include matters of public record, orders, and items appearing in the record of the case. . . . Among the public records a court may examine in order to resolve a motion to dismiss is a judicial proceeding from a different court or case.") (internal citations omitted).

To the extent, however, that Defendants asks for judicial notice of facts gleaned from these documents, the Court declines to do so. A court may take judicial notice of an adjudicative fact if that fact is not subject to reasonable dispute. Fed. R. Evid. 201(b). "A judicially noticed fact must either be generally known within the jurisdiction of the trial court, or be capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Werner v. Werner, 267 F.3d 288, 295 (3d Cir. 2001). "The Third Circuit has cautioned that we may not take judicial notice of a prior court opinion in order to establish the truth of the adjudicative facts on which the opinion is based." Montgomery v. Beneficial Consumer Disc. Co., No. Civ.A.04-2114, 2005 WL 497776, at *4 n.5 (E.D. Pa. Mar. 2, 2005) (citing S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Grp., Ltd., 181 F.3d 410, 426 (3d Cir. 1999) ("Specifically, on a motion to dismiss, we may take judicial notice of another court's opinion—not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity.")); see also Ables Labs., 2008 WL 1967509, at *17 n.21 ("Taking judicial notice of the existence of other proceedings does not convert a motion to dismiss into a motion for summary judgment as long as the court does not take judicial notice of those proceedings to find facts."). "Taking judicial notice of the truth of the contents of a filing from a related action could reach, and perhaps breach, the boundaries of proper judicial notice." Werner, 267 F.3d at 295.

In the present case, Defendants ask the Court to take judicial notice "of the fact that the District Court Judge in the MCS-Caremark Litigation twice denied MCS's attempt to amend its complaint." (Defs.' Mem. Supp. Mot. for Judicial Notice 6.) In their concurrently-filed Motion to Dismiss, Defendants then expand their request to judicial notice of the fact that the audit "led

to litigation based on the contract between MCS and Caremark" and "of the MCS-Caremark litigation and MCS's unsuccessful attempt in that litigation to amend its complaint to assert causes of action based upon the same audit findings alleged by Pharm/DUR as Spay asserts here." (Defs.' Mem. Supp. Mot. to Dismiss 30 n.17.) Although Defendants vigorously argue that such facts are true and reasonably inferrable from the noticed documents, judicial notice of such facts is not appropriate. To do so would "breach[] the boundaries of proper judicial notice."

Accordingly, the Court will grant Defendants' Request and take judicial notice of Exhibits B through O to their Motion to Dismiss to establish the existence of those documents. The Court, however, declines to make findings of fact based on those documents or rely on those documents for the truth of the matters asserted.

### B. Plaintiffs' Motion to Strike, or, in the Alternative, Objections to Exhibits to Defendants' Motion to Dismiss

Having taken judicial notice of all exhibits attached to Defendants' Motion to Dismiss, the Court must now consider Plaintiff's Motion to Strike/Specific Objections to Exhibits. In deciding Rule 12(b)(6) motions, "courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint, and matters of public record." Pension Benefit Guar. Corp. v. White Consol. Indus. Inc., 998 F.2d 1192, 1196 (3d Cir. 1993) (citations omitted). A court may also consider an exhibit to a defendant's motion to dismiss if the plaintiff's claims are based on that document and if that document is indisputably authentic. Id.; Pryor v. Nat'l Collegiate Athletic Ass'n, 288 F.3d 548, 560 (3d Cir. 2002).

Plaintiff now moves to strike and/or objects to all but two of the exhibits attached to Defendants' Motion to Dismiss. In so doing, however, Plaintiff does not withdraw his prior

concession—discussed in the previous section of this Memorandum—that the Court may take judicial notice of these documents. Rather, for each allegedly problematic exhibit, he offers a string cite of objections followed by the applicable evidentiary rule, but with absolutely no supporting case law or analysis. For example, with respect to Exhibit A, Plaintiff argues as follows:

> Plaintiff objects to this Exhibit because it does not relate to this Court's consideration of the jurisdictional issues raised by Defendants in their Motion to Dismiss. Moreover, it is being offered by Defendants for the truth of the matters asserted therein and therefore cannot be considered by this court at this stage of the proceedings. In addition, it constitutes inadmissible hearsay (Fed. R. Evid. 802); it lacks foundation and has not been properly authenticated (Fed. R. Evid. 901); it fails to satisfy the "best evidence" Rule (Fed. R. Evid. 1002); and it is not relevant (Fed. R. Evid. 402) at this stage of the proceedings to this Court's consideration of Defendants' Motion to Dismiss.

(Pl.'s Mem. Supp. Mot. to Strike 4.)

Aside from the fact that such cursory objections provide insufficient analysis on which their merits may be assessed, Plaintiff's arguments are entirely improper at this stage of the proceedings. Primarily, as Plaintiff did not oppose the Court's taking of judicial notice of these documents, his current objections as to authenticity are waived. Moreover, the Court's judicial notice is limited to what was known and in existence in the public realm at the time and not to demonstrate the truth of everything contained in those documents. As such, Plaintiff's objections based on hearsay and the "best evidence" rule are premature. Finally, to the extent Plaintiff broadly objects to the documents based on relevancy, the Court must consider the context in which each document is offered in order to determine whether it is relevant. Such an objection is not, at this juncture of the litigation, an appropriate basis on which to exclude an entire

document.

Ultimately, Plaintiff's argument appears to assume that Defendants' Motion to Dismiss is being converted into a motion for summary judgment. This is not the case. The Court considers the Motion to Dismiss under the standards set forth in Federal Rule of Civil Procedure 12(b)(6). By taking judicial notice of the Defendants' exhibits, the Court does not necessarily accept these documents for the truth of their content. Rather, the Court continues to take the well-pled allegations of the Amended Complaint as true. Therefore, Plaintiff's Motion to Strike and/or Objections is denied in its entirety.

## III. RULE 12(b)(6) STANDARD OF REVIEW

Under Rule 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P.12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). In Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), the United States Supreme Court recognized that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 555. Following these basic dictates, the Supreme Court, in Ashcroft v. Iqbal, 556 U.S. 662 (2009), subsequently defined a two-pronged approach to a court's review of a motion to dismiss. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. at 678. Thus, although "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era . . . it does not

unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." Id. at 678–79. Second, the Supreme Court emphasized that "only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 679. "Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. A complaint does not show an entitlement to relief when the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct. Id.; see also Phillips v. Cnty. of Allegheny, 515 F.3d 224, 232–34 (3d Cir. 2008) (holding that: (1) factual allegations of complaint must provide notice to defendant; (2) complaint must allege facts suggestive of the proscribed conduct; and (3) the complaint's "'factual allegations must be enough to raise a right to relief above the speculative level.'" (quoting Twombly, 550 U.S. at 555)).

Notwithstanding these new dictates, the basic tenets of the Rule 12(b)(6) standard of review have remained static. Spence v. Brownsville Area Sch. Dist., No. Civ.A.08-626, 2008 WL 2779079, at *2 (W.D. Pa. July 15, 2008). The general rules of pleading still require only a short and plain statement of the claim showing that the pleader is entitled to relief and need not contain detailed factual allegations. Phillips, 515 F.3d at 233. Further, the court must "accept all factual allegations in the complaint as true and view them in the light most favorable to the plaintiff." Buck v. Hampton Twp. Sch. Dist., 452 F.3d 256, 260 (3d Cir. 2006). Finally, the court must "determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Pinkerton v. Roche Holdings Ltd., 292 F.3d 361, 374 n.7 (3d Cir. 2002).

Notably, however, it is well-established that *qui tam* actions brought under the False Claims Act must be pled with particularity under Federal Rule of Civil Procedure 9(b). United

States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 n.9 (3d Cir. 2004) (citing United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998)); U.S. ex rel. Budike v. PECO Energy, ___ F. Supp. 2d __, 2012 WL 4108910, at *10 (E.D. Pa. Sep. 14, 2012); United States ex rel. Atkinson v. Pa. Shipbuilding Co., No. Civ.A.98-7316, 2000 WL 1207162, at *10 (E.D. Pa. Aug. 24, 2000). In order to satisfy this exacting standard, the plaintiff must "plead (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage." Shapiro v. UJB Fin. Corp., 964 F.2d 272, 284 (3d Cir. 1992) (citing Christidis v. First Pa. Mortg. Trust, 717 F.2d 96, 99 (3d Cir. 1983)). The stringency of this requirement stems from the Federal Rules' goal of:

> [P]rotect[ing] a defending party's reputation from harm, to minimize strike suits, and to provide detailed notice of a fraud claim to a defending party. The Rule [9(b)] also discourages meritless fraud accusations that can do serious damage to the goodwill of a business or a professional person. The requirements of Rule 9(b) effectively prevent a claimant from searching for a valid claim after a civil action has been commenced.

2 James Wm. Moore et al., Moore's Federal Practice, § 9.03[1][a] (3d ed. 2002) (citations omitted). Rule 9(b) commands that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Pursuant to this heightened pleading standard, plaintiffs must "plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent

behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). This standard requires a description of the "'who, what, when, where and how' of the events at issue." In re Rockefeller Ctr. Props., Inc. Secs. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (internal quotation marks and citation omitted). Rule 9(b) is generally considered satisfied when a defendant has "fair notice" of the charges against it. United States v. Kensington Hosp., 760 F. Supp. 1120, 1126 (E.D. Pa. 1991).

## IV. MERITS OF DEFENDANTS' MOTION TO DISMISS

Defendants now move to dismiss the entirety of Plaintiff's Amended Complaint on three broad grounds. First, they contend that Plaintiff cannot plead the elements of a cause of action under the False Claims Act. Second, they argue that Plaintiff's attempts to broaden the scope of his complaint to plead "nationwide" FCA violations fail to allege fraud with particularity as required by Federal Rule of Civil Procedure 9(b). Finally, Defendants assert that Plaintiff's suit is barred in its entirety by the False Claims Act's Public Disclosure Provision. The Court addresses each argument in turn.[3]

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[3] As noted above, the United States filed a Statement of Interest in Response to Defendants' Motion to Dismiss. In that Statement, the government emphasized that its decision not to intervene should not be interpreted as a comment on the merits of Plaintiff's claims. In support of this position, the government cites a number of supportive cases. United States ex rel. Atkins v. McInteer, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006) ("We do not assume that in each instance in which the government declines intervention in an FCA case, it does so because it considers the evidence of wrong doing insufficient or the *qui tam* relator's allegations for fraud to be without merit. In any given case, the government may have a host of reasons for not pursuing a claim."); United States ex rel. Chandler v. Cook County, Ill., 277 F.3d 969, 974 n.5 (7th Cir. 2002) ("There is no reason to presume that a decision by the Justice Department not to assume control of the suit is a commentary on its merits. The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney."), aff'd 538 U.S. 119 (2003); Anderson v. McTish, Kunkle & Assoc., No. Civ.A.04-754, 2006 WL 1985762, at *1 n.1 (M.D. Pa. July 13, 2006) ("We are

A. **Whether Plaintiff Pleads the Elements of a Cause of Action under the False Claims Act**

Plaintiff's Amended Complaint centers on the False Claims Act ("FCA"), 31 U.S.C. § 3729, et seq, (1994).[4] The False Claims Act enables the government to recover losses it has incurred as a result of fraud. United States v. Educ. Mgmt. Corp., __ F. Supp. 2d ___, 2012 WL 1658482, at *8 (W.D. Pa. May 11, 2012). "Its roots can be traced to the Civil War, when it was enacted in response to contractors who sold faulty weaponry, rancid food and unseaworthy ships to the government." Id. Because of the difficulty in having the government discover and prosecute all potential violations, the False Claims Act "provides a *qui tam* enforcement

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not permitted to draw any inference from the decision of the United States not to intervene in this case.").

In response, Defendants cite to United States ex rel. Jamison v. McKesson Corp., 649 F.3d 322, 331 (5th Cir. 2011) as holding that a government's declination to intervene means that the claims "presumably lacked merit." (Defs.' Reply Br. 3 n.1.) That case, however, did not make any such ruling. Rather, the court, when considering whether the relator's suit was based on public disclosures, stated as follows:

> The arbitrariness of Jamison's selection of defendants is indicated by the fruits of his suit. After a lengthy investigation, the government chose to intervene against only the seven defendants named in this appeal, out of the almost 450 defendants. The cases against the others presumably lacked merit, which would be consistent with the inference that Jamison selected them arbitrarily.

Jamison, 649 F.3d at 331. At no point did the court suggest that there is any per se presumption of lack of merit based solely on the government's decision to not intervene. As the United States Court of Appeals for the Third Circuit has yet to opine on this precise issue, this Court follows the overwhelming weight of authority from other circuits to find that no such presumption should be imposed.

[4] The False Claims Act was amended in 2009. The amendments, however, explicitly state that "[t]he amendments made by this section shall take effect on the date of enactment of this Act [May 20, 2009] and shall apply to conduct on or after the date of enactment." 31 U.S.C. § 3729(4)(f) (2009). Because the conduct at issue in this case occurred in 2006 and 2007, the amendments do not apply. Accordingly, the Court uses the pre-2009 version of the FCA.

mechanism, which allows a private party (i.e., a relator) to bring a lawsuit on behalf of the government and against an entity to recover money the government paid as a result of fraudulent claims." Id. (quotations omitted). In return, relators, may keep a percentage of the proceeds from any judgment or settlement in their cases. Id.

The Amended Complaint in this case appears to allege violations of three separate sections of the FCA. These sections provide that a person is liable to the United States government when that person: "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1); "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government," 31 U.S.C. § 3729(a)(2); and "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7).

Defendants now set forth four separate arguments for dismissal of these causes of action: (a) Plaintiff cannot plead falsity as a matter of law under 31 U.S.C. § 3729(a)(1); (b) Plaintiff's 31 U.S.C. § 3729(a)(2) claim fails to allege that Caremark submitted or caused to be submitted a "claim" to the Government "to get" a claim paid; (c) any FCA conspiracy claim, under 31 U.S.C. § 3729(a)(3), fails as a matter of law; and (d) Plaintiff's reverse false claims cause of action, under 31 U.S.C. § 3729(a)(7), fails as a matter of law. The Court individually considers each argument.

### 1. Whether Plaintiff Properly Pleads Falsity for Purposes of Subsection (a)(1)

"A plaintiff, in order to establish a prima facie FCA violation under section 3729(a)(1), must prove that '(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.'" United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011) (quoting United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004); Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 182 (3d Cir. 2001)). Defendants' primary argument in favor of dismissal focuses on the second element—falsity—which, as noted above, must be pled with particularity under Rule 9(b).

An allegation under this section of the FCA may proceed under two theories: (1) a legally false claim under the false certification theory and (2) a worthless services theory. See In re Genesis Health Ventures, Inc., 112 F. App'x 140, 143 (3d Cir. 2004) (recognizing various theories); Wilkins, 659 F.3d at 305 (referencing a legally false claim theory and a factually false claim theory, which is comparable to worthless services). Plaintiff, in this matter, puts forth allegations under both of these theories and the Court addresses them separately.

#### a. False Certification Theory

The crux of Plaintiffs' FCA allegations focus on legally false claims. "A legally false FCA claim is based on a 'false certification' theory of liability." Wilkins, 659 F.3d at 305. "[C]ourts have recognized that there are two types of false certifications, express and implied." Id. (citations omitted). "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to

Government payment in connection with the claim for payment of federal funds." Id. (citations omitted). In addition, there is an "implied false certification" theory which occurs "when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." Id. In other words, it "is premised 'on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.'" Id. (quoting Mikes v. Strauss, 274 F.3d 687, 699 (2d Cir. 2001)). The Third Circuit, however, has cautioned that "the implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs." Id. at 307. "Thus, under this theory a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." Id.

Plaintiff alleges that he has sufficiently pled that Defendants submitted, or caused to be submitted, claims for payment that are false under the FCA. In particular, he asserts that Defendants are required, as a condition of payment under the Part D Program, to certify that the PDE's they submit are "true, accurate, and complete," "based on best knowledge information and belief." 42 C.F.R. § 423.505(k)(1) and (3). Yet, Defendants knowingly submitted false and inaccurate Medicare Part D PDEs to Medicare in violation of both their express certifications and Medicare Regulations that condition payment on the submission of true, accurate, and complete PDEs. (Am. Compl. ¶¶ 99, 101, 136, 139–47, 334–35.) Defendants' alleged false certification that each PDE was "true, accurate, and complete," in violation of this condition of payment,

rendered the claims they submitted false under the FCA.

Defendants' offer a three-fold argument for dismissal of this claim. First they assert that 42 C.F.R. § 505(k)—requiring that PDEs be certified as "true, accurate, and complete"— does not apply to PBMs as a condition of payment that can form the basis of a False Claims Act violation. Second, even if this regulation were to apply to PBMs, Defendants assert that none of the individual violations allegedly committed by Defendants involve "data related to payment" within the confines of this section. Finally, assuming *arguendo* both that 42 C.F.R. § 505(k) is a condition of payment applicable to PBMs and the errors by Defendants involve data related to payment, Plaintiff has not pled that Defendants submitted any false, inaccurate, or incomplete data. The Court first considers the definition of a "condition of payment and then addresses the substance of Defendants' three arguments.

**i. What is a Condition of Payment?**

The United States Court of Appeals for the Third Circuit has held that the False Claims Act was not designed for use as a "blunt instrument" to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment. Wilkins, 659 F.3d at 307. A violation concerns a "condition of payment" if such violation "might cause [the government] to actually refuse payment." Id. (citing United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1220 (10th Cir. 2008)).

Notably, conditions of payment are not the equivalent of conditions of participation. The regulations define "Conditions of Participation" as "the requirements providers . . . must meet to participate in the Medicare program. . . ." 42 C.F.R. § 488.1. "Conditions of Participation are

quality of care standards directed towards an entity's continued ability to participate in the Medicare program rather than a prerequisite to a particular payment." U.S. ex rel. Landers v. Baptist Mem'l Health Care Corp., 525 F. Supp. 2d 972, 978 (W.D. Tenn. 2007). A legally false certification of compliance with a statute or regulation cannot form a viable FCA cause of action unless *payment* is expressly conditioned on that certification. United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004) ("[A] false certification of compliance creates liability when certification is a prerequisite to obtaining a government benefit."); United States ex rel. Willard v. Humana Health Plan of Tex., Inc., 336 F.3d 375, 381 (5th Cir. 2003) ("The False Claims Act does not create liability merely for a healthcare provider's disregard of government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asked the government to pay amounts it does not owe." (citation omitted)). Rather, as stated by the Third Circuit, "under [the false certification] theory a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." Wilkins, 659 F.3d at 307. Absent this requirement, the FCA could turn "into 'a blunt instrument to enforce compliance with all . . . regulations' rather than 'only those regulations that are a precondition to payment.'" Id. (quotations omitted).

**ii. Whether Defendants are Required as a Condition of Payment Under the Part D Program, to Certify that the PDEs They Submit are True, Accurate, and Complete**

Plaintiff's false certification theory alleges that Defendants' non-compliance with 42 C.F.R. § 423.505(k) was a condition of payment on which an FCA claim may be based. This

provision, entitled "Certification of data that determine payments," provides, in pertinent part, as follows:

> (1) General rule. ***As a condition for receiving a monthly payment*** under subpart G of this part (or for fallback entities, payment under subpart Q of this part), ***the Part D plan sponsor agrees*** that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, ***must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to the payment.*** The data may include enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> . . .
>
> (3) Certification of claims data. 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) (or for fall back entities, under § 423.871(f)) 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.***

42 C.F.R. § 423.505(k)(1) & (3) (emphasis added).

Defendants now reason that section 423.505(k)(1) only makes it a "condition of payment" for the *Part D Plan Sponsor* to certify that all data related to a requested payment from the government be accurate, truthful, and complete. Caremark, however, was the *PBM*, a subcontractor of a Part D sponsor and, thus, was bound only by subsection (k)(3), which simply stated that a PBM must "similarly certify" the accuracy, completeness, and truthfulness of the data and "acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." Because that subsection does not include the "condition of payment language,"

the canon of construction *expressio unius est exclusio alterius*[5] requires a finding that the "condition of payment" language was not meant to apply to subsection (k)(3). In turn, Defendants conclude that because a PBM's improper certification under subsection (k)(3) is not a condition of payment, it cannot serve as a basis for an FCA cause of action.

The Court, however, must disagree with Defendants' interpretation. While Defendants correctly observe that subsection (k)(3) does not use the "condition of payment" language, it is a well-established principle that "the text of a statute must be considered in the larger context or structure of the statute in which it is found." Alli v. Decker, 650 F.3d 1007, 1012 (3d Cir. 2011) (quotations omitted). Subsection (k)—under which both subsections (k)(1) and (k)(3) are found—is entitled "Certification of data that determine payments." It logically follows then that all subparts to this heading necessarily relate to certifications that "determine" or, potentially, are a "condition" of payment, even if those subparts do not specifically use such terms. Reading the three ensuing subparts of subsection (k) together reveals that, as a condition for receiving payment, a Part D sponsor must certify the accuracy, completeness, and truthfulness of all data, including claims data, related to the requested payment from the government. When that claims data is generated by a subcontractor of a Part D Sponsor, such as a PBM, the subcontractor must similarly certify, as a condition of payment, the truthfulness, accuracy, and completeness of the data.[6]

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[5] This canon presumes that where Congress includes particular language in one section of a statute but omits it in another, Congress acted intentionally and did not mean the language to apply to the section from which it is absent. United States v. Thornton, 306 F.3d 1355, 1359 (3d Cir. 2002).

[6] In their Reply Brief, Defendants appear to argue that for an FCA claim to lie against a PBM, the violated regulation must be a condition of payment *to a PBM*. (Defs.' Reply Br. 6.)

This interpretation finds support in CMS's Prescription Drug Benefit Manual. Section 80.1, entitled "The False Claims Act," specifically references section 423.505(k)(3) and provides as follows:

> 80.1 — The False Claims Act
>
> Sponsors should devise their compliance programs so that their policies and procedures are consistent with the Federal Civil False Claims Act . . . When submitting claims data to CMS for payment, Sponsors ***and their subcontractors*** must certify that the claims data is true and accurate to the best of their knowledge and belief [footnote referencing section 423.505(k)(3)]. The False Claims Act is enforced ***against any individual/entity*** that knowingly submits ***(or causes another individual/entity to submit)*** a false claim for payment to the Federal government.

(CMS Prescription Drug Benefit Manual, Chapter 9 - Part D Program to Control Fraud, Waste and Abuse ("CMS Prescript Drug Benefit Manual Chapter 9"), at 67, § 80.1 (footnotes omitted).) The plain import of this language suggests that Section 423.505(k)(3) was designed precisely to make a subcontractor's certification of the truthfulness, accuracy, and completeness of claims data a condition of payment. Further, it indicates that false certification by a subcontractor of this information, which "causes" the Part D Sponsor to submit a false claim for payment to the government, is grounds for an FCA claim.

Finally, the Court's reading of this provision finds guidance from the decision in United States v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430 (E.D. Pa. 2004). In that case, relators and United States brought action under the FCA, Public Contracts Anti-Kickback Act ("AKA"), and common law alleging that the pharmacy benefit manager had defrauded

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This argument creates an incorrect limitation on FCA claims. Rather, the violated regulation must simply be a condition of payment *by the Government*. See Wilkins, 659 F.3d at 305–06. There is no restriction on the entity to whom that payment must be made.

United States by billing for services not rendered, fraudulently avoiding contractual penalties, fraudulently inducing physicians to authorize drug switches, and favoring one pharmaceutical manufacturer over other manufacturers. Id. at 433–34. Confronting a challenge to the "falsity" element of the FCA claim in the context of a motion to dismiss, the court remarked that "[t]he FCA reaches 'all fraudulent attempts to cause the Government to pay out sums of money.'" Id. at 438 (quoting Hutchins, 253 F.3d at 183). It went on to note that

> Medco [the PBM] billed Blue Cross [the sponsor and health insurer] and hence the Government for services it was required to render in accordance with its contract and with state law—any claims submitted that do not fulfill these prerequisites are false. In some cases, such as the drug shorting allegations, Medco allegedly billed for products that it simply did not provide. If the allegations are true, these bills could form the basis of a false claim. Moreover, Medco was required to submit certifications of its performance which were used to assess contractual penalties and to determine whether its contract with Blue Cross would be renewed. To the extent that these certifications were false, they could have fraudulently induced Blue Cross to renew its contract with Medco.

Id. at 439.

Although this case did not touch on the interpretation of section 423.505(k), its reasoning makes clear that governmental regulations and conditions of payment on a Medicare Part D plan sponsor may be similarly imposed upon the sponsor's subcontracting PBM via the relevant contract between the sponsor and PBM for purposes of the FCA. Specifically, in this matter, by improperly certifying the truthfulness, accuracy, and completeness of its claims data to the MCS, Defendants—like the defendants in Merck-Medco—caused MCS to improperly submit requests for payment to the Government that were not true. In other words, even though the "condition of payment" language in subsection (k)(1) only applies to MCS as the Part D Plan Sponsor, Defendants' improper certification fraudulently caused MCS to seek payment from the

Government, thereby making Defendants liable.[7]

Defendants attempt to counter this reasoning by relying on the Third Circuit decision in United States ex rel. Wilkins v. United Health Group, 659 F.3d 295 (3d Cir. 2011), a *qui tam* False Claims Act case in which the relators alleged that their employer had knowingly violated several Medicare marketing regulations. Id. at 300. Proceeding under an implied certification theory, the Third Circuit cautioned that it "should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs." Id. at 307. It held that the alleged violations of Medicare marketing regulations were not conditions of payment, but rather conditions of participation. Id. at 309. The court further noted that the relators had failed to cite to any regulation demonstrating that a participant's compliance with Medicare marketing regulations was a condition for its receipt of payment from the government. Id. at 309–10. Indeed, the court found that while the government considered substantial compliance with marketing regulations a condition of ongoing participation, it did not require absolute compliance for receiving Medicare payments for services rendered. Id. at 310.

The present case, however, is distinguishable from Wilkins on several grounds. First, PDE records, which are used by CMS for payment purposes are simply not analogous to

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[7] Plaintiff also argues that Defendants signed an Electronic Data Interchange ("EDI") Agreement, which must be executed in order for an eligible organization, including Defendants, to submit PDEs electronically to CMS. In the Part D EDI Agreement, Defendants certified that "each submission of PDE data pursuant to this Agreement will be accurate and complete to the eligible organization's best knowledge, information and belief." (Am. Compl. ¶¶ 141–42.) While this Agreement further bolsters Defendants' obligation to certify the accuracy of its data, a violation of this Agreement does not clearly give rise to an FCA claim.

Medicare marketing regulations. Moreover, the FCA claim in this case is not premised on noncompliance with the PDE requirements, but rather the false *certification* of compliance. Under 42 C.F.R. § 505(k). Indeed, as indicated above, CMS's Prescription Drug Benefit Manual specifically envisions False Claims Act liability for the certification and submission of inaccurate or false PDE data. In the absence of such liability, a subcontractor to a Part D Sponsor—in this case, Defendants—"would be virtually unfettered in its ability to receive funds from the government while flouting the law." United States v. Educ. Mgmt. Corp., __ F. Supp. 2d __, 2012 WL 1658482, at *20 (W.D. Pa. May 11, 2012).[8]

In short, the Court finds that when properly interpreted, 42 C.F.R. § 505(k) makes proper certification of data a "condition of payment." In turn, failure of either a Part D Plan sponsor or the Sponsor's subcontractor to submit accurate, complete, and truthful data related to payment may give rise to an FCA claim. Accordingly, the Court rejects this portion of Defendants' argument.

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[8] In their Response to the Government's Statement of Interest, Defendants cite to the purportedly analogous case of United States ex rel. Fox Rx, Inc. v. Omnicare, No. Civ.A.11-962 (N.D. Ga. Aug. 29, 2012). In that case, the relator brought a *qui tam* action against a PBM for seeking reimbursement for Medicare Part D beneficiaries that (a) were off-label drugs; (b) involved prescription-filling; (c) filling certain prescriptions without getting prior authorization; and (d) failing to charge co-payments. The court found that none of these alleged violations were conditions of payment, and thus dismissed the FCA claim. Id.

Defendants' citation of this case again disregards the fact that it is not the false PDE data in and of itself that constitutes the false certification for purposes of the FCA. It is the false certification of their truth, accuracy, and completeness of such PDE data, under 42 C.F.R. § 423.505(k)(3), that results in the alleged FCA violation. Accordingly, the Court does not find Omnicare analogous.

### iii. Whether Any of the Allegedly False Data Submitted by Defendants Was "Data Related to Payment" Under 42 C.F.R. § 423.505(k)

Having found that section 423.505(k)(1) is a condition of payment that applies to Defendants, the Court must next consider whether any of the allegedly false data submitted by Defendants was data "related to payment," and thus within the confines of this provision.[9] They contend that only four of the thirty-seven data fields on a PDE record are actually used to determine payment. In support of this proposition, Defendants cite only to the Amended Complaint, wherein Plaintiff alleges that:

> CMS specifically relies upon and uses the following PDE cost and payment fields in its year end reconciliation: gross drug cost above out-of-pocket threshold, gross drug cost below out-of-pocket threshold, low-income, cost-sharing subsidy, and covered D Plan paid amount (the four PDE data elements). The Sponsor, or its PBM calculates the four data elements from the point-of-sale claims data submitted by the pharmacy using instructions provided by CMS.

(Am. Compl. ¶ 127.). Because the six alleged defects in the PDE records submitted by Defendants have nothing to do with payment, Defendants' certification of this purportedly false data does not, according to Defendants, fall within the bounds of § 423.505(k). In turn, Defendants contend that it cannot form the basis of a False Claims Act violation.

Defendants' argument, however, is misplaced in several respects. First, to the extent Defendants rely on paragraph 127 of the Amended Complaint, their reliance is faulty. Plaintiff does not attempt, in this paragraph, to define "data related to payment." Rather, the cited

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[9] In their initial brief, Defendants contended that none of the six alleged errors in the PDEs are conditions of payment. Apparently recognizing that Section 423.505(k)—and their alleged false certification of the truth, accuracy, and completeness of their claims data—could constitute a condition of payment, Defendants' Reply Brief now argues that none of Plaintiff's claims plead that Defendants submitted false data "related to payment."

paragraph simply defines *some* of the information CMS relies upon in its year-end reconciliation. At no point does Plaintiff attempt to provide a comprehensive list of data related to determining the monthly subsidy payments sent to Part D Sponsors.

More importantly, this Court's own review of the regulations and administrative materials reveals that "data relating to payment" has a far more expansive meaning than that proposed by Defendants. As set forth above, Sections 423.505(k)(1) and (k)(3) require that a Part D plan sponsor and its subcontractors certify "the accuracy, completeness, and truthfulness of all *data related to the payment.* " 42 C.F.R. § 423.505(k)(1) (emphasis added). This section goes on to state that "[t]he data may include enrollment information, claims data, bid submission data, and other data that CMS specifies." Id. While "data relating to payment" is not otherwise defined in this section, reference to other sections within this part of the regulations provides some guidance. Subpart G of Part 423 of the Medicare Regulations—under which § 423.505(k) falls—is entitled, "Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage." Within the confines of this title, 42 C.F.R. § 423.322 discusses the "Requirement for Disclosure of Information" and states, in pertinent part, that "Payments to a Part D sponsor *are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law."* Id. § 423.322(a) (emphasis added).

CMS's Instructions for submission of Part D prescription PDE claims data then clarify § 423.322 and confirm that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. These Instructions state, in pertinent part, as follows:

> ***As a condition of payment***, all Part D plans must submit data and information necessary for CMS to carry out payment provisions (§1860D-15(c)(1)(C) and (d)(2) of the Act, and 42 CFR §423.322). This document describes how CMS will

> implement the statutory payment mechanisms ***by collecting a limited subset of data elements on 100 percent of prescription drug "claims" or events***. We describe the required data submission per event, the mode and frequency of submission, and how the data will be used to make payment and conduct reconciliation. These requirements apply to all Part D plans as defined in §423.401 unless separate instructions are issued.
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> . . .
>
> 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.[10]

(CMS Instructions, at intro (emphasis added).) Section 1.1 of these Instructions goes on to note that:

> 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. Section 2 lists the required set of data elements for all PDE records (15 data elements from the NCPDP billing transaction, 5 data elements from the NCPDP billing response transaction, and 17 data elements defined by CMS for purposes of administering Part D, for a total of 37 data elements).

(Id. § 1.1.) Finally, Section 2 goes on to list the thirty-seven data elements "that must be submitted on PDE records ***for payment***." Id. (emphasis added).

In light of such materials, it becomes abundantly obvious that, contrary to Defendants' belief, 42 C.F.R. § 423.505(k)(1)'s reference to "data related to payment" includes all thirty-seven data fields on a PDE record. This is, of course, not to say that such data fields are

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[10] Defendants attempt to interpret this paragraph as meaning that only a few of the data fields will be used for payment. (Defs.' Mem. Supp. Mot. Dismiss 10; Defs.' Reply Br. 10.) A more logical interpretation of this paragraph indicates that while all of the data fields will be used for payment, many of them will be used "primarily" for payment and the remainder will be used for payment and for other purposes such as validation and other legislated functions.

"conditions of payment," such that submission of these records with incomplete or inaccurate data automatically gives rise to a violation of the False Claims Act. Rather, it is the act of certifying the truth, accuracy, and completeness of these fields under § 423.505(k)(1) & (3) when such data is not actually truthful, accurate, or complete, that gives rise to a False Claims Act cause of action.[11]

Plaintiff's Amended Complaint asserts that Defendants falsely and/or inaccurately identified the physicians who wrote the prescriptions to Medicare beneficiaries (fields 12 and 13). (Am. Compl. ¶¶ 271–88.) Further, it claims that Defendants falsely and/or inaccurately inflated the cost that the Part D Plan incurred for the prescription drugs being dispensed (field 28). (Id. ¶¶ 315–18.) The Amended Complaint goes on to allege that, in violation of Section 423.505(k), Defendants then falsely certified the truth, accuracy, completeness of those data fields.[12] Such allegations give rise to a proper claim under the False Claims Act.[13]

**iv. Whether Plaintiff Has Adequately Pled that Any Statements on the PDE's were False**

In a last ditch effort to establish that Plaintiff has failed to plead "falsity" for purposes of

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[11] Again, this point distinguishes the present matter from Wilkins wherein plaintiff could not show that the government ever sought recovery of Medicare payments for services that a provider actually performed due to non-compliance with marketing regulations. Wilkins, 659 F.3d at 310.

[12] The Court notes that Plaintiff's Amended Complaint alleges six areas of alleged false information on the PDE claims data. In his Response in Opposition, however, he appears to focus on only two of these areas with respect to his false certification theory.

[13] Defendants' opening brief spends an excessive number of pages individually discussing each data field and how it is not a condition of payment. This argument again misses the point. These data fields are merely data "related to payment," bringing them within the confines of 42 C.F.R. § 505(k).

the FCA, Defendants contend that Plaintiff does not adequately plead how Defendants' PDE submissions were false. Specifically, Defendants contend that "[e]ven if 42 C.F.R. § 423.505(k)(1) did apply here, and even if it applied to all data rather than just 'data related to payment,' it addresses certification 'based on best knowledge, information, and belief' to the 'accuracy, completeness, and truthfulness' of the data." (Defs.' Reply Br. 12.) They go on to note that out of the six fraud allegations raised by Plaintiff, the only two that suggest that any data was inaccurate, incomplete, or untrue are his Maximum Allowable Cost ("MAC") pricing and provider identifier claims.[14] (Id.) Defendants now assert that the Amended Complaint fails to plead falsity in these fields. The Court now considers each of these allegations individually.

**a. Maximum Allowable Cost Pricing**

According to the Amended Complaint, "Maximum Allowable Cost" or "MAC" pricing means the unit price established by Defendant SilverScript for a generic drug included in Defendant SilverScript's MAC list. (Am. Compl. ¶ 315.) The PDE reports require that the following three data elements that relate to the cost of the drugs dispensed be included in the report: Field 27 (Ingredient Cost Paid); Field 28 (Dispensing Fee); and Field 29 (Sales Tax). (Id. ¶¶ 162, 332.) The audit found that SilverScript "fraudulently failed to apply MAC pricing to all of the MAC drugs." (Id. ¶ 316.) According to Plaintiff, this intentional and fraudulent failure to apply MAC pricing caused both the Part D beneficiary to pay a higher co-pay and the Plan to report higher Part D costs to CMS. (Id. ¶ 318.)

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[14] In his Response in Opposition, Plaintiff also cursorily suggests that Defendants falsely and/or inaccurately identified the gender of Medicare beneficiaries in the PDEs. Aside from this one sentence statement, Plaintiff does not elaborate on this allegation and does not bring it up again until he addresses his worthless services theory of FCA liability. Accordingly, the Court presumes that Plaintiff does not intend to rest a false certification claim on this allegation.

Defendants contend that Plaintiff does not and cannot plead that the costs that Defendants allegedly reported in the PDE data were not the costs that MCS actually paid. They reason that there can be no falsity when a PBM reports the price actually charged, even if that price is different from or higher than a list of MAC pricing, especially because MAC pricing is strictly a private contractual arrangement between a Part D Sponsor and a PBM. Moreover, the government is prohibited by statute from requiring particular price structures. 42 U.S.C. § 1395w-111(i), meaning it could not find any falsity in the non-application of MAC pricing by a PBM. Thus, the remedy for a PBM charging a price allegedly in violation of a contract with a Part D Sponsor is not an FCA claim, but for the Part D Plan sponsor to sue the PBM for breach of contract. (Defs.' Reply Br. 11.)

At this juncture of the litigation, and taking Plaintiff's allegations as true, the Court must reject Defendants' argument. 42 C.F.R. § 423.104 requires that a Part D Plan sponsor—in this case MCS—"provide its Part D enrollees with access to negotiated prices for covered Part D drugs included in its Part D plan's formulary." 42 C.F.R. § 423.104(a). While this provision clearly applies to the Part D sponsor, the Part D sponsor then places a similar obligation on the PBM by contracting with the PBM for MAC pricing on certain Part D drugs. (Am. Compl. ¶ 315.) The regulations, in turn, require that the PDE report list the ingredient cost paid, dispensing fee and sales tax. (Am. Compl. ¶¶ 162, 332.) When the PBM inaccurately charges above the negotiated MAC pricing to beneficiaries, that reported pricing information can be deemed "inaccurate" since the negotiated prices were not provided to Part D enrollees. Because such information regarding cost is generated by the PBM, the PBM must certify the truth, accuracy, and completeness of that information. 42 C.F.R. § 423.505(k)(3). That PDE is then

submitted to CMS to allow for payment on the claim and results in CMS unknowingly paying higher than the required "negotiated prices" required to be provided to beneficiaries under 42 C.F.R. § 423.104. In short, by charging above MAC pricing, reporting such pricing on a PDE, and certifying the accuracy of that pricing, a PBM can be deemed to be submitted to the government a claim for payment that is false.

Nor does Defendants' reliance on 42 U.S. C. § 1395w-111(i) allow it to dodge this outcome. Section 1395w-111(i) states:

> In order to promote competition under this part and in carrying out this part, the Secretary–
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> **(1)** may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and
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> **(2)** may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

42 U.S.C.A. § 1395w-111. Defendants argue that because the government is prohibited from requiring particular price structures for the reimbursement of covered Part D drugs and from interfering with Part D Sponsors' pricing negotiation, compliance with MAC pricing could not possibly be a condition of payment imposed by the government. (Defs.' Mem. Supp. Mot. Dismiss 18.) This argument, however, again misunderstands the applicable "condition of payment." While the government may not impose "particular" pricing structures and may not "interfere with negotiations" between sponsors and PBMs, the government does require that any negotiated pricing be provided by the Part D sponsor, through the PBM, to beneficiaries. 42 C.F.R. § 423.104. When a PBM certifies its pricing information on a PDE record, it implicitly certifies that it has provided this negotiated pricing to beneficiaries. That certification—not the negotiated price itself—is, as discussed in detail above, a condition of payment. When that

certification is false, it causes both beneficiaries and CMS to pay out higher costs and, in turn, violates the False Claims Act.

Ultimately, the question remains whether CMS, who has born the cost of the alleged falsity, would deem the prescriptions valid for purposes of the False Claims Act despite the fact that the negotiated rate was not provided to the beneficiaries or the government. Based on the information presently of record, however, the Court errs on the side of not dismissing this claim.

**b. Physician Identification Numbers**

In addition to the false pricing information, the Amended Complaint alleges that Defendants knowingly submitted, or caused the submission of, numerous PDEs that falsely and/or inaccurately identified the physicians who wrote the prescriptions reflected in those claims. Specifically, the Amended Complaint states as follows:

> 271. Pharm/DUR's analysis demonstrated that the Caremark Defendants fraudulently paid claims where fictitious physician identifiers (including "Physician Push Numbers" or other obviously incorrect numbers) were used to populate PDE Fields 12 and 13[15] and to adjudicate the Part D claim.
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> 272. Physician "push" numbers are fictitious physician identifiers created by inserting a random alpha-numeric data of the appropriate number of characters where PDE data element No. 13 belonged on the electronic PDE record. The most commonly used "push number" or false physician identifier used was "AA00000000," which Defendant Caremark fraudulently, knowingly and recklessly permitted to occupy Field 13 on 4,360 claims involving 993 members.
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> 273. The creation of these false identifier numbers also caused PDE claims, particularly Field No. 12, the "Prescriber ID Qualifier," which describes the type of identifier (for example, DEA number or state license number), to contain false data.

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[15] Fields 12 and 13 reference the "Prescriber ID Qualifier" and the "Prescriber ID." (CMS Instructions.)

> 274. The Caremark Defendants adjudicated 15,903 claims using obviously fictitious physician identifiers—just during the time period covered by the audit. The Caremark Defendants submitted or caused to be submitted to CMS at least 31,806 false PDE data items (2 data items, Fields 12 and 13, associated with each false prescriber) in the PDE data records for the affected Part D claims in a fraudulent attempt to obtain payment from CMS. . . .
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> 275. None of these claims involved paper or non-standard claims which would have permitted the use of a default DEA identifier.
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> 276. Significantly, of the claims involving physician push numbers, many originated at Defendant CVS Caremark's own facilities. For example, Caremark Miramar Pharmacy, LLC, a mail order pharmacy located in Miramar, Florida was the source of at least 330 claims (and likely thousands more) with physician push numbers involving total payments of $43,152.52. . . .

(Am. Compl. ¶¶ 271–76.) The Amended Complaint goes on to allege that Defendants admitted that "[a]n edit to reject claims for unidentified prescribers is not a system edit that Caremark provides its customers." (Id. ¶ 280.)

Defendants' Reply Brief[16] contends that Plaintiff does not adequately plead how invalid prescriber identifiers are inaccurate. In support of this position, Defendants rely on statements from CMS following its studies on the use of invalid prescriber identifiers. In an April 5, 2010 statement, CMS recognized that an invalid prescriber identifier "is not generally indicative of invalid prescriptions." (Defs.' Mot. to Dismiss, Ex. H, at 16.) "Instead, it often reflects that the pharmacy did not have access to the prescriber's DEA number when filling prescriptions for non-controlled substances. So while CMS agrees that invalid prescriber identifiers can hinder

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[16] In their opening brief, Defendants argue that valid physician identifiers are not a "condition of payment," as established by various statements from CMS. As repeatedly discussed above, however, the applicable condition of payment is the certification by either the Part D Sponsor or the responsible PBM that the information contained in the PDE record is truthful, accurate, and complete. To the extent that a portion of information in that record is not truthful and the PBM certifies it as such, there is falsity on which an FCA claim may be premised.

program oversight efforts for monitoring prescribing practices of specific prescribers, this is not an automatic indication for invalid prescriptions or pharmacy claims." (Id.) In addition, Defendants also point to a 2010 CMS statement that "it will continue to instruct Part D sponsors not to implement point-of-sale edits to reject Part D claims with 'invalid' prescriber identifiers because of the significant potential to interrupt medically necessary drug therapies." (Id. at 15.)

While such statements are perhaps indicative that either (1) Defendants did not intentionally submit false claims that were not condoned by CMS or (2) CMS may not deem PDEs with incorrect prescriber identifiers false for purposes of the FCA, such findings are improper at this early stage of the litigation.[17] The clear statutory and regulatory provisions require that PBMs certify the accuracy, completeness, and truthfulness of data contained in PDEs and that physician identifiers are one of the fields of data that the PBMs must certify. Moreover, viewing the aforementioned statements in context reveals that CMS has indeed expressed some concern about the impact of invalid physician identifiers. In fact, it has specifically recognized that "invalid prescriber identifiers can hinder program oversight efforts for monitoring prescribing practices of specific prescribers." (Id. at 17.) It has further indicated its intent to "remind Part D plans and their pharmacies of the requirement to provide prescriber

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[17] Defendants argue that "Plaintiff does not explain how prescriber identifier fields filled in with all zeroes were not as accurate as Defendants could make them under the circumstances, 'based on best knowledge, information, and belief.'" (Defs.' Reply Br. 13 (citing 42 C.F.R. § 423.505(k).) Whether the incorrect prescriber identities were intentionally false or were simply used as a placeholder in order to allow a prescription to be field is a question for discovery and need not be pled in the Amended Complaint. See Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.").

[identifiers] on pharmacy claims except in those *rare* situations when the prescriber does not have an [identifier] or the pharmacy is unable to obtain the prescriber's [identifier]." (Id. at 17 (emphasis added).) Moreover, although CMS suggested that Part D sponsors not "simply" reject all Part D claims with "invalid" prescriber identifiers, it has cautioned that Part D sponsors and their pharmacies must implement procedures to address potential noncompliance with the prescriber identity requirements. (Id. 15–17.) Finally, although invalid prescriber identifiers are "not generally indicative of invalid prescriptions," the use of the word "generally" suggests that there may be situations where the invalid identifiers do invalidate the prescriptions. Whether the government would have ultimately refused payment on the claims submitted by the Defendants with false prescriber identities remains a matter for discovery.

In a final effort to allege that there was no "falsity" in the invalid prescriber identity claims, Defendants cite to a series of cases for the proposition that the government's knowledge of and payment for obviously false information vitiates the fraud. More precisely, Defendants note that, according to the First Amended Complaint, the physician identifier numbers were "obviously incorrect" and "obviously fictitious." (Id. ¶¶ 271, 274.) Because the government could clearly discern that the numbers included on the PDE records were "not intended to represent an actual prescriber's number, as opposed to a number entered so that a prescription could be filled," (Defs.' Reply Br. 14), the PDEs were not false. See United States ex rel. Watson v. Connecticut Gen. Life Ins. Co., No. Civ.A.98-6698, 2003 WL 303142, at *6 (E.D. Pa. Feb. 11, 2003) (noting, on a summary judgment motion, that the fact that the government knew of defendant's practice suggests that it was not fraudulent) (citing United States ex rel. Durcholz v. FKW Inc., 189 F.3d 542, 544–45 (7th Cir. 1999) ("The government's prior knowledge of an

allegedly false claim can vitiate a FCA action."); Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir.1992) ("The fact that the government knew of FMC's mistakes and limitations, and that FMC was open with the government about them, suggests that while FMC might have been groping for solutions, it was not cheating the government in the effort.")), aff'd 87 F. App'x 257 (3d Cir. 2004).

In the present case, however, nothing in the record properly before the Court—which includes the Amended Complaint and the documents of which the Court took judicial notice—indicates that the government had any prior knowledge of the improper physician identifier numbers and nonetheless condoned such practices.[18] Clearly, such an argument is best reserved for summary judgment motion practice following a period of discovery.

In light of the foregoing, the Court finds that Defendants' alleged inclusion of invalid physician identifier numbers on PDE records used for payment from CMS can form the basis for a false claim. In turn, the Court declines to dismiss this portion of Plaintiff's claim.

### v. Conclusion as to False Certification Theory

In essence, this Court simply cannot dismiss Plaintiff's false certification FCA claim without allowing at least some discovery to proceed. Plaintiff has (1) adequately identified a condition of payment, *i.e.* the requirement that a PBM certify the accuracy of its data relating to payment; (2) has established that "data relating to payment" includes the thirty-seven fields on

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[18] Compare United States v. Southland Mgmt. Corp., 326 F.3d 669, 676–77 (5th Cir. 2003) (finding, based on a complete evidentiary record, that defendants' submitted claims were not false as a matter of law despite their false certifications of decent, safe, and sanitary housing, because the government knew of the condition of the housing and had not given notice of rejection of the claims).

the PDE records; and (3) has alleged falsity in some of those fields with sufficient particularity. Accordingly, the Court denies Defendants' Motion on this ground.

**b. Worthless Services Theory**

The second aspect to Plaintiff's FCA claim under subsection (a)(1) pleads a "worthless services" theory. As recognized by the Third Circuit, "[c]ase law in the area of 'worthless services' under the FCA addresses instances in which either services literally are not provided or the service is so substandard as to be tantamount to no service at all." In re Genesis Health Ventures, Inc., 112 F. App'x 140, 143 (3d Cir. 2004). "[A] worthless services claim asserts that the knowing request of federal reimbursement for a procedure with no medical value violates the Act irrespective of any certification." Mikes v. Straus, 274 F.3d 687, 702 (2d Cir. 2001). "Neither false certification nor a showing of government reliance on false certification for payment need be proven if the fraud claim asserts fraud in the provision of goods and services." United States ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001).

In the present case, Plaintiff's worthless services claim alleges that Defendants violated the FCA by submitting or causing the submission of numerous PDE claims where the government was not provided with the bundle of services that it paid for and that were required by federal regulations. In particular, the Amended Complaint asserts that Defendants were obligated to provide concurrent drug utilization review ("DUR") for all medications they dispensed under Part D. Nonetheless, they purportedly failed to do so in four specific areas: (1) failure to provide DUR for gender contraindications; (2) failure to dispense drugs in compliance with State pharmacy laws by adjudicating claims for expired drugs; (3) failure to obtain required

prior authorizations for Tier 2 and Tier 4 drugs; and (4) improper approval of claims for drugs in excess of limits permitted by the Sponsor's plan or the drug manufacturer. As a result of these failures, Plaintiff asserts that Defendants submitted false claims for drugs not covered by Part D and then collected payment for DUR services not provided in their dispensing of these drugs.

In response, Defendants offer three arguments. First, they contend that the Amended Complaint does not plead that Defendants ever billed or caused MCS to bill for the services that were allegedly not provided, or otherwise falsely stated to the government that Defendants were performing such services when they were not. Second, they assert that even if Plaintiff had pleaded a bill or a certification by Defendants that it performed these services, Plaintiff claims only that Defendants performed these services imperfectly, not that they failed to perform them at all. Finally, Defendants argue that Plaintiff cannot plead an obligation to performed DUR for any of the four specified areas. The Court considers each argument individually.

**i. Whether the Amended Complaint Pleads that Defendants Ever Billed or Caused MCS to Bill for Services Not Provided**

Defendants' primary challenge to the "worthless services" theory contends that Plaintiff is required to plead that the claimant (a) misrepresents what goods or services it provided to the Government or (b) submitted claims for alleged services not provided. Defendants aver, however, that the Amended Complaint is devoid of an allegation that Caremark billed the government for performing DUR for gender contraindications, prescriptions filled over alleged plan limits, prescriptions without prior authorizations, or prescriptions with expired NDC codes. Without such pleading, Plaintiff cannot state a worthless services claim.

This argument is mistaken. The Amended Complaint clearly alleges that "Part D Sponsors often contract with PBMs for the adjudication of Part D claims and the submission to CMS of Part D data necessary to receive payment. Federal Regulations specifically require that Part D PBMs agree to perform all services in compliance 'with all Federal laws, regulations and CMS instructions.' 42 C.F.R. § 423.504(i)(4)(iv)." (Am. Compl.¶ 194.) The Amended Complaint goes on to assert that Defendants contracted that its activities would comply with MCS's obligations to CMS as a Part D plan Sponsor and would comply with applicable CMS laws and regulations. (Id. ¶¶ 238–39.) Such laws and regulations, as pled in the Amended Complaint, required concurrent DURs to ensure that claims for expired drugs, gender contraindicated drugs, and drugs without prior authorizations were not approved and paid out. (Id. ¶¶ 196–222.) According to the terms of the Agreement, the Medicare Part D PBM services to be provided by Defendants included DUR services for retail or point of sales claims. (Id. ¶ 245.) The Agreement then required Defendants to submit to CMS, on behalf of MCS, data reflecting Part D claims paid by MCS. (Id. ¶ 259.) Notwithstanding their various obligations to conduct concurrent DURs, Defendants "illegally and fraudulently adjudicated, paid, and submitted to CMS claims for Medicare Part D drugs," with gender specific deviations, expired drugs, no prior authorizations, and over limits quantities. (Id. ¶ 268.) The Amended Complaint further attaches, as an exhibit, a table containing representative Part D claims adjudicated by the Defendants and submitted to CMS that suffer from these specified defects. (Id. Ex. C.)

Taking these well-pled allegations—and all reasonable inferences derived from them—as true, the Court must find that Plaintiff adequately pled that Defendants billed the government for performing DUR not actually provided. According to the Amended Complaint, federal

regulations mandate that a Part D Plan sponsor's contract with a PBM obligates the PBM to all federal requirements, including the requirement to perform concurrent DUR for point of sale transactions. The Agreement in this case did so and also required that Defendants directly provide claim information for payment directly to CMS. By ultimately submitting claim information to CMS, Defendants effectively represented that they had performed the proper DUR services and were submitting and seeking payment for only claims that were paid in accordance with federal regulations. Although the money reimbursed to Defendants by CMS on these claims was filtered through MCS, that money was ultimately paid by CMS. See United States v. Merck-Medco Managed Care, L.L.C., 336 F. Supp. 2d 430, 451 (E.D. Pa. 2004) ("As discussed above, the Government has alleged facts which indicate that it reimbursed Blue Cross for actual claims paid—meaning that, even if payments to Medco were filtered through a health plan, the money, or some portion of it, was ultimately paid by the Government."). Such pleading is sufficient to survive a Rule 12(b)(6) motion.[19]

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[19] Defendants cite Chesbrough v. VPA, P.C., 655 F.3d 461, 468–72 (6th Cir. 2011) for the proposition that the failure to plead that a defendant submitted claims for alleged worthless services is grounds for dismissal of an FCA claim. In Chesbrough, the court found merit to the allegation that if the defendant medical provider sought reimbursement for medical tests that it knew were not just of poor quality but had *no* medical value, then it would have effectively submitted a false claim. Id. at 468. The court dismissed the claim, however, because the plaintiff failed to plead with particularity that the medical provider actually billed the government for the allegedly worthless services or tests. Id. at 472. Specifically, it noted that plaintiffs had "no personal knowledge that claims for nondiagnostic tests were presented to the government, nor do they allege facts that strongly support an inference that such billings were submitted." Id.

The Amended Complaint in this case does not suffer the same defect. Indeed, aside from the excessively detailed allegations within the Amended Complaint itself, Plaintiff attaches, as Exhibit C, a table specifically listing various claims submitted by Defendants, the amounts, the drug, the filling pharmacy, and the precise DUR omission. Such pleading is more than sufficient to satisfy the heightened pleadings standard of Rule 9.

### ii. Whether the Amended Complaint Pleads that Defendant Performed "Worthless Services"

Defendants' second argument asserts that even if Defendants had billed for such services, Plaintiff does not claim that Defendants performed none of these services, only that it did so imperfectly. To state a worthless services claim, according to Defendants, a plaintiff must plead more than just non-performance of compliance with certain regulations or rules while supplying a product or service. Rather it requires billing for a product or service not provided at all. According to Defendants, Plaintiff's allegations of mere regulatory noncompliance are not actionable under the FCA.

The Court, however, finds that the Amended Complaint adequately pleads that the benefits covered under the government's Part D program include both the actual prescription medication and a bundle of services—including pharmacy services, prescription claims processing, and concurrent DUR—all provided with the aim of avoiding Medicare waste, fraud, and abuse, *i.e.* paying out on claims that should not be paid. (Am. Compl. ¶¶ 166–171.) The Agreement between MCS and Defendants required Defendants to "comply with applicable CMS Laws and Regulations" and to "process both electronic and paper claims in keeping with CMS standards." (Am. Compl. ¶¶ 239–40.) Further, the Agreement provided that the PBM services to be provided by Defendants include" Concurrent Drug Utilization Review (DUR) services for retail or point of sale (POS) claims." (Id. ¶ 245.) Notwithstanding these obligations, Defendants allegedly failed to provide concurrent DUR for gender contraindications (id. ¶¶ 289–94), dispensed expired drugs (id. ¶¶ 295–99), failed to obtain required prior authorization for Tier 2 and Tier 4 drugs (id. ¶¶ 300–05), and improperly approved claims for drugs in excess

of limits. (Id. ¶¶ 306–14.) Yet, it submitted claims to CMS for the dispensed drugs with the implicit understanding that the concurrent DUR was performed and allowed for the dispensing of the drugs. Such allegations go beyond mere regulatory non-compliance. See Merck-Medco, 336 F. Supp. 2d at 439 ("Medco billed Blue Cross and hence the Government for services it was required to render in accordance with its contract and with state law—any claims submitted that do not fulfill these prerequisites are false. In some cases, such as the drug shorting allegations, Medco allegedly billed for products that it simply did not provide. If the allegations are true, these bills could form the basis of a false claim.") Accordingly, this claim can survive a Motion to Dismiss.

The cases cited by Defendants in support of their argument are inapposite. For example, Defendants cite Chesbrough v. VPA, P.C., 655 F.3d 461, 468 (6th Cir. 2011) as "affirming dismissal because relator's claims that tests did not comply with industry standards, but still had some value, could not form basis for 'worthless services' theory of liability." (Defs.' Reply Br. 17.) Crucially, however, the court found that the relator's theory—i.e., that the medical provider performed tests known to be of no medical value and, thus, were so deficient as to be equivalent to no performance at all—was sufficient to state a claim for worthless services. Id. at 468. The court dismissed the claim only because of the relator's failure to plead with particularity that the medical provider actually *billed* the government for these tests. Id. at 472.

Moreover, Defendants cite United States ex rel. Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1221 (E.D. Cal. 2002) for the proposition that a challenge to the level of care and amount of services provided by a medical professional is insufficient to state a worthless services claim where there is no allegation that the defendant failed to provide *any* services to its

patients. In that case, however, the defendant was paid by the government at a per diem rate for providing room and board and routine care services for Medicare patients housed at a certain facility. Id. at 1221. The plaintiff did not allege that the defendant failed to provide any services to the patients or that the neglect was so severe that the patients were receiving no services at all. Id. Rather, it merely alleged that the level of care and the amount of services received as a result of understaffing were substandard. Id. These facts are distinguishable from the present matter wherein Plaintiff specifically alleges that, pursuant to its contractual obligations and federal/state laws, Defendant was obligated when filling Medicare prescriptions, to perform certain DUR services. Because it did not provide those services at all, but billed CMS for the prescriptions filled—regardless of whether those prescriptions would have been filled had the proper DUR been performed—Plaintiff has properly alleged that Defendants billed for worthless services.[20]

Ultimately, only discovery will tell whether Defendants' alleged failures constituted "worthless services," whether they were simply isolated instances of noncompliance among "billions" of prescriptions filled per year, or whether the alleged failures caused any loss to CMS. At this juncture of the litigation, however, the Court finds that Plaintiff has properly

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[20] Defendants also cursorily cite Scherfel v. Genesis Health Ventures, Inc., 112 F. App'x 140 (3d Cir. 2004) for the proposition that a worthless services claim requires instances where services literally are not provided or the service is so substandard as to be tantamount to no service at all. In that case, however, the plaintiff's worthless services theory was "indistinguishable from his alternatively advanced false certification theory—under both, he contends the government was duped into paying twice for the same drugs and that West End made misrepresentations in order to procure such payment." Id. at 143. In the present matter, however, Plaintiff's false certification claim is based on Defendants' allegedly improper certification, under 42 C.F.R. 423.505(k)(3), that the information on the PDEs was accurate, when it was not. Plaintiff's worthless services claim, on the other hand, focuses on Defendants' alleged failure to perform concurrent DUR when filling Part D prescriptions.

alleged a claim for "worthless services."

### iii. Whether Defendants Was Obligated to Perform DUR for the Alleged Items

In a final challenge to Plaintiff's worthless services claim, Defendants assert that Plaintiff cannot plead that Defendants had an obligation to perform DUR in the four areas alleged in the Amended Complaint: gender-contraindications, prescriptions filled over alleged plan limits, prescriptions without prior authorizations, and drugs with expired NDC codes. Defendants remark that the MCS-Caremark Agreement merely requires Caremark to provide "its automated concurrent DUR Services for point of sale (POS) Claims" without specifying the type of DUR services that must be provided. (Am. Compl., Ex. B ¶ 1.8(a).) Absent this specification, Plaintiff cannot pinpoint any actionable failure by Defendants.

In order to discern precisely what Defendants were required to do in their "concurrent DUR Services," two inquiries are necessary. First, the Court must determine what the MCS-Caremark Agreement stated on this subject. The contract between the parties indicates that Defendants agreed "to participate, as a subcontractor to [MCS], in the management of [MCS's] Part D Plan, and [Defendants] understand[] that [their] activities must, to the extent these are communicated to [Defendants], be consistent and comply with [MCS's] contractual obligations to CMS as a Part D Plan Sponsor." (Am. Compl., Ex. 1 § 1.1.) In addition, each party agreed that it would comply with applicable CMS laws and regulations "without the need for further notice to and approval from the other party." (Id.) The Agreement further stated that Defendants would provided DUR services for point-of-sale claims, (id. § 1.8), and that Defendants would "collect and report to CMS Claims data as specified in Section 3.13,

subsections 4 and 5 of the Part D Application, and such additional information for purposes of reconciliation of risk factors, low income subsidy payments, reinsurance payments, and risk corridor as required by CMS." (Id. § 1.10.)

This contract is similar to that at issue in United States v. Merck-Medco Managed Care LLC, supra. As previously discussed, defendant Medco was a pharmacy benefit manager, like Defendants, that contracted to provide PBM services to the patients of Blue Cross Blue Shield Association, a health plan that contracted with the government to provide health care to federal employees retirees and their families. 336 F. Supp. 2d at 434. The complaint alleged that Medco and Blue Cross had a contractual relationship whereby Medco made certain performance guarantees. Id. at 436. The crux of plaintiffs' FCA claims grew out of Medco's alleged billing for services not rendered and fraudulent avoidance of contractual penalties. Id. The court found that "Medco billed Blue Cross and hence the Government for services it was required to render in accordance with its contract and with state law—any claims submitted that do not fulfill these prerequisites are false." Id. at 439.

Applying the same logic to the present case, Defendants, through their Agreement with MCS, were expressly obligated to perform DUR services that complied with MCS's obligations to CMS as a Part D sponsor. (Am. Compl. ¶252.) The Amended Complaint alleges as much by specifically pleading that, "[t]he MCS-SilverScript PBM Agreement required that SilverScript adhere to all requirements of the Medicare Part D Program, both those contained in CMS's Laws and Regulations, as well as those contained in the contract between the Sponsor, MCS and CMS." (Id.) As in Merck-Medco, Defendants billed the government for services it was required to render in accordance with its contract and with federal and state law and any failure to render

such services results in a "worthless services" claim.[21]

Having determined that the MCS-Caremark Agreement required Defendants to perform concurrent DUR services in accordance with federal and state laws, the Court then turns to the second inquiry: whether the applicable law incorporated by the Agreement required the specific DUR services that Defendants allegedly failed provide. To resolve this issue, the Court first turns to the requirements set forth by CMS, which state, in pertinent part, as follows:

> (a) General rule. Each Part D sponsor must have established, for covered Part D drugs furnished through a Part D plan, a drug utilization management program, quality assurance measures and systems, and an MTMP as described in paragraphs (b), (c), and (d) of this section.
>
> (b) Drug utilization management. A Part D sponsor must have established a reasonable and appropriate drug utilization management program that address all of the following:
>
> (1) Includes incentives to reduce costs when medically appropriate.
>
> (2) Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.
> (3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.
> (4)(i) Establishes a daily cost-sharing rate and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than 30 days, and in the case of a monthly copayment, multiplies the daily cost-sharing rate by the days supply actually dispensed--

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[21] Defendants attempt to distinguish Merck-Medco by alleging that the worthless services theory survived a motion to dismiss "because the relator alleged that the PBM charged for services that it failed to provide and because the PBM did not dispute that it had an obligation to perform those services." (Defs.' Reply Br. 18–19.) This is a distinction without a difference. In this case, Plaintiff has properly alleged that Defendants charged for services it failed to provide and that Defendants had an obligation to perform those services via its agreement to comply with all state and federal regulations. The Court must accept these facts as true on a Rule 12(b)(6) motion. Any factual dispute as to the scope of Defendants' obligations must be pursued after discovery.

. . .

(c) Quality assurance. 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.***

(2) ***Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution.*** The review must include, but not be limited to,

(i) Screening for potential drug therapy problems due to therapeutic duplication.
(ii) ***Age/gender-related contraindications.***
(iii) ***Over-utilization and under-utilization.***
(iv) Drug-drug interactions.
(v) ***Incorrect drug dosage or duration of drug therapy.***
(vi) Drug-allergy contraindications.
(vii) Clinical abuse/misuse.

(3) Retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a sponsor's Part D plan,'or associated with specific drugs or groups of drugs.

(4) Internal medication error identification and reduction systems.
(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

42 CFR § 423.153 (emphasis added). A basic reading of this regulation reveals that the errors alleged in the Amended Complaint were seemingly part of the statutorily-mandated DUR services.

First, screening for such gender-contraindications is included in the specific DUR mandated by CMS. 42 C.F.R. § 423.153(c)(2)(ii). Thus, to the extent the Amended Complaint asserts that "the Caremark Defendants adjudicated Part D claims without editing for gender-

specific deviations (that is, drugs used exclusively in males but prescribed for females and vice versa)," (Am. Compl. ¶ 289), a worthless services claim exists.[22]

Second, as to prescriptions filled over the plan limits, the regulations, as applied to Defendants through the MCS-Caremark Agreement, required Defendants to conduct concurrent DUR for overutilization.[23] 42 C.F.R. § 423(c)(2)(iii). As such, the Court again finds that this alleged omission in DUR can form the basis of a worthless services claim.

Third, as to prescriptions filled without prior authorization, CMS's Instructions for submitting prescription drug event data defines a "covered Part D drug" as one that "meets the definition of a Part D drug [described in § 1927(k)(2)(A) of the Act] ***and is also covered under a PBP***." (Def.'s Mot. Dismiss, Ex. B, 20 (emphasis added).) A "non-covered Part D drug" is one that meets the definition of a Part D drug, but the PBP does not cover, usually because it is off-formulary or the plan does not find it is reasonable and necessary. (Id.) CMS then instructs that "Plans shall only pay for covered part D drugs ('covered drugs')." (Id.); see also 42 C.F.R. § 423.100 ("Covered Part D drug means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal."). According to the Amended Complaint the MCS formularies at issue

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[22] Plaintiff engages in a discussion of what constitutes medically-accepted indications under Part D, including uses approved by the Food and Drug Administration and certain "off-label" uses supported by statutorily approved compendia. (Pl.'s Resp. Opp'n Mot. Dismiss 46.) At this stage of the litigation, the Court finds no reason to consider this discussion.

[23] To the extent Defendants discuss the "plan formulary's exceptions process" or the plan limits, this argument is irrelevant. (Defs.' Mem Supp. Mot Dismiss 27; Defs.' Reply Br. 21.) The fact remains that the regulations require a Part D Sponsor to conduct overutilization DUR and Defendants' Agreement with MCS

required prior authorization before dispensing Tier 2 and Tier 4 drugs, yet Defendants permitted participating pharmacies to dispense drugs without required Part D formulary prior authorizations and illegally paid these claims.[24] (Am. Compl. ¶ 302.) Thus, to the extent that Defendants were required to ensure prior authorization for certain drugs before dispensing them, but did not do so, they are subject to a worthless services claim.

Finally, as to expired NDC codes, Defendants argue that Plaintiff points to no rule that drugs with expired or obsolete NDC codes are not covered under Medicare Part D.[25] Specifically, Defendants argue that an NDC is not determinative as to whether a drug is otherwise a covered Part D drug. (Defs.' Mem. Supp. Mot. Dismiss 15 (citing CMS Memo from Cynthia Tudor, Director, Medicare Drug Benefit Group to All Part D Plan Sponsors Re: CMS/FDA CY 2010 Non-Matched NDC List, Oct. 21, 2009, at 1 (stating that the NDC list was not designed to be used to "determine a drug's status as approved or unapproved.")).) Moreover, Defendants claim that Plaintiff conflates the notion of an expired or obsolete NDC with an expired drug, even though CMS has recognized that the mere fact that NDCs were expired does not suggest that any expired drugs were actually dispensed. (Defs.' Mem. Supp.

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[24] The mere fact that Part D Sponsors can make prior authorization less restrictive without CMS approval and that CMS has instructed that the absence of a prior authorization should not prevent a prescription from being filled is of no moment for purposes of the present Motion. The obligatory DUR services provided for by federal regulations and mandated by the Agreement require that a formulary be devised and followed by the Part D Plan Sponsor and its subcontractors. Failure to do so while billing for the concurrent DUR can constitute worthless services.

[25] The National Drug Code is a unique 10-digit, 3-segment numeric identifier assigned to each medication listed under Section 510 of the US Federal Food, Drug, and Cosmetic Act. The segment identifies the labeler or vendor, product (within the scope of the labeler), and trade package (of this product). http://en.wikipedia.org/wiki/National_Drug_Code_System (last visited December 3, 2012).

Mot. Dismiss 15.) Finally, Defendants aver that even had Plaintiff adequately alleged that terminated drugs were dispensed, the government itself has stated that, "Federal regulations do not specifically prohibit coverage of terminated drugs under the Medicare Part D Program." (Defs.' Mem. Supp. Mot. Dismiss 15 & Ex. I.)

The regulations, however, state 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." 42 C.F.R. § 423.153(c)(1). This requirement is incorporated into the MCS-Caremark Agreement by the provision wherein each party agreed that it would comply with applicable CMS laws and regulations "without the need for further notice to and approval from the other party. (Defs.' Mot. Dismiss, Ex. 1 § 1.1.) The Amended Complaint then identifies laws in at least four states/territories (Pennsylvania, Illinois, Puerto Rico, and Florida) that prohibit a pharmacist from selling or giving away expired drugs. (Am. Compl. ¶¶ 182,189.) It goes on to allege that "the Caremark Defendants paid Medicare Part D claims for drugs with NDC numbers that were 'outdated, stale and/or obsolete . . . and that [t]he payment of these claims should be rejected . . . payment of these claims leaves the client potentially at risk of legal actions should a serious adverse reaction.'" (Am. Compl. ¶ 295.) Finally, Plaintiff pleads with great particularity a sampling of claims wherein the drugs dispensed contained expired or obsolete NDCs. (Id. ¶ 296.) Each of these claims was purportedly submitted to CMS for payment. (Id. ¶ 297). To the extent that Defendants dispensed medication with expired NDC

codes and to the extent those codes reflected an expired medication,[26] Defendants would have improperly filled prescriptions and, in turn, would have failed to render the requisite DUR services for which it billed CMS.

Ultimately, as this case progresses, the Defendants may establish that they were not required, contractually or otherwise, to perform the concurrent point-of-sale DUR as specified by Plaintiffs and, in turn, did not falsely bill the government for services not provided. The Court, however, must accept as true the well-pled allegations that Defendants' DUR obligations included review for gender contra-indications, over-utilization, prior approval, and expired drugs.

**iv. Conclusion as to Worthless Services Theory**

In sum, the Court declines to dismiss Plaintiff's FCA claim based on a worthless services theory. First, by submitting PDE data reflecting Part D claims paid by MCS, Defendants effectively billed CMS or caused CMS to be billed for such services. Second, the Amended Complaint properly pleads that the services provided and billed for by Defendants included not solely the dispensing of medications, but also a bundle of other services, including concurrent DUR. A gross failure to perform such services, combined with continued collection of funds for such services from the government through the Part D sponsor, could constitute a false claim. Finally, the Amended Complaint sufficiently avers that (1) the DUR requirements included screening of claims for gender-contraindications, over-utilization, prior approval, and expired

[26] While the Court acknowledges Defendants' argument that a drug with an obsolete NDC does not necessarily evidence an expired or non-covered drug, we note that whether any of the drugs with obsolete NDC codes dispensed by Defendants were actually expired is a question of fact to be resolved after discovery.

drugs; and that (2) on numerous instances, Defendants did not properly perform such screenings. As such, Plaintiff has adequately pled that Defendants falsely caused CMS to pay for services not provided and ultimately to pay out on prescriptions that should have not been dispensed by Defendants. In turn, this portion of Defendants' Motion to Dismiss shall be denied.

### 2. Whether Plaintiff Has Alleged that Defendants Submitted or Caused to be Submitted a "Claim" to the Government Under the False Claims Act in Order "To Get" a Claim Paid by the Government under 31 U.S.C. § 3729(a)(2)

Defendants next challenge Plaintiff's FCA claim pursuant to 31 U.S.C. § 3729(a)(2). This section imposes liability on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." Id. Defendants argue that Plaintiff does not and cannot allege that the PDE data about which he complains constituted or contained any request or demand for money or property from the government. Rather, the PDE records, which Plaintiff alleges are "claims" or "requests for payment" under the FCA, are nothing more than data used for accounting purposes and for MCS's and CMS's year-end reconciliation process. Moreover, Defendants assert that Plaintiff cannot allege any false record or statement by Caremark made for the purpose "to get" a claim paid. The Court individually considers each argument.

#### a. Whether Plaintiff Properly Alleges a "Claim"

Under the FCA, a "claim" is a "request or demand . . . for money or property." 31 U.S.C. § 3729(c). The statute goes on to state that, "[f]or purposes of this section, 'claim' includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion

of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." Id. § 3729(c).[27] "In order to prove a claim under § 3729(a)(2), a plaintiff must also show that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004). 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. Atkinson v. Pa. Shipbuilding Co., 255 F. Supp. 2d 351, 365 (E.D. Pa. 2002).

Defendants now allege 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. The Court, however, must disagree. According to the CMS Instructions, "[e]very time a beneficiary fills a prescription covered under Part D, plans must submit a . . . PDE record to CMS." (CMS Instructions 6.) "The PDE record contains prescription drug cost and payment data ***that will enable CMS to make payment*** to plans and otherwise administer the PDE benefit." (Id. (emphasis added).) They go on to note that "[t]he submitted data components fit together to allow calculation of payment under the four legislated payment mechanisms." (Id.) These PDE records are "condition[s] of payment" that are "necessary for CMS to carry out payment provisions . . . of the Act." (Id. at 9.) Later in the Instructions, CMS "list[s] the

[27] The parties dispute whether the 2009 amendments to the FCA apply in this case. As explained in detail in footnote 4, *supra*, the pre-2009 of the statute applies to the present matter.

required data elements that must be submitted on PDE records ***for payment***." (Id. at 11.) Further, in the CMS Prescription Drug Manual, Chapter 9 § 80.1, CMS states that:

> When submitting claims data to CMS for payment, Sponsors and their subcontractors ***must certify that the claims data is true and accurate*** to the best of their knowledge and belief. The False Claims Act is enforced against ***any individual/entity*** that knowingly submits (or causes another individual/entity to submit) a false claim for payment to the Federal government.

(CMS Prescription Drug Manual, Ch. 9, § 80.1 (emphasis added).) As succinctly summarized by one commentator:

> As a condition of payment, all Part D sponsors must submit data and information necessary for CMS to carry out payment provisions. 42 U.S.C. § 1395w-115(c)(1)(C) & (d)(2) (2006); 42 C.F.R. § 423.322 (2010). Every time a beneficiary fills a prescription covered under Part D, plans must submit a summary record called the prescription drug event (PDE) record to CMS. ***The PDE record contains prescription drug cost and payment data that will enable CMS to make payment to plans*** and otherwise administer the Part D benefit.

Jennifer L. Herbst, "The Short Sighted Value of Inefficiency: Why We Should Mind the Gap in the Reimbursement of Outpatient Prescription Drugs," 2 Case W. Reserve J.L. Tech. & Internet 1, 16 n.61 (2011) (emphasis added).

Given such guidance, the PDE records submitted by Defendants to CMS are clearly claims for payment. Indeed, the PDE data is the only record submitted from PBMs or Part D sponsors that triggers CMS's payment obligation to the Part D sponsor. The mere fact that CMS refers to PDE submissions as "data" and not "claims" does not change what these PDE submissions are in the Medicare Part D scheme—claims on which CMS makes payment. Any

effort by Defendants to argue to the contrary constitutes mere linguistic maneuvering.[28] Unlike false statements that "ultimately lead to a request or demand for money or property," which the Third Circuit has expressly deemed to not be "claims," the PDE record is, standing alone, the demand for money from CMS. Stated differently, the foregoing authorities clarify that CMS will only determine and issue further payment upon the receipt of the PDE records. To now deem the PDE record not a "claim" simply because that word does not appear in the definition of a PDE record would improperly elevate form over substance.[29]

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[28] Defendants make much out of the CMS Prescription Drug Manual's use of the term "claims data" and not "claims." A plain language reading of that provision, cited above, however, reveals that the "claims data" is merely part and parcel of the overall "claim" and that that overall claim, inclusive of the claims data, can form the basis of FCA liability.

[29] Nor does the Court find Defendants' case citations particularly helpful to its position. Defendants reference Atkinson, 255 F. Supp. 2d 351 for the general definition of "claim" as a "request or demand for payment." Id. at 366. As noted above, however, even under this definition, PDE records, as requests for payment, seemingly constitute claims.

Moreover, Defendants cite United States ex rel. Bauchwitz v. Holloman, 671 F. Supp. 2d 674 (E.D. Pa. 2009) for the proposition that a financial status report submitted to the government which detailed how funds were spent, was not a "claim" under the FCA. That matter took place in the context of grants submitted by the defendants to the National Institute of Health. Id. at 679. The court there noted that a financial status report, whether final or annual, was not a claim for payment from the government, but rather a budget reconciliation form submitted to the government as an accounting of how the grantee spent the funds it received during the report payment. Id. at 691. Because no payment was received after a financial status report's submission, it could not constitute a "claim" under the FCA. Id. at 691. In the same opinion, however, the court found that progress reports were prerequisites to the NIH releasing funds for a subsequent budget period. Id. at 689. It remarked that,

**b. Whether Plaintiff Properly Alleges that Defendants Made Statements "To Get" a Claim Paid by the Government**

Taking an alternative tact, Defendants assert that to state a claim under § 3729(a)(2), a defendant must intend that the government pay the claim, not merely that the claim be paid with government funds. According to Defendants, under the MCS-Caremark Agreement, Defendants were paid by MCS on a fixed rate basis per claim processed, not based on the content of the PDE data. Moreover, they argue that their requests to MCS for payment under the MCS-Caremark contract could not have been false records or statement to get a claim paid by the government because Defendants sought payment from MCS, not the government, and did not intend that the government pay the claim.

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> Although the initial NGA is considered an obligation for the entire project period, the agency does not guarantee funding for the entire project period, and is "committed" to funding the grant for only the current one-year budget period. As a prerequisite to obtaining funding for each subsequent annual budget period, the grantee must submit an annual progress report to NIH. Funds are released only if the grantee has achieved satisfactory progress toward meeting the objectives of the project and Congress appropriates the funds. Therefore, because approval of a progress report is a prerequisite to the release of funds for a subsequent budget period, a progress report is a claim or demand for payment under the FCA.

Id. The PDE reports in the present case are more akin to the progress reports in Bauchwitz than the financial status reports. Although CMS provides prospective payments to the Part D sponsor, who in turn prospectively pays the PBM, the PDE records are prerequisites to obtaining additional payments and to reconcile the accuracy of any previous payments already made. Thus, because submission of a PDE is a condition for any future payment, a PDE is a claim or demand for payment under the FCA.

Finally, Defendants cite Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 182–84 (3d Cir. 2001). That case held that a law firm's submission of inflated bills to the bankruptcy court for approval did not constitute a "claim" under the FCA since that approval did not involve a request or demand for money *from the government*. Id. at 183–84. In this case, however, Plaintiff adequately pleads that the submission of a PDE is indeed a condition of payment and an actual request for the government to pay out money. (Am. Compl. ¶¶ 129–38, 358–69.)

As noted above, the FCA holds liable, "[a]ny person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government."[30] 31 U.S.C. § 3729(a)(2). The United States Supreme Court, in Allison Engine Co., Inc. v. U.S. ex rel. Sanders defined the requirement "to get a . . . claim paid"

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[30] The Fraud Enforcement Recovery Act of 2009 ("FERA"), Pub. L. No. 111–021, § 4(a)(1), 123 Stat. 1617, 1621 (May 20, 2009), amended 31 U.S.C. § 3729(a)(2) (1986) and recodified it as 31 U.S.C. § 3729(a)(1)(B) (2009), removing the requirement that a false record or statement have been made "to get" a claim paid by the federal government. See Pub L. No. 111–021, § 4(a)(1)(B). Before FERA, § 3729(a)(2) stated that liability attaches when a defendant "knowingly makes, uses, or causes to be made or used, a false record or statement *to get a false or fraudulent claim paid* or approved by the Government." 31 U.S.C. § 3729(a)(2) (1994) (emphasis added). The post-FERA version of the provision (now § 3729(a)(1)(B)) states that liability exists for any person who "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)(B) (emphasis added). The new version broadens the intent required to trigger liability, because it creates the possibility of FCA liability even where a false statement or records is not made "for the purpose" of getting a false or fraudulent claim paid or approved by the federal government.

Notably, FERA contains a special retroactivity provision which applies only to section 3729(a)(1)(B), and provides that that clause "take[s] effect as if enacted on June 7, 2008, and appl[ies] to all claims under [the FCA] that are pending on or after that date." 31 U.S.C. § 3729(4)(f)(1). Courts within this Circuit have found that the word "claims" means false claims for payments for purposes of the False Claims and not "cases." See United States v. Albinson, No. Civ.A.09-1791, 2010 WL 3258266, at *9 (D.N.J. Aug. 10, 2010) (finding that the word "claims" was intended to mean false claims that were submitted, not cases); United States Dept. of Transp. ex rel. Arnold v. CMC Eng'g, 745 F. Supp. 2d 637, 646 (W.D. Pa. 2010) (holding that "[t]he plain meaning of section 4(f) of FERA indicates that 'claims' refers to claims for payments and not cases pending under the FCA"). This Court is persuaded by the reasoning in those cases and thus adopts the same interpretation.

Plaintiff argues that because Defendants' fraud is still ongoing, the FERA amendments should apply to this case. (Pl.'s Resp. Opp'n 6 n.9 (citing Am. Compl. ¶¶ 3, 143, 323.) The language of the retroactivity provision, however, is clear: it applies only to claims "pending" on or after June 7, 2008. The Amended Complaint's cursory reference to "continued" activity, made upon information and belief (Am. Compl. ¶ 323), does not suffice to plead with specificity that Defendants had any false claims pending on or after this date. Accordingly, the Court declines to apply the FERA amendments to this matter.

as follows:

> What § 3729(a)(2) demands is not proof that the defendant caused a false record or statement to be presented or submitted to the Government but that the defendant made a false record or statement for the purpose of getting "a false or fraudulent claim paid or approved by the Government." ***Therefore, a subcontractor violates § 3729(a)(2) if the subcontractor submits a false statement to the prime contractor intending for the statement to be used by the prime contractor to get the Government to pay its claim.*** If a subcontractor or another defendant makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim "by the Government." In such a situation, the direct link between the false statement and the Government's decision to pay or approve a false claim is too attenuated to establish liability. Recognizing a cause of action under the FCA for fraud directed at private entities would threaten to transform the FCA into an all-purpose antifraud statute. Our reading of § 3729(a)(2), based on the language of the statute, gives effect to Congress' efforts to protect the Government from loss due to fraud but also ensures that "a defendant is not answerable for anything beyond the natural, ordinary and reasonable consequences of his conduct."

553 U.S. 662, 671–72 (2008) (emphasis added). 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." United States Dept. Of Transp., ex rel. Arnold v. CMC Eng'g, 564 F.3d 673, 678 (3d Cir. 2009). "In 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. 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.

Under this definition, Plaintiff's FCA claim clearly survives Rule 12(b)(6) scrutiny. 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. Specifically, the Amended Complaint alleges that "[t]he paid claims data provided by the Caremark Defendants to Pharm/DUR represents the value of Part D claims adjudicated and reported to CMS between January 1, 2006 and December 31, 2006." (Am. Compl. ¶ 328.) It goes on to assert that

> The PDE data fraudulently submitted by the CVS Caremark Defendants on behalf of MCS, together with other information required by CMS, was an express condition of payment of Part D benefits by CMS. Each fraudulent Part D PDE claim submitted by the CVS Caremark Defendants on behalf of MCS beneficiaries contained the CVS Caremark Defendants' express certification to CMS of "the accuracy, completeness, and truthfulness of that data;" ***and the CVS Caremark Defendants' acknowledgment "that the data will be used for purposes of obtaining Federal reimbursement.***"

(Id. ¶ 334 (emphasis added).) Drawing all reasonable inferences from these allegations in favor of Plaintiff, the Court finds that Defendants submitted the PDE data directly to CMS, on behalf of MCS, "to get" such claims paid by CMS. It is irrelevant that MCS, not Defendants, received the initial payment from CMS. The Amended Complaint adequately pleads 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. In 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." Merck-Medco Managed Care, 336 F. Supp. 2d at 451.

### 3. Whether Plaintiff Has Pled an FCA Conspiracy under 31 U.S.C. § 3729(a)(3)

Defendants next seek dismissal of Plaintiff's FCA conspiracy claim under 31 U.S.C. § 3527(a)(3). Via his Response in Opposition, however, Plaintiff states that he "is not alleging, at this stage, a claim for 'conspiracy' under the FCA." (Def.'s Resp. Opp'n 60 n.62.) Accordingly, the Court need not address this claim any further.

### 4. Whether Plaintiff Has Properly Pled a Reverse False Claims Cause of Action under 31 U.S.C. § 3729(a)(7)

Plaintiff's final theory of FCA liability rests on 31 U.S.C. § 3729(a)(7)—the reverse false claims act provision. This provision of the FCA imposes liability on any person who knowingly makes, uses, or causes to made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7). "To make a prima facie case of liability under 31 U.S.C. § 3729(a)(7), the plaintiff must prove that the defendant did not pay back to the government money or property that it was obligated to return." United States ex rel. Quinn v. Omnicare, Inc., 382 F.3d 432, 444 (3d Cir. 2004). In addition, there must be a "clear" obligation or liability to the government. Id. at 445, 446. "Congress's purpose in enacting subsection (a)(7) was to ensure that one who makes a false statement in order to avoid paying money owed the government would be equally liable under the Act as if he had submitted a false claim to receive money." United States ex rel. Thomas v. Siemans AG, 708 F. Supp. 2d 505, 514 (E.D. Pa. 2010) (internal quotation marks and quotations omitted). "Its purpose was not to provide a redundant basis to state a false statement claim under subsection (a)(2)." Id.

Defendants argue that Plaintiff's reverse false claims cause of action fails as a matter of law on three grounds. First, they contend that Plaintiff cannot plead falsity for the reasons set forth with respect to his claims under subsection (a)(1). Second, they assert that Plaintiff has not pled any "clear" obligation on the part of Defendants to pay money to the government. Rather, Caremark received payments from MCS, not the government, and only MCS has the ability, much less the obligation, to return overpaid funds to the government. Finally, Defendants suggest that Plaintiff's allegations relating to MCS's submission of reconciliations which failed to disclose errors do not satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b).

The Court rejects Defendants' first argument for the same reasons discussed above regarding Plaintiff's claim under subsection (a)(1). As noted earlier, Defendants' submission of PDE claims to CMS for prescriptions that should not have been paid under Part D constituted a false certification that those records were truthful, accurate, or complete under Medicare laws and regulations. In turn, such PDE claims, which allegedly overstated amounts properly paid by Defendants, were relied upon by CMS when reconciling the claims and served to decrease the amount Defendants owed at reconciliation.

Defendants' second argument has been expressly considered and rejected by a highly persuasive decision from the Fifth Circuit. In United States v. Caremark, 634 F.3d 808 (5th Cir. 2011), the government argued that Caremark made false statements to state medicaid agencies, who received over half their funding from the government, that allowed Caremark to fraudulently avoid making payments to the state Medicaid agencies. Id. at 815. The district court found that Caremark did not have any obligation to the government for denials of

reimbursement requests that Caremark submitted to state Medicaid agencies. Id. The Fifth Circuit disagreed and found that even if Caremark did not owe an "obligation" to the federal government, its false statements caused state Medicaid agencies to make false statements to the federal Government, which is itself a violation of subsection (a)(7). Id. It reasoned as follows:

> The States have a legal duty to return federal funds if they are able to recover from third parties 42 C.F.R. § 433.140. . . . The States also have a legal duty to seek reimbursement from a third party for dual-eligible individuals. 42 U.S.C. § 1396a(a)(25)(A). . . . These requirements impose an obligation on the States to the Government. If Caremark made false statements that an individual is not covered by a plan, these false statements would cause the state Medicaid agencies to pay for the prescription and seek reimbursement from the Government rather than from Caremark. This, in turn, would cause the States to receive and to keep federal funds to which they would otherwise not be entitled. Caremark's actions therefore could have impaired the States' obligation to the Government under 42 U.S.C. § 1396a(a)(25) . . . The statute does not require that the statement impair the defendant's obligation; instead, it requires that the statement impair "***an*** obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7) (emphasis added) . . . Because Caremark's allegedly false statements could have caused the state Medicaid agencies to impair their obligations to the Government, we conclude that the district court erred in granting summary judgment to Caremark on its § 3729(a)(7) claims.

Id. at 817; see also Merck-Medco Managed Care, 336 F. Supp. 2d at 444 ("The fact that Medco [a PBM] may not have been in direct contractual privity with the Government . . . is not an automatic bar to § 3729(a)(7) liability."); United States ex rel. Koch v. Koch Indus., Inc., 57 F. Supp. 2d 1122, 1128–29 (N.D. Okla. 1999) (finding that subsection (a)(7) allowed for indirect reverse false claims and holding that defendants' false statements to lessee may have caused lessee to understate its royalty obligation to the government).

Extending the same logic to the present case, Plaintiff's reverse false claim theory survives Rule 12(b)(6) scrutiny. Plaintiff alleges that "[d]uring the Medicare Part D annual

reconciliation, overpayments by CMS to Part D Plans or Sponsors, including MCS, must be returned." (Am. Compl. ¶ 371.) Yet, "MCS and/or the CVS Caremark Defendants have submitted annual reconciliations since 2006 without revealing the thousands of improperly adjudicated Medicare Part D claims which, therefore, contained false PDE data and constituted false claims." (Id. ¶ 372.) According to the Amended Complaint, "[a]t the time of their periodic Medicare Part D reconciliation, the Caremark Defendants and/or MCS failed to report their submission of false PDE data to CMS, and MCS also failed to return payments received from CMS based upon false Part D claims." (Id. ¶ 373.) "As a result of Defendants' failure to make accurate Medicare Part D annual reconciliations, Defendants submitted false claims in order to avoid returning overpayments to CMS." (Id. ¶ 374.) Such allegations clearly allege "*an* obligation" on the part of MCS to pay or transmit money to the government, which, due to the alleged false claims by Defendants, was not paid or transmitted.

Finally, Defendants contend that Plaintiff has not pled with particularity that any costs Caremark allegedly reported in the PDE data were not the costs that MCS actually paid. Whether Defendants actually paid out on the claims, however, is irrelevant. The key question is whether Defendants *should have* paid these claims and submitted them to CMS, ultimately causing MCS to fail to return overpayments from CMS. The repeated, detailed allegations of the Amended Complaint expressly allege that Defendants dispensed medications and submitted claims that should have never been submitted. Specifically, the Amended Complaint noted that Defendants had adjudicated and fraudulently paid 48,702 Medicare Part D claims, with a total cost of $4,283,546.13 to MCS, all of which were submitted to CMS for payment. (Id. ¶ 269.) Over the next one hundred paragraphs, Plaintiff details those various claims, ultimately

concluding that "MCS and/or the CVS Caremark Defendants have submitted annual reconciliations since 2006 without revealing the thousands of improperly adjudicated Medicare Part D claims which, therefore, contained false PDE data and constituted false claims." (Id. ¶ 372.) Such allegations clearly satisfy the heightened pleading requirements of Rule 9(b). See Frazier ex rel. United States v. Iasis Healthcare Corp., 392 F. App'x 535, 537 (9th Cir. 2010) (An FCA plaintiff "is not required to plead representative examples of false claims submitted to the Government to support every allegation, but he must plead with sufficient particularity to lead to a strong inference that false claims were actually submitted."). Therefore, the Court finds that this claim has been properly pled.

**B. Plaintiff's Nationwide FCA Claims**

Via Defendants' second broad challenge to the Amended Complaint, Defendants contend that Plaintiff's attempts to broaden the scope of his Amended Complaint to plead "nationwide" FCA violations fails to plead fraud with particularity. In the Amended Complaint, Plaintiff expands his allegations far beyond the MCS PDE data that Pharm/DUR reviewed to allege that the violative processes identified in the Amended Complaint were carried out on a nationwide basis. Yet, according to Defendants, Plaintiff's nationwide FCA allegations do not satisfy the heightened pleadings standards of Rule 9(b), as they merely speculate that because there were FCA violations relating to MCS, there must have been FCA violations relating to other contracts as well across the country.

In support of this position, Defendants rely heavily on the case of United States ex rel. Waris v. Staff Builders, Inc., No. Civ.A.9601969, 1999 WL 179745 (E.D. Pa. Mar. 4, 1999),

wherein the plaintiff had brought a *qui tam* action under the False Claims Act for alleged Medicare fraud. Id. at *1. The Plaintiff alleged that defendants had defrauded the United States by obtaining reimbursement from Medicare for consulting services that were either not rendered or not reimbursable. Id. Defendants objected to the complaint because the plaintiff had alleged "on information and belief" that defendants engaged in serious Medicare fraud based on nothing more than the one alleged episode in which the plaintiff received a false invoice from the defendants, which was submitted to Medicare. Id. at *5. The court found that "[t]he alleged facts upon which plaintiff's 'on information and belief' allegations are based are too thin a reed to support the entire complaint." Id. The court further remarked that plaintiff rested his FCA claims against defendants entirely on one false invoice that one defendant sent to plaintiff in response to plaintiff's first monthly consulting bill. Id. It concluded that, even under "relaxed" Rule 9(b) standards "[t]he alleged circumstances surrounding the invoice do not appear enough in themselves to allow a strong inference that defendants were engaging in fraud with regard to Waris' consulting services, much less with regard to other, unnamed consultants." Id.

Waris is factually distinguishable from the present case. Waris rested a nationwide scheme of false claims based entirely on one invoice. In the present matter, however, Plaintiff identifies over 49,000 problematic claims and describes, with great detail, a large number of them. Unlike in Waris, little is left to speculation with respect to the alleged false claims within the scope of the MCS-Caremark contract.

The question then remains whether Plaintiff's pleading goes far enough to give rise to a reasonable inference that Defendants' alleged violations of the FCA were a national company policy. "The standard for 9(b) is a generous one in this Circuit," Blue Line Coal Co. v.

Equibank, 683 F. Supp. 493, 497 (E.D. Pa. 1988) (quotations omitted), and the Third Circuit Court of Appeals has cautioned that "focusing exclusively on [Rule 9(b)'s] particularity language 'is too narrow an approach and fails to take account of the general simplicity and flexibility contemplated by the rules.'" Christidis v. First Pa. Mortgage Trust, 717 F.2d 96, 100 (3d Cir.1983) (quoting 5 C. Wright & A. Miller, Federal Practice and Procedure § 1298, at 407 (1969)). Rule 9(b) does not require date, time, and place allegations, provided that the plaintiff gives the defendants other means of precision and substantiation. Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984).

Applying a similar relaxed pleading standard, several courts have found that allegations of specific claims in one state or region satisfy Rule 9(b) requirements by establishing a nationwide inference of fraud.[31] See, e.g., U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 30–31 (1st Cir. 2009) ("Although Duxbury does not identify specific claims, he has alleged the submission of false claims across a large cross-section of providers that alleges the 'the who, what, where, and when of the allegedly false or fraudulent representation.' . . . Duxbury has alleged facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide."); U.S. ex rel. Drennen v. Fresenius Med. Care Holdings, Inc., No. Civ.A.09-10179, 2012 U.S. Dist. LEXIS 29136, at *5–6 (D. Mass. March 6, 2012) (holding that despite plaintiff's

[31] Defendants contend that Plaintiff "cites no authority showing that the Third Circuit allows the extrapolation of nationwide allegations from specific allegations of purported fraud in one location." (Defs.' Reply Br. 30.) Notably, however, Plaintiff has cited numerous cases from outside the Third Circuit condoning this practice and Defendants have failed to cite authority from within the Third Circuit rejecting—either explicitly or implicitly—this approach. On a motion to dismiss, Defendants bear the burden of disproving Plaintiff's theories.

failure to plead names of defendant's employees who submitted the false claims or when the false bills were submitted to Medicare, the identification of six patients on whom the sixty-four unnecessary tests were performed, the period in which the tests were performed, the locations of the clinics which performed the tests, and the costs billed was sufficient to satisfy Rule 9(b) pleading standards. In turn, plaintiff's allegation that "by reason of [defendant's] national billing practices, this billing likely occurred at [defendant's] other facilities throughout the country" was sufficient to allege nationwide false claims under Rule 9(b)); U.S. ex rel. Hudalla v. Walsh Constr. Co., 834 F. Supp. 2d 816, 823 (N.D. Ill. 2011) (holding that defendants were on notice since first served with plaintiff's complaint that plaintiff was challenging its practices concerning projects beyond the projects specifically named in complaint, as was "readily apparent from [plaintiff's] detailed allegations regarding the nature of the alleged fraud; his contention that he had been told that defendant billed in the same way on other projects, his identification of several of those projects, and his statement that his claim 'includ[es], but [is] not limited to,' the named projects"); United States ex rel. Schuhardt v. Wash. Univ., 228 F. Supp. 2d 1018, 1034 (E.D. Mo. 2002) ("Plaintiffs have named specific doctors, and have identified specific dates and services supporting their allegations of improper Medicare billings. Further, plaintiffs have identified specific amounts billed for specific patients as representative samples of the alleged fraudulent billing. The Court does not believe now, nor did it believe at the time of the earlier order, that plaintiffs should be required to provide a specific allegation to substantiate each and every general allegation within the complaint.").[32]

[32] In their Reply Brief, Defendants attempt to distinguish this case. (Defs.' Reply Br. 31 n.26.) Oddly, however, when doing so, Defendants do not discuss the court's opinion during Rule 12(b)(6) proceedings, wherein the court allowed the remaining, unspecified fraud claims to

In the present case, Plaintiff attaches, as Exhibit C to his Amended Complaint, a chart of claims reflecting the various false PDE information submitted by Defendants and listing the violations using various identifiers including drug name, offending pharmacy, date filled, expiration date, patient co-pay, prescriber name where available. While many of the prescriptions originated from pharmacies located in Puerto Rico—the center of MCS's service area—others originated from CVS Caremark's mail order facilities in Florida and Illinois, as well as other pharmacies in New York and Pennsylvania. (Am. Compl. ¶¶ 260, 276, 278 & Ex. C.) The allegations of the Amended Complaint itself specifically outline numerous precise examples of Defendants' alleged fraud. (Id. ¶¶ 280, 284, 289, 295.) The Amended Complaint then goes on to assert that these allegedly improperly practices, for which numerous specific examples are identified, have been performed on a nationwide basis. (Id. ¶¶ 280 ("The Caremark Defendants admitted that 'An edit to reject claims for unidentified prescribers is not a system edit that Caremark provides its customers.' Thus incredibly, the Caremark Defendants essentially conceded that it had been engaging in systemic Part D fraud across all of its plans nationwide in connection with its submission of PDE data"); 288 ("CVS Caremark utilizes a

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proceed. Rather, it cited to the court's ruling during *summary judgment proceedings* after which the court dismissed the fifteen specifically pleaded claims and then dismissed the remaining unspecified fraud claims under Rule 9(b). U.S. ex rel. Schuhardt v. Wash. Univ., 261 F. Supp. 2d 992, 1019 (E.D. Mo. 2003).

Defendants also rely on this case to argue that if this Court allows the specified claims of fraud to proceed, then discovery should be limited to such claims and should not yet be expanded to the nationwide claims of FCA violations. Unlike in Schuhardt, however, allowing full discovery to proceed in the present case would not result in any similar "fishing expedition." As noted, Plaintiff does not focus on particular fraudulent claims, but rather specific fraudulent practices, which he contends were carried out with respect to Defendants' contracts with other Part D Sponsors other than MCS. Based on the allegations of the Amended Complaint, discovery on the scope of these broader practices will not create any undue burden on Defendants.

nationwide claims adjudication system and has admitted that they intentionally make no effort to ensure that prescribers are identified or to deny claims for excluded or unlicensed providers . . . This is particularly true when considered in light of the fact that Caremark has been adjudicating and submitting Part D claims for thousands of other Plans, including Federal Government Plans."); ¶ 290 ("In response to these findings, Caremark admitted that its nationwide system does not even reject claims for drug/gender deviations); ¶ 299 ("Defendants' intentional and knowing practice of paying claims for prescription drugs with expired or obsolete NDC numbers is not limited to the MCS contracts, but is common across the Caremark Defendants' entire nationwide network and affects all of Caremark's Medicare Part D pharmaceutical customers involved in Medicare Part D as Sponsors."); ¶ 319 ("The Caremark Defendants nationwide Part D claims adjudication system failed to have the required concurrent DUR, including gender contraindications and review for overutilization.").

The Amended Complaint then includes an entire section dedicated to arguing that Defendants have illegally caused CMS to make inflated Medicare Part D subsidy payments to CVS Caremark's customers other than MCS Life, as follows:

> 339. Caremark (now CVS Caremark) uniformly and systemically analyses, processes and documents all prescriptions managed by CVS Caremark using CVS Caremark's nationwide proprietary prescription management system.
>
> 340. CVS has admitted that its nationwide system does not conduct gender edits, check for false physician identifiers, or reject claims with expired NDCs.
>
> 341. The following Part D claims processing failures detected by Pharm/DUR involve company-wide or system-wide non-compliance with Part D requirements by the caremark Defendants: fraudulent failure to conduct gender edits as part of concurrent DUR and the adjudication of claims containing gender deviations; fraudulent failure to reject claims for false physician identifiers and submission of physician push numbers; the fraudulent failure to exclude expired drugs and the adjudication [of] claims

with expired NDCs for three years past the inactive dates.

342. These intentional company-wide Part D claims adjudication failures involve false claims submissions to CMS and increased payments in terms of monthly Part D subsidies and other payments, and to the CVS Caremark Defendants' customers nationwide who participate in the Part D program. This includes, but is not limited to the Part D plans operated by CVS Caremark subsidiaries, as well as non-CVS Caremark based Part D Plans.

(Id. ¶¶ 339–42.)[33]

Taking these well-pled allegations as true, the Court finds a strong inference that Defendants submitted false claims nationwide. Indeed, the sheer number of claims identified by Plaintiff in at least three states and Puerto Rico suggests, without need for speculation, that Defendants' reporting practices likely occurred at Defendants' other facilities throughout the country. Certainly, Plaintiff cannot be expected to plead with particularity each and every false claim nationwide without the benefit of at least some discovery, as such information rests solely

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[33] As further support for his nationwide claims, Plaintiff also makes a number of allegations that CMS improperly paid retiree drug subsidies ("RDS") to Defendants' other Part D customers, including the Federal Employee Health Benefits Program. (Am. Compl. ¶¶ 347–51.) The RDS program, however, has a separate statutory, regulatory, and operational structure from Part D. See 42 U.S.C. § 1395w-132; 42 C.F.R. Part 423, Subpart R - Payments to Sponsors of Retiree Prescription Drug Plans. In particular, the RDS program does not have PDE requirements generally. Accordingly, because Plaintiff has not pled any specific false claims relating to RDS payments, Plaintiff is hard-pressed to pursue a nationwide claim on these RDS payments. In the face of Defendants' challenge (raised solely in a footnote) to these allegations, Plaintiff offers no response.

Nonetheless, the Court is not clear whether Plaintiff raises such allegations as mere examples of nationwide fraud by Defendants or as a separate basis for FCA liability. To the extent these allegations are merely part of Plaintiff's overall "nationwide" FCA claim and the Court has already found that the nationwide claim survives Rule 12(b)(6) scrutiny, the Court rejects Defendants' arguments.

within Defendants' control.[34] In turn, such allegations are sufficient to allege, at this stage of the litigation, a nationwide False Claims Act under Rule 9(b). The Court therefore declines to dismiss this claim.[35]

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[34] In an apparent effort to suggest that such particularity is required with respect to all of the claims, Defendants cite U.S. ex rel. Thomas v. Siemens AG, 708 F. Supp. 2d 505, 515 (E.D. Pa. 2010). In that case, the court found that plaintiff had properly alleged that defendant had made false claims in four contracts with the government. Id. at 513. The defendant then argued that a listing of seventeen other contracts provided as an exhibit to the complaint could not constitute false claims under the FCA because plaintiff failed to allege with any particularity a single false statement in any one of the contracts. Id. at 515. In response, plaintiff argued that because defendant had misrepresented discounts with respect to the four contracts he did specify, it must have made similar misrepresentations in securing each of the contracts listed in the exhibit. Id. The court found this to be nothing more than conjecture. Id.

The present case is distinguishable. Far from alleging misrepresentations with respect to specific Part D prescription claims, Plaintiff alleges generalized practices by Defendants that have caused Defendants to make multiple false claims at its various pharmacies nationwide. In turn, Plaintiff has identified a series of specific claims, originating from various Caremark pharmacies, wherein the PDE data submitted on those claims was false or did not accurately reflect the required concurrent DUR. Further, Plaintiff has alleged that Defendants have seemingly admitted that these claims are consistent with their company-wide practices. Accordingly, a nationwide false claims cause of action would not, unlike in Siemens, be based on conjecture.

[35] By way of one of the seventy-six footnotes—written in ten-point font—in his Response in Opposition, Defendant argues that Defendants violated the FCA by submitting claims to CMS after they fraudulently induced CMS to contract with them as a Part D Plan and/or as a Part D PBM knowing they could not comply with Federal Part D requirements. (Pl's Resp. Opp'n Mot. Dismiss 56–57 n.61.) Aside from one cursory allegation in the Amended Complaint as to fraudulent inducement, however, (Am. Compl. ¶ 357), Plaintiff provides no specific pleading on this claim. See Willard v. Humana Health Plan of Texas, Inc., 336 F.3d 375, 384–85 (5th Cir. 2003) (holding that plaintiff failed to assert a single fact to support his allegation that defendant entered into a contract with the Health Care Financing Administration of the United States government with no intent to perform since he did not allege who was involved in the negotiations, where or when the negotiations took place, and what was said before, during, or after the contract negotiations to indicate that the contract was entered with no intent on defendant's part to enroll eligible participants from rural counties). Accordingly, the Court will not permit Plaintiff to proceed on any fraudulent inducement claim.

### C. Whether Plaintiff's Suit is Barred by the False Claims Act's Public Disclosure Provision

In a final effort to dismiss the entirety of Plaintiff's Amended Complaint, Defendants argue that the FCA forecloses this case pursuant to its public disclosure provision. Specifically, they note that Plaintiff's allegations are based upon the public disclosure of allegations or transactions in a civil hearing as well as in a "report." Moreover, they assert that Plaintiff does not qualify as "an original source of the information" on which the Complaint is based. 31 U.S.C. § 3730.

Defendants' argument is premised on § 3730(e)(4)(A) of the FCA, which provides that:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or actions in a criminal, civil or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action in an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (1994). "In other words, if [a plaintiff's] complaint is 'based upon' allegations that were previously disclosed in certain qualifying public sources, his claim is barred unless he is an original source of those allegations. The list of qualifying sources includes certain government reports and the news media . . . It also includes allegations contained in civil complaints." United States ex rel. Feldstein v. Organon, Inc., 364 F. App'x 738, 741 (3d Cir. 2010). "To determine whether a plaintiff is barred by the FCA's public disclosure provisions, we must first assess whether the relator's claim is based on publicly disclosed allegations or transactions." U.S. ex rel. Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506, 519 (3d Cir. 2007). "This, in turn, requires a twofold analysis. First, we determine whether

the information was disclosed via one of the sources listed in § 3730(e)(4)(A). Second, we decide whether the relator's complaint is based on those disclosures." Id. "To be 'based upon' the publicly revealed allegations or transactions the complaint need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." Id. (citing United States ex rel Mistick PBT v. Hous. Auth. of City of Pittsburgh, 186 F.3d 376, 385–88 (3d Cir. 1999)). Finally, if these two elements are satisfied, the plaintiff may fall within an exception to the public disclosure bar by proving that he or she is an "original source." Atkinson, 473 F.3d at 515.

In the present case, Defendants contend that Plaintiff's allegations were publicly disclosed prior to his Complaint, that the Amended Complaint is based upon these public disclosures, and that Plaintiff is not an original source. The Court considers each argument individually.

### 1. Whether Plaintiff's Allegations Were Publicly Disclosed Prior to His Complaint

The FCA defines several sources of prior public disclosures that can bar an FCA action. Specifically, if the allegations upon which the complaint is based were previously publicly disclosed (a) in a criminal, civil, or administrative hearing; (b) in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation; or (c) by the news media, the court has no jurisdiction over the action. 31 U.S.C. § 3730(e)(4)(A). Defendants, in this case, argue that two of those sources are implicated by this case. First, they assert that the prior disclosure in discovery in the 2007 MCS-Caremark Litigation (and related efforts to amend the pleadings) of precisely the same six audit findings that Plaintiff raises in

this case is a public disclosure that bars this suit. Second, they assert that even before Pharm/DUR was retained to audit the 2006 PDE data at issue in this case, Caremark reported the "identical" data directly to CMS, which constituted additional public disclosures of the same transactions that form the basis of Plaintiff's Amended Complaint.

**a. Production of Audit Report During Civil Litigation**

Defendants' first argument contends that in the MCS-Caremark Litigation, MCS produced 341 pages of documents on March 10, 2008, in response to Caremark's discovery requests. (Def.'s Mem. Supp. Mot. Dismiss. 31.) This production included a report summarizing each of Pharm/DUR's six audit findings, which encompassed precisely the same six allegations set forth in Plaintiff's Amended Complaint filed here. (Id. at 31–32.) According to Defendants, this is a public disclosure under 31 U.S.C. § 3730(e)(4)(A).

Defendants rest their argument on the Third Circuit case of United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149 (3d Cir. 1991). In that matter, the defendant argued that certain memoranda on which the *qui tam* complaint was based were publicly disclosed during discovery in a prior litigation between the parties. Id. at 1157. To resolve the question of whether discovery produced in litigation constitutes a "public disclosure," the court "focus[ed] on the characterization of the discovery once it has been produced, and whether a person who acquires such material has received it through a 'public disclosure' for purposes of the FCA." Id. It noted that in the absence of a protective order, the information disclosed in discovery is "potentially accessible to the public." Id. at 1158. It went on to cite a series of cases noting that if good cause for a protective order has not been shown,

discovery materials receive no judicial protection and are therefore open to the public. Id. (citing cases). Remarking that no protective order was in place in the prior litigation to shield from public access the information at issue, the court held that "disclosure of discovery material to a party who is not under any court imposed limitation as to its use is a public disclosure under the FCA." Id. at 1158. The court went on to find that

> We do not think that it is significant, for purposes of interpreting the 'public disclosure' provision of the FCA, whether the discovery has in fact been filed. Due to the large volume of discovery materials, many district courts have adopted local rules which provide that discovery materials should not be filed with the court except by order of the court. Such local rules do not generally preclude access by interested persons to nonfiled material. In fact, the Local Rules of some district courts provide that the court may order the filing of discovery materials at the request of any person who has an interest in reviewing the materials.

Id. at 1158–59 (footnotes omitted). Moreover, it remarked that Federal Rule of Civil Procedure 5(d) required filing of discovery material in the absence of a court order excusing filing because "such materials are sometimes of interest to those who may have no access to them except by a requirement of filing, such as members of a class, litigants similarly situated, or the public generally." Id. at 1159 (quoting Fed. R. Civ. P. 5(d) advisory committee note to 1980 amendment). The court declined to draw a distinction based on actual filing since it would make application of the public disclosure provision dependent on the form of discovery. Id. Ultimately, the court concluded that "the presumption under Rule 5(d) of public access to civil discovery that is not subject to a protective order leads us to conclude that information received as a result of such discovery should be deemed based on a 'public disclosure' for purposes of the FCA jurisdictional bar." Id. "It follows that the jurisdictional bar of section 3730(e)(4)(A) for actions based on the 'public disclosure' of allegations or transactions in a 'civil hearing' is

applicable because [plaintiff] acquired the information upon which it based its *qui tam* complaint through the material produced by [defendant] Provident in discovery." Id. at 1159–60.

While, at first blush, Stinson appears determinative of the present issue, Plaintiff astutely points on that Stinson rested on crucial facts not present in the current matter. First, the court in Stinson relied heavily on the fact that the information disclosed in discovery was not under any type of protective order and, thus, was open to the public. It held that "disclosure of discovery material to a party who is not under any court imposed limitation as to its use is a public disclosure under the FCA." Id. at 1158. The court appeared most concerned with whether the information was "potentially accessible to the public." Id. Both parties in the present case, however, agree that the Audit Report was never actually filed with the court in the federal court action in the Caremark litigation. (Defs.' Reply Br. 34.) More importantly, prior to participating in the audit, Caremark and Pharm/DUR entered into a Confidentiality Agreement, dated March 7, 2007, wherein any confidential and proprietary information of SilverScript and Caremark—including costs and pricing, financial and technical information, ideas, designs, specifications, techniques, models, data, programs, documentation, processes, know-how, customer lists, marketing plans, and information discussed at any Company meetings in which Pharm/Dur and SilverScript and/or Caremark were present—was to be kept entirely confidential. (Affidavit of Anthony Spay ("Spay Aff.") ¶ 19, Ex. 2.) The Audit Report was based on precisely such information disclosed by Caremark and SilverScript to Pharm/Dur pursuant to that Confidentiality Agreement. Therefore, when it was produced during the Caremark litigation, it remained under the Confidentiality Agreement, and was not "potentially accessible to the

public." Although that Agreement was not a "court-imposed limitation," as discussed in Stinson, there was a clear potential for the imposition of such an official limitation under section two of the Agreement. That section provided that if the confidential information were to be disclosed "as part of a judicial process," the disclosing party was to give prior written notice to the other part to allow that other party to seek an appropriate, court-imposed protective order. (Id.) In other words, there was a strong likelihood that "good cause" would exist for the court to impose a protective order under Rule 26(c), thereby precluding public access to the information.[36]

Second, the Stinson court relied heavily on "the presumption under Rule 5(d) of public access to civil discovery that is not subject to a protective order" to conclude that information received as a result of such discovery should be deemed based on a "public disclosure" for purposes of the FCA jurisdictional bar. Id. at 1159–60. At the time of that case, Federal Rule of Civil Procedure 5(d) provided that

> All papers after the complaint required to be served upon a party, together with a certificate of service, ***shall be filed with the court*** within a reasonable time after service, but the court may on motion of a party or on its own initiative order that depositions upon oral examination and interrogatories, requests for documents, requests for admission, and answers and responses thereto not be filed unless on order

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[36] In Stinson, the court never addressed this precise issue, remarking that it "need not consider whether information subject to a protective order which is either advertently or inadvertently disclosed could be considered to be received pursuant to a 'public disclosure'" because "[t]here was no reason to shield from public access the information referring to Prudential appearing in the Provident discovery, and Stinson does not suggest any." Stinson, 944 F.2d at 1158.

Quite to the contrary in this case, Plaintiff has suggested ample reason to shield from public access the information contained in the Audit Report. Accordingly, this Court finds that, given the present factual scenario, the Third Circuit would deem such information not part of a public disclosure.

> of the court or for use in the proceeding.

Fed. R. Civ. P. 5(d) (emphasis added). As noted by the United States Court of Appeals for the Second Circuit, this Rule was intended to "embod[y] the [Advisory] Committee's concern that class action litigants and the general public be afforded access to discovery materials whenever possible. " In re Agent Orange Prod. Liab. Litig., 821 F.2d 139, 146 (2d Cir. 1987), abrogated on other grounds by In re Oxford Health Plans, Inc., 383 F. App'x 43 (2d Cir. 2010).

Subsequent to Stinson, however, this Rule was amended to read, in pertinent part:

> Any paper after the complaint that is required to be served—together with a certificate of service—must be filed within a reasonable time after service. ***But disclosures under Rule 26(a)(1) or (2) and the following discovery requests and responses must not be filed until they are used in the proceeding or the court orders filing***: depositions, interrogatories, requests for documents or tangible things or to permit entry onto land, and requests for admission.

Fed. R. Civ. P. 5(d)(1) (2007) (emphasis added). Via the comments to the amendments, the Advisory Committee explained that this amendment was meant to conform to many local rule practices and provide that discovery materials and disclosures under Rule 26(a)(1) and (a)(2) must not be filed until they are "used in the proceeding," referring to proceedings in court and not use in other discovery activities such as depositions. Id. at cmt. to 2000 amendments. As such, the Advisory Committee made a conscious effort to shift away from the principle of making discovery materials available to the public whenever possible in favor of making them available only when "used" in a court proceeding.[37]

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[37] Defendants argue, citing to the comments to the 2007 amendments, that the amended language to Rule 5(d) was intended to be "stylistic" only to make them more easily understood. Notably, however, the crucial language change at issue was made in 2000. Nothing in the comments to those amendments suggests that the change was merely "stylistic."

In the present case, Defendants have made no showing that the Audit Report was ever "used" in court proceedings during the MCS-Caremark litigation. Moreover, an issue of fact remains as to whether, if the Audit Report were proposed to be "used," either party would have obtained a protective order that would have shielded the documents from public disclosure. In short, the Court declines to find that the exchange of the Audit Report between the parties in the MCS-Caremark litigation constituted a public disclosure for purposes of the FCA.[38]

**b. Filing of PDE Data Reports to the Government**

Second, Defendants assert that even before Pharm/DUR was retained to audit the 2006 PDE data at issue in this case, Caremark reported the "identical" data directly to CMS. According to Defendants, Caremark's PDE data reports to the government, on which the Audit Report was based, were additional public disclosures of the same transactions that form the basis of Spay's Complaint. Defendants' theory is that the term "report" in the FCA includes a defendant's submission to the government, which was available through a Freedom of Information Act request.

In support of their argument, Defendants focus on the United States Supreme Court's broad interpretation of "report," as used in the FCA. Schindler Elevator Corp. v. U.S. ex rel. Kirk, 131 S. Ct. 1885 (2011). In that matter, the Court found that "[a] written agency response to a [Freedom of Information Act] request falls within the ordinary meaning of 'report.'" Id. at

[38] Plaintiffs argue that Stinson is outdated law that has been rejected by a number of other courts finding that discovery exchanged between parties, but not filed with the court, does not constitute a "public disclosure." (See Pl.'s Resp. Opp'n Mot. Dismiss 79 (citing cases).) While this Court would tend to agree that Stinson may ultimately be overruled, this Court does not have the authority to deviate from it to the extent it would apply here. Nonetheless, as noted above, there are significant enough factual distinctions in order to distinguish it from the present case.

1893. Schindler, however, did not read "report" to constitute an entity's *submission* of reports *to* the government or even a request made under the Freedom of Information Act. Rather, it concerned a governmental *response* to a Freedom of Information Act request. There is no showing that the PDEs at issue here constitute that type of response.[39] Id.

To now accept Defendants' theory would mean that by their very act of submitting their allegedly false claim via the PDE reports, Defendants have effectively shielded themselves from FCA liability through the public disclosure bar. This clearly cannot be the correct result. As persuasively argued by the United States in its Statement of Interest, "Caremark's argument is tantamount to the claim that everything the government has in its files is public information. . . . Were such an interpretation to be accepted, relators would be seriously handicapped in using the False Claims Act to prosecute fraud on behalf of the United States." (U.S. Statement of Interest 14.)

Indeed, both parties agree that from 2006 to 2008, PDE data was not available to anyone outside the government. (Defs.' Reply Br. 37.) Effective June 27, 2008, PDE data became available for purposes of "other research, analysis, reporting, and public health functions." 73 Fed. Reg. 30664-01. This Final Rule made clear that:

Through the application of our "minimum data necessary policy", with some

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[39] This distinction is particularly crucial in the face of Defendants' argument that public releases for PDE data are available through a Freedom of Information Act request. (Defs.' Resp. Govt.'s Statement of Interest 13.) Defendants have made no showing that there was any Freedom of Information Act request made for the PDE data at issue here, let alone any response by the government that would fall within the bounds of Schindler. Notably, Defendants citation to United States ex rel Mistick PBT v. Hous. Auth. of City of Pittsburgh, 186 F.3d 376, 384 (3d Cir. 1999) is distinguishable on the same grounds. Id. (holding that the disclosure of documents under the FOIA triggers the jurisdictional bar of 31 U.S.C. § 3730(e)(4)(A)).

> additional restrictions to protect beneficiary confidentiality and commercially sensitive data of Part D sponsors, and our data sharing procedures (which ensure the agency's compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Privacy Act of 1974, and other applicable laws), we will limit the use and disclosure of Part D claims data to ensure that the data are only used or disclosed as permitted or required by applicable law, and not inappropriately disclosed in a manner which could undermine the competitive nature of the Part D program.

73 Fed. Reg. 30664-01, at 30666. The Rule emphasized that "we will not release Part D claims information for commercial purposes." Id. at 30680.[40]

Thus, far from being "publicly available," the PDE reports were not even minimally available until 2008. Only then did the government agree to begin releasing such information to certain entities and for certain specified purposes, subject to various regulations to prevent improper disclosure. Such regulations are the antithesis of the "publicly available" information found to trigger the public disclosure bar of the FCA. Certainly, if the release of such

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[40] Indeed, in an official CMS document entitled "Questions and Answers in Obtaining Prescription Drug Event (PDE) Data," the following information is provided:

> **For what purposes can I get Part D Prescription Drug Event data?**
>
> The Part D data final rule allows the public to receive identifiable Part D data for **research** purposes. We are using the definition of research in the HIPAA Privacy Rule which defines research as *"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."* We do not release identifiable data to external entities when their research is not designed to develop or contribute to generalizable knowledge. States and federal government agencies may also request Part D PDE data for additional purposes. The data will be made available to beneficiaries for their personal health records. We will not release identifiable data for commercial purposes.

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/downloads/PartDClaimsDataQA.pdf (last visited November 27, 2012) (emphasis in original).

information from the government remains restricted, then it defies logic to suggest, as Defendants do, that the submission of such information could constitute public disclosure.[41]

**2. Whether Plaintiff's Complaint is Based Upon Public Disclosures**

Defendants also argue that the allegations of the Amended Complaint are "based upon" the public disclosures. The Third Circuit has held, consistent with the majority of other Courts of Appeals, "that the term 'based upon' means 'supported by' or 'substantially similar to,' not 'actually derived from.'" United States ex rel. Paranich v. Sorgnard, 396 F.3d 326, 334–35 (3d Cir. 2005) (citing cases). "Substantial similarity exists where there is 'substantial identity' between the publicly disclosed allegations and the allegations in the relator's complaint." U.S. ex rel. Feldstein v. Organon, Inc., 364 F. App'x 738, 741 (3d Cir. 2010). Moreover, the Third Circuit has remarked that "'a *qui tam* action is "based upon" a qualifying disclosure if the disclosure sets out either the allegations advanced in the *qui tam* action or all of the essential elements of the *qui tam* action's claims.'" Id. (quoting Mistick, 186 F.3d at 388).

While the parties contest whether or not the Amended Complaint is "based upon" the alleged public disclosures, the Court need not reach this issue. A precondition to reaching this inquiry is a preliminary finding that there has been some sort of public disclosure within the

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[41] Defendants' reliance on Nevada ex rel Hager v. Countrywide Home Loans Serv., L.P., 812 F. Supp. 2d 1211 (D. Nev. 2011) is unconvincing. Defendants contend that, in that case, Defendants allegedly violated the FCA because they stated on Declaration of Value forms that Fannie Mae was a government agency exempt from taxation and made a false statement on the amount of transfer tax due. Id. at 1215. The court found that the FCA claims were barred by the public disclosure bar. In doing so, it held that, "[b]ecause the Nevada Legislature mandates that Defendants publicly record these transactions, Plaintiffs may only maintain this lawsuit if they are the original sources of information." Id. at 1219. In the present case, Defendants do not and cannot suggest that PDE claims were required to be publicly recorded.

meaning of Section 3730(e)(4)(A). Paranich, 396 F.3d at 334; see also United States ex rel. Doe v. John Doe Corp., 960 F.2d 318, 322 (2d Cir. 1992) ("Public disclosure of the allegations upon which the *qui tam* complaint rests is the bedrock of § 3730(e)(4)(A)'s jurisdictional bar.") The only alleged "public disclosures" identified by Defendants are the Audit Report created by Pharm/DUR—Plaintiff's company—and Caremark's PDE reports of the data to the government. (Defs.' Mem. Supp. Mot. Dismiss. 33.) As set forth in detail above, however, neither of these items was publicly disclosed for purposes of the FCA. Accordingly, no further discussion of the "based upon" element is required.[42]

### 3. Whether Plaintiff is an Original Source

Finally, Defendants argue that Plaintiff is not an "original source" under 31 U.S.C. § 3730(e)(4)(B), meaning that the public disclosure bar applies. Given the foregoing discussion, however, this inquiry is again unnecessary. As the Court of Appeals for the Third Circuit has explained, "[t]he jurisdictional requirements of the FCA involve assessing whether the allegations and transactions constituting the bases of the claims were publicly disclosed and whether, *if they were,* the relator is an original source-meaning that he has direct and independent knowledge of the information." Atkinson, 473 F.3d at 515 (emphasis added). "Thus, for the jurisdictional bar to apply, the complaint must be based on material that was *publicly disclosed* in the first instance." United States ex rel. Landsberg v. Levinson, No.

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[42] Although Plaintiff contends that the allegations in the Amended Complaint were not "based upon" the Audit Report, the Court notes that there is substantial identity between the Audit Report and the allegations in the Amended Complaint to satisfy the Third Circuit's standard. Nonetheless, because the Audit Report was not publicly disclosed, this finding is irrelevant.

Civ.A.03-1429, 2008 WL 2246308, at *2 (W.D. Pa. May 29, 2008) (emphasis in original). "Section 3730(e)(4)(B) merely creates an exception to the public disclosure bar where the realtor is nevertheless an 'original source' of the information." Id. Therefore, "the question of whether the relator is an original source is only reached if it has already been determined that the relator's claims are based upon allegations that were publicly disclosed." Id.; see also United States ex rel. Barth v. Ridgedale Elec., Inc., 44 F.3d 699, 703 (8th Cir. 1995) ("A court reaches the original source question only if it finds the plaintiff's suit is based on information that has already been publicly disclosed.").

Given Defendants' failure to show public disclosures upon which the Amended Complaint was based, Defendants have not established the bedrock principles of the FCA's jurisdictional bar. As such, Plaintiff need not come forward with any proof that he falls within the exception to this bar as an "original source."[43]

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[43] An "original source" within the meaning of the FCA is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). The Third Circuit has explained that to be an original source, a relator must have had (1) direct and (2) independent knowledge of the information on which the allegations are based and (3) have voluntarily provided the information to the Government before filing the action. Paranich, 396 F.3d at 335. "'Independent knowledge' is knowledge that does not depend on public disclosures. 'Direct knowledge' is knowledge obtained without any intervening agency, instrumentality or influence: immediate." Atkinson, 473 F.3d at 520 (internal citations and some quotation marks omitted).

Defendants argue that Plaintiff is not an original source because (1) his knowledge is not "direct," *i.e.* it has not arisen from his own efforts as opposed to the labor of others; (2) his knowledge is not dependent because it depends upon public disclosures; and (3) he fails to allege that he voluntarily provided the information on which his Amended Complaint is based to the government before filing this action. In light of the information available, the Court would be inclined to find that Plaintiff was indeed an original source. Using his experience and skill as a pharmacist and pharmacy auditor, Plaintiff independently reviewed non-publicly available PDE data to determine that Defendants violated numerous federal regulations and fraudulently billed

## V. CONCLUSION

In light of the foregoing, the Court finds that Plaintiff's Amended Complaint sufficiently pleads a cause of action under the False Claims Act to survive judicial scrutiny under Federal Rule of Civil Procedure 12(b)(6). Primarily, the Court finds that Plaintiff has pled a plausible claim for relief under three key sections of the False Claims Act. First, Plaintiff has properly pled falsity for purposes of 31 U.S.C. § 3729(a)(1) under both a false certification theory and a worthless services theory. Second, Plaintiff has sufficiently alleged that Defendants submitted or caused to be submitted a "claim" to the government in order "to get" paid by the government under 31 U.S.C. § 3729(a)(2). Third, Plaintiff has set forth an actionable Reverse False Claims cause of action under 31 U.S.C. § 3729(a)(7). Moreover, the Court finds that Plaintiff's nationwide FCA claim has been pled with particularity as required by Federal Rule of Civil Procedure 9(b). Finally, the Court finds no merit to Defendants' allegation that Plaintiff's suit is barred by the False Claims Act's Public Disclosure Provision in light of Defendants' failure to identify any publicly disclosed information on which the allegations of the Amended Complaint were based. Accordingly, the Court denies Defendants' Motion to Dismiss in its entirety and directs Defendants to file an Answer to the Amended Complaint within twenty-one days of the date of the Order accompanying this Memorandum.

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the government for either improperly dispensed drugs or services not provided. As such, his knowledge was not only independent of the PDE claims, but was direct knowledge acquired through his own labor and effort and not through any intervening agencies. Finally, Plaintiff's attached exhibits reveal that this information was voluntarily provided to the government before the filling of the action.