IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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. September 22, 2015

Currently pending before the Court is (a) the Motion for Summary Judgment by Defendants CVS Caremark Corporation, Caremark Rx, LLC, Caremark, LLC, and Silverscript, LLC (collectively "Defendants" or "Caremark") and (b) the Motion for Partial Summary Judgment by Plaintiff/Relator Anthony R. Spay ("Plaintiff"). For the following reasons, Defendants' Motion is granted in its entirety and Plaintiff's Motion is denied in its entirety.

I. STATEMENT OF FACTS[1]

[1] The parties present over one thousand factual allegations, hundreds of pages objecting to or disputing the other party's factual allegations, and thousands of pages of evidence. These submissions are separate and apart from the hundreds of pages spent actually briefing the legal issues in this matter. In an effort to streamline discussion of this case, the Court will stray from normal practice and, for each fact upon which the parties agree, will not cite to the parties' evidentiary submissions. To do so would result in an exorbitantly lengthy opinion with little benefit to the parties. Rather, the Court will limit its evidentiary citations to situations where

A. Procedural Background[2]

In 2009, Plaintiff/Relator Anthony R. Spay filed under seal the instant qui tam action on behalf of the United States government, alleging violations of the Federal False Claims Act. In June 2011, the United States declined to intervene in this action. Thereafter, on August 5, 2011, Plaintiff filed the First Amended Complaint ("FAC") contending that six different practices by Defendants resulted in false claims being presented by Defendants to the Centers for Medicare

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they are necessary to eliminate an issue of fact or where the Court is quoting directly from a source. Where a fact is disputed, the Court will review the parties' referenced evidentiary submissions. If the dispute is not genuine and the alleged fact is clearly supported by the evidence, the Court will deem it established for purposes of summary judgment. If the dispute is genuine and not able to be resolved by reference to the cited evidence, the Court will not include the alleged fact in the statement of facts and will, instead, discuss the dispute as required by the legal issues in this matter.

Notably, the Court will not give consideration to arguments of relevance based purely on the fact that the citing party did not use the fact in its corresponding summary judgment motion. Rather, the Court resolves relevancy concerns as needed and disregards any fact that does not appear probative of the issues before the Court on summary judgment review. Moreover, with respect to the remaining evidentiary objections, the Court remains mindful that, in reviewing a motion for summary judgment, a court considers the non-moving party's *admissible* evidence. Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986). To be considered at this stage, the non-moving party's evidence need not be in a form that would be admissible at trial, but it must be evidence that could be later presented in a form that "would be admissible at trial" or reducible to admissible form. J.F. Feeser, Inc. v. Serv-A-Portion, Inc., 909 F.2d 1524, 1542 (3d Cir. 1990) (citing Williams v. Borough of West Chester, Pa., 891 F.2d 458, 466 n.12 (3d Cir. 1989)).

Finally, both parties' statements of fact and responses are replete with legal arguments, legal interpretations, and general statements best reserved for the legal discussion sections of their Motions and/or Responses. The Court does not address any such "allegations of fact" in this section.

[2] The Court uses the outline and headings adopted by Defendants in its Statement of Undisputed Facts as a framework for a review of the crucial facts in this case. Nonetheless, the Court has fully incorporated Plaintiff's Responses and Objections to Defendants' Statement of Facts and Plaintiff's own Statement of Undisputed Facts into this summary. The Court has also reviewed the parties' multiple other additions to their Statements of Facts and responses to the other party's statement of facts. Needless to say, given the thousands of allegations of "fact," the Court has had to pare down the allegations and list only the most important, relevant, and undisputed facts.

and Medicaid Services ("CMS") under the Medicare Part D Program.

Defendants filed a motion to dismiss on April 23, 2012, which the Court denied in its entirety. Fact discovery ran from March 13, 2013 until October 31, 2014, and expert discovery proceeded from November 1, 2014 to March 20, 2014, resulting in the production of over 1.4 million pages of documents, and the deposition of over thirty witnesses. Plaintiff now seeks damages and statutory penalties on behalf of the United States, including damages under the treble damages provision and civil penalty provision of the Federal False Claims Act.

B. The Parties

1. Plaintiff/Relator

Plaintiff Anthony R. Spay is a registered pharmacist (R.Ph) with approximately thirty-five years of diversified experience within the pharmacy industry. He is not only a licensed pharmacist, but has also been involved with pharmacy management, benefits management, long-term care, behavioral health, executive management, prescription drug fraud/abuse detection, auditing, and recovery for many of the nation's largest payers and pharmacy claims processors. In 1992, Plaintiff founded Pharm/DUR, Inc. ("Pharm/DUR"), which was an auditing company that performed principally retail pharmacy audits in the form of both desk audits and in-store audits.

For a desk audit, the company would send out letters to pharmacies for around twenty claims and request a copy of the prescription and signature log. A team would then go over the prescription and signature log for any discrepancies that were specified by each client, and Pharm/DUR would send out a letter to the pharmacy with the discrepancies found. The pharmacy would have thirty days to respond with any documentation, which would then be re-

reviewed by Pharm/DUR for any remaining discrepancies. (Defs.' Mot. Summ. J., Ex. 11, Dep. of Claire Briggs ("Briggs Dep."), 25:23–26:20, April 15, 2014.) For in-store audits, Pharm/DUR would send a letter out to the pharmacy indicating the date it planned to visit, and would conduct the audit in the store, looking at copies of prescriptions and signature logs for about 200 claims. Any suspicious claims would be scanned into Pharm/DUR's system for a review team to look over, and a letter would be sent to the pharmacy listing any remaining discrepancies. The pharmacy then had thirty days to respond with documentation and, following several back and forth exchanges, a final list of discrepancies would be generated. (Id. at 26:21–28:11.) Audits were done on contingency fee, flat fee, or yearly rate bases, but the majority were contingency fee based. (Id. at 29:21–30:9.)

The Medicare Part D program began on January 1, 2006. In 2006, Medical Card System, Inc. ("MCS"), a large health administration and health insurance company in Puerto Rico, hired Pharm/DUR, on a contingency fee basis, to conduct an audit of the Medicare Part D pharmacy benefit manager ("PBM") and other services that Defendant SilverScript, LLC, or its affiliates, provided. Pharm/DUR audited MCS's paid pharmacy claims data for claims adjudicated by SilverScript between January 1, 2006 and December 31, 2006. Some of the claims in this case are identical to the findings Pharm/DUR made in its audit on behalf of MCS.

Xerox is the successor to Pharm/DUR. Pharm/DUR was acquired by Affiliated Computer Services ("ACS") in July of 2009 and, in February of 2010, ACS was acquired by Xerox. As a result of these acquisitions, Pharm/DUR was no longer in existence at the time of the corporate designee depositions in this case. Nonetheless, both corporate designees—Claire Briggs and Kelly O'Brien—were former Pharm/DUR employees.

2. Defendants

In 2006–2007, Defendant Caremark Rx LLC was one of the largest pharmacy benefit managers ("PBMs") in the United States. On March 22, 2007, Caremark Rx LLC merged with CVS Corporation to form Defendant CVS Caremark Corporation. The Defendants are various subsidiaries of Defendant CVS Caremark Corporation ("CVS Caremark"). Since January 1, 2006, a number of different subsidiaries of Caremark Rx LLC (and, as of March 22, 2007, of CVS Caremark), including Defendant Silverscript, LLC ("Silverscript"), have provided PBM services to various types of clients. In the 2006 to 2007 time period, Defendant SilverScript contracted with thirty-nine Sponsors to provide PBM services and those Sponsors entered into eighty-five different Part D contracts with the Centers for Medicare and Medicaid Services to offer Part D plans. Defendants generated 114,125,392 unique prescription drug event ("PDE") records for their Part D Sponsor-clients in 2006–2007.

C. The Drug-Delivery System Generally[3]

1. Drug-Dispensing Process

Generally, pharmacists are licensed under state law to dispense prescription medications. While the requirements for the contents of prescriptions for pharmaceuticals vary from state to state, such prescriptions generally detail the name of the patient, date of birth, address, name of the drug, dosage form, strength, quantity to dispense, dosing instructions, and refill information. State laws define what constitutes a valid prescription, although federal law and regulations impact prescriptions for controlled substances. See 21 U.S.C. § 829. Pharmacists bear

[3] The parties are in decided disagreement as to this process, with each side offering an expert report to bolster their position. In the interest of not deciding issues of material fact, the Court sets forth a basic and general description of this system.

responsibility under state law for validating a prescription to ensure that it is written by an authorized provider.

Since the 1990s, most state pharmacy codes have required pharmacists to perform concurrent drug utilization review ("DUR") prior to dispensing any prescription drug, although pharmacists do not alone have this responsibility. DUR is a process by which a patient's prescribed drug therapy is evaluated for safety and appropriateness. DUR can take several forms: (1) the pharmacist makes his or her own personal consideration of the prescribed therapy for the patient; (2) electronic edits supplied by a pharmacy's own DUR software supplement a pharmacist's manually-performed DUR; and (3) electronic edits supplied by a PBM supplement the pharmacist's manually-performed DUR. Once the pharmacist determines that the medication is safe to dispense, he or she physically prepares the prescription by selecting the product, checking the expiration date on the packaging, counting the number of dosage units needed to fill the order, and placing the counted medication into a prescription vial. The pharmacist then performs a final check of the prescription, counsels the patient when appropriate, and records the dispensing transaction.

2. Claims Adjudication

Although there is no single uniform process for filling prescription drugs under an insurance plan, a common method is that the pharmacist submits certain information about the patient and the prescription—the "pharmacy claim"—to the insurer for a coverage and payment determination via a process called "claims adjudication." If a patient has no insurance or otherwise opts to pay for the entire cost of the prescription out-of-pocket, a pharmacy claim might not be submitted for adjudication.

In 2006–2007, all electronic claims were submitted by pharmacies for adjudication using the HIPAA-mandated National Counsel for Prescription Drug Programs ("NCPDP"). Some data fields on the NCPDP Version 5.1 pharmacy claim were mandatory, meaning that the claim would be rejected if the field was not populated with a properly-formatted value. Other fields were optional.

Generally, the pharmacy initiates the adjudication process by submitting the pharmacy claim to an online platform called an "adjudication platform." Adjudication platforms are generally operated by third-party administrators, such as PBMs, who handle claims processing on behalf of payers. Although not uniform among platforms, the adjudication platform typically performs a series of checks on the pharmacy claim to verify that all mandatory fields are populated and/or conform to certain formatting requirements, determines the eligibility of the patient, confirms that the drug is covered by the plan's formulary and that the prescription complies with the plan's benefit design, determines whether a prior authorization is necessary, and determines if the prescription complies with the plan's benefit design. The claims adjudication platform also performs concurrent DUR and may apply a set of DUR "edits" to the pharmacy claim information (such as patient or drug information). The adjudication platform further calculates the patient's deductible or co-pay, calculates the reimbursement to the pharmacy, and transmits a response to the pharmacy that includes either a payable or rejected claim code.

These processes take place virtually instantaneously, and the average Version 5.1 pharmacy claims transaction is completed within five seconds, letting the pharmacy know whether the claim was approved or rejected. Although not uniform, an "accepted" response

generally notifies the pharmacy both that the insurer will subsidize the prescription and what the amount of the beneficiary's out-of-pocket costs are. A "rejected" response will notify the pharmacy that insurance will not pay, and will also include a code indicating why the claim is rejected. These "accepted" or "rejected" codes were not necessarily the sole communications between a pharmacy and a PBM/Payer regarding a pharmacy claim.

In 2006–2007, Caremark operated three claims adjudication platforms: Quantum Leap ("QL"), RxClaim, and RECAP. The RxClaim platform hosted the majority of Part D Sponsors for which Caremark served as PBM. Caremark's adjudication platforms were responsible for, among other things, adjudication of pharmacy claims submitted by pharmacies on behalf of Part D enrollees in plans assigned to the platform. The platforms also generated the PDE records for approved Part D claims. In 2006 and 2007, pharmacy claims submitted electronically to a PBM or Payer were required by the federal HIPAA statute to follow a standard format, known as the NCPDP Telecommunication Standard Version 5.1, which contained more than 150 fields of information.

D. The Medicare Part D Program

1. Statutory History and Policies

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 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 is 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. Sponsors must hold licenses issued by state insurance regulators. 42 U.S.C. § 1395w-112(a)(1). The Part D plan Sponsor must provide qualified prescription drug coverage, including "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 cover certain drugs that would qualify as covered Part D drugs if they are 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). CMS contracts only with Sponsors to administer the Part D benefit; healthcare providers do not bill the government directly for services provided to Part D beneficiaries. 42 U.S.C. § 1395w–12(b)(1).

Part D plan Sponsors subcontract with many "first-tier 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. A first-tier entity is defined as "any party that enters into a written arrangement, acceptable to CMS, with a Part D plan Sponsor or applicant to provide administrative services or health care services for a Medicare-eligible individual under Part D." 42 C.F.R. § 423.501. 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) (emphasis added). 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 the data 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).

Notably, first-tier entities may subcontract with "downstream entities" to perform functions on behalf of the Sponsor. A "downstream entity" is defined as "any party that enters into a written arrangement, acceptable to CMS, *below* the level of arrangement between a Part D plan Sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services." 42 C.F.R. § 423.501. Pharmacies and pharmacists may be considered "downstream entities" if they enter into a written arrangement that complies with the foregoing definition. CMS "defer[s] to existing authority for regulating pharmacy practice" and "plans must provide [CMS] with representation that their network providers are required to comply with minimum standards for pharmacy practice established by the states' Medicare Program; Medicare Prescription Drug Benefit." 70 Fed. Reg. 4194, 4278 (Jan. 28, 2005).

According to Tom Hutchinson, former Director of CMS's Medicare Plan Payment Group in 2006–2007, one of the overriding policy objectives of Part D was "ensuring that beneficiaries got access to the drugs that they were entitled to." (Defs.' Mot. Summ. J., Ex. 1, Dep. of Tom Hutchinson ("Hutchinson Dep."), 14:16–23, 22:14–27, Oct. 17, 2014.) Tracey McCutcheon, Deputy Director of the Medicare Drug Benefit Group in 2006–2007, expounded on that point, noting that having Sponsors provide benefits to enrollees remained a top priority. (Defs.' Mot.

Summ. J., Ex. 2, Dep. of Tracey McCutcheon ("McCutcheon Dep."), 17:13–18:4, 35:4–16, 61:2–6, Oct. 22, 2014.) CMS was also concerned with accurately compensating Part D Sponsors for the costs incurred in providing the Part D benefit to enrollees in their plans. CMS's ability to do so depended upon the truth, accuracy, and completeness of the claims for payments submitted to the Part D Program.

2. Payment Structure and PDE Records Generally

A Part D Sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. 42 C.F.R. § 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. Id. § 423.293.

At the end of each year, CMS conducts a retrospective review of each plan's actual expenses relative to the costs estimated in the plan's approved bid. This process is known as "reconciliation." During reconciliation, CMS compares the finalized prospective payments for the direct, low-income, and reinsurance subsidies with the plan's actual costs as reported on the PDEs. Based on the year-end reconciliation, and under the "risk-sharing" aspect of the Part D program, the plan either can receive additional government payments to make up a portion of

costs that exceeded those on which its bid and the government's resulting prospective payments were based, or may have to repay to the government a portion of any revenue in excess of its estimated costs and targeted profits.

The Final Part D Rules' preamble indicates that CMS requires the submission of four categories of data for 100 percent of the prescription drug clams in order to administer the Part D risk adjustment process and to calculate reinsurance and risk-sharing payments: (1) beneficiary identification; (2) prescription identification information; (3) cost information; and (4) payment information. 70 Fed. Reg. 4194, 4307. In 2005, CMS announced the Prescription Drug Event ("PDE") record, a creation of the Part D Program. The PDE record signifies that a pharmacy claim was paid, and is not generated for a claim for which payment was rejected by the Sponsor. 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 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. Thirty-four of the thirty-seven PDE data fields are mandatory for standard (*i.e.*, electronic) claims. CMS uses the data in the PDE claims to assist in performing the year-end reconciliation and determining the level of cost-sharing between the beneficiary, the plan, and CMS. Some of the data elements, however, such as pharmacy and prescriber identifiers, were to be used for validation of the claims, as well as for other legislated functions, such as quality. (Decl. of Marc Raspanti ("Raspanti Decl."), Ex.5-20–21.)

The Part D Program requires Sponsors (or their agents) to submit to CMS a PDE record for 100% of the prescriptions dispensed to a Part D beneficiary. 70 Fed Reg. at 4307. In 2006–2007, plans submitted PDE data to the Prescription Drug Front-End System ("PDFS"), which performed format, integrity, and validity checks on the file and batch level records. (Defs.' Mot. Summ. J., Ex. 75.) PDFS performed limited edits on detail level records. (Id.) Once the file passed the PDFS front-end edits, PDFS forwarded the file to the Drug Data Processing System ("DDPS") at CMS, which edited the detail level records for format, integrity, and validity before storing the data for future payment calculation. (Id.) After applying the edits, the DDPS designated each PDE as accepted ("ACC"), rejected ("REJ"), or informational ("INF"). CMS used automated systems to review incoming PDE submissions in 2006–2007, as it did not have the personnel necessary to manually review every data field in each of the millions of PDE records submitted in 2006–2007. CMS considered only PDEs with an ACC or INF status when performing its year-end reconciliation process, while those with an REJ status were not included in reconciliation and the information was not stored. After processing the PDE claim, DDPS would automatically send a "DDPS Return File" to the plan or designee that submitted the PDE.

The 2006 PDE Instructions were enforced by CMS in 2006 and 2007 and indicated that its "requirements apply to all Part D plans as defined in 423.301 unless separate instructions are issued." (Raspanti Decl., Ex. 5-20.) These instructions stated that "[a]s 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 described how CMS would implement the statutory payment mechanisms by collecting a limited

subset of data elements on 100 percent of prescription drug "claims" or "events." (Id.) The April 2006 PDE Instructions required that "[e]very 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." (Id. at 21.)

In 2006 and 2007, CMS's DDPS would reject individual PDE claims for a variety of reasons known as "error codes," all of which were listed in CMS's written guidance. For rejected PDE claims, CMS's DDPS Return File would indicate an "Error Code" describing the reason that the PDE claim was rejected by CMS. Plans or their designees had the opportunity to resubmit rejected PDE claims with the information necessary to resolve the applicable error code or codes. CMS also assumed some responsibility for correcting certain errors.

3. The Prescriber ID and Prescriber ID Qualifier Fields

The PDE's Prescriber ID and Prescriber ID Qualifier fields were taken from the NCPDP Version 5.1 Telecommunication Standard (*i.e.*, the pharmacy claim). The Prescriber ID and Prescriber ID Qualifier fields were mandatory in the 2006–2007 PDE layout for all PDEs reporting standard pharmacy claims. On standard PDEs, the DDPS would reject any PDE on which either the Prescriber ID or Prescriber ID Qualifier was blank, or on which the Prescriber ID Qualifier did not contain one of four specified values. As designed, the specified values for the Prescriber ID Qualifier were "01," signifying the National Provider Identifier ("NPI"), "06," signifying the Universal Provider Identification Number ("UPIN"), "08," signifying the state license number, or "12," signifying the DEA number. The value populating the prescriber ID field would follow the qualifier (*i.e.*, an NPI, UPIN, state license number, or DEA number). Thus, the PDE's layout accepted one of four compatible forms of prescriber ID.

In January 2004, CMS published a rule establishing the standard for a unique health identifier for health care providers for use in the health care system and announced the adoption of the National Provider Identifier (NPI) as that standard. 69 Fed. Reg 3434, 3434 (Jan. 23, 2004). The 2006 PDE Instructions stated, under "Prescriber ID," that "[t]his field will contain the prescriber's unique identification number." (Raspanti Decl., Ex. 5-28.) CMS repeated this mandate for a prescriber's "unique identification number" in several subsequent documents issued in 2006 and 2007. (Raspanti Decl., Ex. 5-2, 13; Raspanti Decl., Ex. 8-232.) All acceptable numbers are a nine-character alphanumeric combination of two letters and seven numbers.

In 2006–2007, few prescribers used the NPI since there was no universal form of Prescriber ID issued to all prescribers in the United States. The NCPDP Version 5.1 Telecommunication Standard accepted up to fifteen different types of identifiers, including "Plan-Specific" and "Other." Many PBMs' and claims processors' claims adjudication technology could not screen out dummy prescriber IDs submitted by pharmacies. (Defs.' Mot. Summ. J., Ex. 5, Report of Annette Gabel ("Gabel Rep."), ¶¶ 66–67, 70.) It is unclear, however, whether Defendants' own claims adjudication systems were capable of screening out dummy prescriber IDs. (Compare Raspanti Decl., Ex.2-62–63, Expert Report of Dr. Craig Stern ("Stern Rep.") with Defs.' Mot. Summ. J., Ex. 80, at SPCM00762839.) On that point, the parties present competing evidence as to whether, in 2006–2007, there was a comprehensive, reliable database of prescriber IDs, the absence of which prevented claims processors from designing systems that could ensure that prescriber ID values submitted on pharmacy claims were unique numbers.

E. State Pharmacy Laws/Practice

As a general rule, state boards of pharmacy issue licenses and promulgate regulations, rules, and procedures governing the practice of pharmacy. (Defs.' Mot. Summ. J., Ex. 6, Report of Edward McGinley ("McGinley Rep."), 4.) CMS recognized that, before the Part D Program, almost all of the state boards of pharmacy had adopted regulations for pharmacy practice that generally had minimum requirements for DUR, patient counseling, and patient record-keeping. 70 Fed. Reg. 4194-01, 4278. Many, but not all, of these state pharmacy laws defined concurrent DUR procedures, set minimum standards for a pharmacist's performance of DUR, and required that a pharmacist perform DUR in accordance with those standards prior to dispensing a newly prescribed drug. These standards, however, varied from state-to-state and were not related to whether a claim for that prescription was ultimately submitted to a third-party payer. Many pharmacies maintained computer systems to store patient data and perform a series of electronic concurrent DUR edits to assist the pharmacist, but there was no clear uniform practice by all pharmacies across the United States.

F. Caremark's Part D PBM Services

1. Services Generally

Caremark offers a range of PBM services, including, but not limited to, pharmacy network management, plan design and administration, formulary management, and claims processing. A PBM is defined as:

> An entity that provides pharmacy benefit management services, including contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization review; and operating disease management

> programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies.

(Defs.' Mot. Summ. J., Ex. 81, at 6.) As part of its PBM services, Caremark created and managed a network of approximately 60,000 participating pharmacies, including retail CVS pharmacy stores, an on-line pharmacy at CVS.com, and mail order and speciality pharmacies.

2. Contracts with Part D Sponsors

Caremark has both commercial clients and Medicare Part D Sponsor-clients that contract to receive its PBM services. Caremark executed a contract with each of its Part D Sponsor-clients, which identifies the scope of the services that Caremark undertook, as well as the fees it received in compensation for those services. According to the twenty contracts Caremark produced in discovery, Sponsors compensated Caremark for performing a number of different services on a "per-member, per month" ("PMPM") basis. (Defs.' Mot. Summ. J., Exs. 30–64.) A PMPM fee is a fee based on the number of members enrolled in plan per month, without regard to the number of claims submitted by the enrollee or approved for payment by the PBM. Each fee schedule in the twenty identified contracts contains a "Core Administrative Services Package," which is associated with a PMPM fee compensating Caremark for between seven and twelve different services—which vary by contract—including, but not limited to, formulary development and pharmacy and therapeutics ("P&T") oversight, pharmacy network contracting and maintenance, accreditation, providing access to proprietary analytic tools, providing access to claims data to support actuarial equivalence, submitting beneficiary enrollment, providing claims data to support client actuaries to certify creditable coverage status, mailing letters of creditable coverage to each beneficiary annually, submitting electronic claims for year-end

reconciliation, supporting CMS's queries and audits, providing a Medicare account services team, providing e-prescribing services, providing a call center, and providing a CMS-ready standard reporting package. (Id.)

During all or part of the years 2006 and 2007, Defendants served as a PBM for thirty-nine different Part D Sponsors, including: American Health, Amerigroup of Texas, Arcadian Health Plan, Arta Medicare Healthplan, BCBC of South Carolina, BCBC of Tennessee, BlueChoice of South Carolina (Companion Healthcare), Capital District Physicians HP (CDPHP), Capital Health Plan (CHP), Care Improvement Associates (CIP) XL Health, Colorado Access, Coventry First Health, Denver Health Medical Plan, Empire Health Choice Assurance, Fidelis Care New York (Catholic Health Plan), Fidelis Senior Care, Inc., First Medical Comprehensive Health, Fox Systems, Harris Corporation, Horizon (BCBS of NJ), IBC Amerihealth Ins., IBC QCC Insurance, Itasca Medical Care (IMCARE), MAPRE Life Insurance Co., Marion Polk Community Health Plan, Medical Card Systems, Inc. (MCS), Mercy Health Plan, Metropolitan Health Plan, Mount Carmel Health Plan, Neighborhood Health Plan, New West Health Services, OSF Health Plans, Inc., SilverScript Insurance Co., Sterling Life Insurance, Tufts Health Plan, Vantage Health Plans, Inc., and Viva Health, Inc. As noted above, SilverScript is an indirect subsidiary of Defendant CVS Caremark Corporation. In 2006 and 2007, all of Defendants' Part D PBM services were provided pursuant to contracts with Part D Sponsors.

3. Contracts with Network Pharmacies

A pharmacy contracts with Caremark to participate in Caremark's pharmacy network. Caremark incorporated into its contracts with network pharmacies a "Provider Manual" containing various policies and procedures. (Defs.' Mot. Summ. J., Exs. 69, 71.) In 2004,

Caremark issued a Provider Manual which was in effect for its network pharmacies through 2006. (Defs.' Mot. Summ. J, Ex. 69.) The Provider Manual's terms and conditions were incorporated into the pharmacy's (provider's) larger contract with Caremark, *i.e.*, the Provider Agreement. (Id. at SPCM00283797.) The Provider Manual required network pharmacies to comply with applicable federal and state law. (Id. at SPCM00283799, SPCM00283801, SPCM00283845, SPCM00283847.) Identical provisions appear in Caremark's 2007 Provider Manual. (Defs.' Mot. Summ. J., Ex. 71, at SPCM00389406, SPM00389409, SPCM00389445.)

Several months before January 1, 2006, Caremark issued a Medicare Part D Addendum to the Caremark Provider Agreement and Provider Manual "[i]n order to meet regulatory requirements" and "includ[ed] provisions required by the Part D regulations." (Defs.' Mot. Summ. J., Ex. 70, at SPCM00309194.) A pharmacy could participate in Caremark's Medicare Part D Pharmacy Network by agreeing to the terms and conditions of the Part D Addendum. (Id.) Caremark's Provider Manuals stated that "[e]ach claim submitted by Provider will constitute a representation by the Provider to Caremark that . . . the information transmitted is accurate and complete." (Defs.' Mot. Summ. J., Ex. 69, at SPCM00283803; Defs.' Mot. Summ. J., Ex. 71, at SPCM00389410.) Among other things, the Part D Addendum required the providers to "implement such utilization management and quality assurance programs, including drug utilization review, generic substitution and/or therapeutic interchange programs, as Caremark may require, and as consistent with and in compliance with 42 C.F.R. § 423.153(b), (c), and (d) . . . ." (Defs.' Mot. Summ. J., Ex. 70, at SPCM00309195.) Caremark maintained an auditing department for the purpose of auditing pharmacies for compliance with the Provider Manual's terms. (Defs.' Mot. Summ. J., Ex. 16, Dep. of Patrick Jeswald ("Jeswald Dep."),

22:20–24:16, 70:21–72:14, 77:22–78:17, July 2, 2014.)

G. The Pharm/DUR Pharmacy Claims Audit

Effective January 1, 2006, Caremark contracted with Sponsor Medical Card System, Inc. ("MCS") to provide Medicare Part D PBM services to MCS's health insurance plans. The MCS-Silverscript PBM Agreement was in effect from January 1, 2006 until December 31, 2007, when Catalyst Rx took over as PBM for MCS's Medicare Part D Program. On January 1, 2006, the Part D Program went into effect for enrollees and started providing prescription drug coverage. 42 U.S.C. § 1395-w-101(a)(2). Under the MCS-SilverScript Agreement, MCS compensated SilverScript for numerous services pursuant to a fee schedule and Caremark received per-member, per-month fees regardless of the number of claims, as well as an administrative fee per paid retail or mail claim. Defendants processed Medicare Part D claims for MCS plans on Defendants' QL adjudication platform during 2006, but in 2007, Defendants moved the MCS Part D plans to their RxClaim platform.

In February 2007, MCS retained Plaintiff's company, Pharm/DUR, to perform, in part, an audit of its Part D pharmacy claims processed by Caremark during calendar year 2006 (the "Pharm/DUR Audit"). Caremark was aware, as of February 16, 2007, that Pharm/DUR was hired by MCS to conduct a comprehensive audit program entailing retail on-site and desk audits. In 2006, MCS compensated Caremark for 1.7 million prescriptions and, in 2007, MCS compensated Caremark for 3.1 million prescriptions. (Decl. of Paul Traina ("Traina Decl."), Ex. 135, Dep. of Carolyn Rodriguez ("Rodriguez Dep.") 664:2–665:24, May 14, 2014.) Pharm/DUR performed the MCS audit on a 35% contingency fee basis, meaning MCS would pay Pharm/DUR 35% of the amount recovered by MCS from Defendants as a result of the PBM

audit.

The Pharm/DUR Audit reviewed only paid pharmacy claims data where Caremark adjudicated the claims and determined they should be paid under the Part D program, not where pharmacy claims were denied by Caremark. Five documents were generated in relation to the Pharm/DUR Audit: (1) Pharm/DUR's Initial Report (July 11, 2007); (2) Caremark's Initial Response (Aug. 9, 2007); (3) Pharm/DUR's Amended Report (Sept. 6, 2007); (4) Caremark's Final Response (Dec. 6, 2007); and (5) MCS's Updated Audit Response (Sept. 30, 2008). (Defs.' Mot. Summ. J., Exs. 25–29.) In July 2008, MCS terminated its relationship with Plaintiff and Pharm/DUR and used a different auditing firm to conduct subsequent PBM audits. (Defs.' Mot. Summ. J., Ex. 10, Rule 30(b)(6) Dep. of MCS Rep. Carolyn Rodriguez ("Rodriguez Dep.") 84:18–23, May 14, 2014.) Notably, Plaintiff was unaware of MCS's Updated Audit Response until May 2014, during discovery in this case.

Six different issues were discussed in the Pharm/DUR Audit: (1) prior authorizations; (2) quantity limits; (3) maximum allowable cost ("MAC") pricing; (4) use of "dummy"/"push" prescriber ID numbers; (5) obsolete National Drug Codes ("NDCs"); and (6) gender-specific deviations.

1. Prior Authorizations

In its Initial Report of July 11, 2007, Pharm/DUR indicated that there was no "MCS intervention to preauthorized payment" for 819 "Tier 2" Formulary claims and 14,840 "Tier 4" Formulary claims, in a total amount of $2,857,529.52. (Defs.' Mot. Summ. J., Ex. 25, at SPCM00089904-5.) Caremark responded as follows:

[Caremark] responded to 510 (over sixty percent) of the Tier 2 discrepancies and

noted the following:

- Three Hundred Twenty Five (325) of the samples determined the plan did not require a prior authorization.
- One hundred seventy (170) of the samples indicate a prior authorization was obtained for the drug.
- Fifteen (15) of the samples were filled under a transition plan which has no prior authorization limits.

These edits are in place for Tier 2 and Tier 4 drugs. [Caremark] will provide the sample responses and support under separate cover. It is our view that we are in compliance with the plan design, these claims adjudicated correctly and there is [sic] no material financial discrepancies related to this finding.

(Defs.' Mot. Summ. J., Ex. 26, at SPCM00165178.) Caremark provided no comment as to any of the Tier 4 claims.

Pharm/DUR's Rule 30(b)(6) representative testified that Caremark's Initial Response was correct with respect to the 170 claims that had received prior authorization from MCS and the 15 claims filled under a transition plan. When MCS and Pharm/DUR issued the Amended Report in September 2007, it verified Caremark's response and removed the 170 claims that had received prior authorization and the 15 claims filled under beneficiaries' transition plans, thereby reducing the Tier 2 prior authorization finding from 819 claims to 633 claims. The Amended Report did not address any of the Tier 4 prior authorization findings.

Caremark's final response reviewed 571 of the 633 Tier 2 claims cited in MCS's and Pharm/DUR's Amended Report and concluded that there were no financial discrepancies related to this finding. (Defs.' Mot. Summ. J., Ex. 28, at SPCM00225809.) MCS sent Caremark a Final Report on September 30, 2008 confirming that MCS had authorized payment for all but eighty-seven Tier 2 claims, and asking Caremark for further information about those claims. (Defs.' Mot. Summ. J., Ex. 29, at MCS-000056325.) No further information was exchanged on these claims and MCS did not seek payment or recoupment relating to the prior authorization issue.

2. Quantity Limits

According to the Initial Audit Report, issued jointly by Pharm/DUR and MCS, Caremark erroneously adjudicated 14,886 pharmacy claims for Tier 2 and Tier 4 drugs in which a specified quantity limit was exceeded. The claimed amount owed to MCS was $1,263,188.66. Caremark responded that it checked approximately 60% (450) of the cited Tier 2 claims and concluded that quantity limits had not been exceeded because ninety-day supplies were allowed. In the Amended Audit Report, Pharm/DUR admitted that it made a data processing error and its original finding had erroneously included three particular drugs in the Tier 2 report. After removing those drugs, there were no remaining discrepant claims in the Tier 2 category. Pharm/DUR also reissued its Tier 4 finding, dropping the cited discrepancies from 14,109 claims to 1,875 claims.

In its Final Response, Caremark responded to 1221, or 65%, of the quantity limit/days supply Tier 4 discrepancies and noted that (1) 1,106 of the samples passed the therapy protocol which limits the amount of a specific medication to be taken in a particular time frame; (2) seventy-seven of the samples were filled under a transition plan which had no quantity/days supply limits; and (3) thirty-eight of the samples indicated a prior authorization was obtained for the drug. As such, Caremark stated its belief that the claims were being adjudicated accurately. (Defs.' Mot. Summ. J., Ex. 28, at SPCM00225810.) Pharm/DUR's Rule 30(b)(6) designee acknowledged that Pharm/DUR had no reason to doubt that Caremark's information was correct. (Defs.' Mot. Summ. J., Ex. 12, Pharm/DUR 30(b)(6) Dep. Kelly O'Brien ("O'Brien Dep."), 88:4-15, Apr. 15, 2014.) Thereafter, in its Final Updated Audit Response, MCS did an internal validation of most of the Tier 4 revised claim of 1,875 and removed a total of 1,115 claims, but

requested that Caremark validate the remaining 760 claims, with a total paid amount of $93,851.02, and provide a response and support documentation. (Defs.' Mot. Summ. J., Ex. 29, MCS-000056326–27.) No further documentation was exchanged on these remaining claims. MCS sought recoupment related to the quantity limits issues through November 2007, but did not pursue the issue after December 2008. (Rodriguez Dep. 78:2–79:22.)

3. Maximum Allowable Cost ("MAC") Pricing

In its Initial Report, Pharm/DUR claimed that Caremark failed to provide MCS the benefit of maximum allowable cost ("MAC") pricing for 33,400 paid pharmacy claims. Pharm/DUR valued the finding at $704,392.08 owed to MCS. Caremark's Initial Response stated that "Pharm/DUR utilized the MAC list provided by MCS to perform their analysis, not the Caremark MAC list. Additionally, drugs are frequently added and removed from the MAC list." (Defs.' Mot. Summ. J., Ex. 26, at SPCM00165796.) Caremark went on to note that although it was not provided claim level detail, a high level review of the discrepancies determined that 3,235, or 10%, of the samples were claims adjudicated at the Usual and Customary (U&C) amount. (Id. at SPCM00165797.) Plaintiff contends that Pharm/DUR provided Caremark with sufficient detail for Caremark to analyze its audit finding on MAC prices. (Traina Decl., Ex. 45, at SPCM00002335.)

On April 20, 2007, counsel for Defendants provided the SilverScript Part D MAC list to MCS who, in turn, provided it to Pharm/DUR. Thereafter, in its Amended Report, Pharm/DUR reprocessed its MAC findings and reduced the claimed discrepancies by 89%, from 33,400 claims (for $704,392.08) to 3,658 claims (for $101,141.80). In its Final Audit Response, Caremark reviewed the top 25 NDCs involved in the 3,658 claims and concluded that the

company had charged MCS the appropriate price. In its Final Updated Audit Report, MCS stated the following regarding the MAC issue: "MCS will not pursue further action related to this finding" and it considered the issue "closed." (Defs.' Mot. Summ. J., Ex. 29, at MCS-000056319–330.) Based on the testimony of Pharm/DUR's Rule 30(b)(6) designee, Pharm/DUR miscalculated its MAC finding based on a truncation error from a missing digit in the prices on the MAC list. (O'Brien Dep. 101:1–106:24.) Plaintiff, Anthony Spay, indicated that the error resulted from Pharm/DUR "[leaving] off a couple of numbers before the decimal point." (Defs.' Mot. Summ. J., Ex. 14, Dep. of Anthony Spay ("Spay Dep."), 222:17–223:15.)

4. "Dummy"/"Push" Prescriber IDs

Pharm/DUR contended that Caremark had adjudicated 15,903 pharmacy claims with "fictitious physician identifiers," valuing the finding at $673,494.58. Caremark's response stated that "[a] DEA number is not required to adjudicate a claim, however, an identifier is required to verify who the MD is. The purpose of a DEA number is to allow a health care professional to prescribe or dispense controlled substances. Based on our review, there are no material financial discrepancies related to this finding." (Defs.' Mot. Summ. J., Ex. 28, at SPMCM00225807.) When Pharm/DUR indicated that Caremark's response did not adequately address the problem, Caremark provided an updated response noting that "[a]n edit to reject claims for an unidentified prescriber is not a system edit that [Caremark] provides to its customers. Nor is there a reliable and complete source for prescriber identification that would allow for this additional validation and not disrupt MCS members. . . . Because there is no expressed or implicit statement from [Caremark] to MCS that an edit for [an] invalid DEA number is part of our services, and there is not yet a reliable and complete database standard to properly identify all potential prescribers,

this $673,494.58 finding should be removed." (Id. at SPMCM 00225807–08.) MCS accepted Caremark's explanation and chose not to pursue further action on this finding. (Rodriguez Dep. 74:7–75:4,[4] Defs.' Mot. Summ. J., Ex. 29, at MCS-0000563232, MCS-0000565330.)

5. Obsolete NDCs

In its Initial Report, Pharm/DUR claimed that Caremark had adjudicated 11,286 pharmacy claims where the "HCFA expiration date" associated with the drug's National Drug Code ("NDC") was "outdated, stale, and/or obsolete." Pharm/DUR asserted that pharmacy claims involving such NDCs should be rejected, and valued the finding at $399,794 owed to MCS. Caremark's Initial Response stated that "[Caremark's] system does not indicate all NDC's in question are inactive. Importantly, an inactive NDC does not indicate a product has expired. [Caremark] was not provided fill dates for the 11,286 claims in question, making it difficult to determine if the claim was adjudicated prior to the HCFA expiration date." (Defs.' Mot. Summ. J., Ex. 26, at SPCM00165797.) Via its Updated Response, Caremark again indicated that it never received the fill date information for the claims in question and re-explained that an NDC that is inactive in the system does not necessarily mean that a product has expired. (Defs.' Mot. Summ. J., Ex. 28, at SPCMC005806.) In September 2008, MCS provided the fill dates for all of the claims, and asked Caremark to validate all those claims and verify if all the NDC's were

[4] Frequently, throughout his responses to Defendants' statement of undisputed facts, Plaintiff objects to Rule 30(b)(6) depositions on grounds that the deponent lacks personal knowledge to speak for the organization. This objection misunderstands the purpose of Rule 30(b)(6), which is "to create testimony that will bind the corporation." Resolution Tr. Corp. v. Farmer, No. Civ.A.92-3310, 1994 WL 317458, at *1 (E.D. Pa. June 24, 1994). Thus, the testimony of the Rule 30(b)(6) designee is deemed to the be testimony of the corporation itself and it is incumbent upon the designating corporation to identify a deponent with the requisite knowledge. State Farm Mut. Auto. Ins. Co. v. New Horizon, Inc., 250 F.R.D. 203, 212 (E.D. Pa. 2008).

outdated based on batch numbers supplied by manufacturers. (Defs.' Mot. Summ. J., Ex. 29, MCS-000056321.) No further information was exchanged on the issue, and, ultimately, MCS did not pursue a monetary resolution of the NDC audit issue with Caremark, purportedly because the issue simply got "lost in the process" after MCS changed PBMs as of the beginning of 2008. (Defs.' Mot. Summ. J., Ex. 10; Rodriguez Dep. 68:20–70:17.)

6. Gender-Specific Deviations

In its Initial Report, Pharm/DUR claimed that Caremark had approved payment of 507 pharmacy claims involving prescriptions for "Drugs Used Exclusively in Males that were processed for Females," "Drugs Used Exclusively in Females that were processed for Males," or "Drugs Most Likely Used in Females that were processed for Males." Pharm/DUR valued the finding at $53,608 owed to MCS and stated that Caremark "should have an edit in place that would reject the processing of this type of claim unless it is prior authorized." (Defs.' Mot. Summ. J., Ex. 25, at SPCM00089903.) In its Initial Response, Caremark noted that it was not aware of the condition in which the drug was prescribed, and remarked that a prescription "can have more than one common use." (Defs.' Mot. Summ. J., Ex. 26, at SPMC00165796.) It also indicated that the MCS plan design did not dictate that a prior authorization was required for gender-specific drugs. (Id.) In its Final Response, Caremark stated that "our system does not reject for drug/gender because there are certain circumstances and conditions that may warrant the prescription to be filled. Additionally, MCS did not request that a Prior Authorization take place on drugs that may be considered gender specific depending upon circumstances." (Defs.' Mot. Summ. J., Ex. 28, at SPCM00225804.) Notably, in 2006—the year that the pharmacy claims at issue were processed—Caremark indicated that a dedicated "drug-sex" edit was not

included in the QL adjudication platform's standard package of DUR safety edits and, thus, Caremark did not offer this edit to their Part D Sponsor clients. In its Final Updated Response, MCS stated that it would not pursue further action related to this finding. (Defs.' Mot. Summ. J, Ex. 29, at MCS-000056318.)

7. Conclusion of Pharm/DUR Claims Audit

MCS did not recover any money from Caremark based on the Pharm/DUR Audit. Likewise, Pharm/DUR and Plaintiff received no compensation from MCS for performing the audit. In late July 2008, Pharm/DUR received a cancellation notice from MCS.

Effective December 31, 2007, MCS terminated its contract with Caremark and hired a new PBM, Catalyst, for its Part D and commercial business effective January 1, 2008. MCS cited reasons such as service issues, discovery of overpayments in 2007, and concern about "Caremark's ability to administer [MCS's] pharmacy benefit." (Rodriguez Dep. 119:20–120:8, 829:15–831:19.) On August 31, 2007, Defendants notified MCS in writing that it was terminating their Part D PBM agreement. In 2007, MCS sued Caremark for breach of contract based on Caremark's premature termination of the contract. The suit was resolved a few months after filing, but the terms of the resolution are unknown.

In 2012, CMS re-opened both the 2006 and 2007 reconciliation process. CMS mandated that all Part D Sponsors who offered an active Part D plan in 2006 submit an "Attestation" to CMS by June 29, 2012, certifying, pursuant to 42 C.F.R. § 423.505(k)(3), that the PDE claims data submitted to, and accepted by, CMS for dates of service of January 1, 2006 to December 31, 2006, was accurate, complete, and truthful, and would be used for purpose of obtaining federal reimbursement. During that reopening, MCS submitted the required attestations of the PDE

claims that were the subject of that reopening. Defendants also produced the required attestations.

H. The Instant *Qui Tam* Lawsuit

The present lawsuit, commenced in 2009, alleges that Caremark violated the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1), (a)(2), and (a)(7). In connection with this action, the parties deposed, as fact witnesses, three current or former CMS officials pursuant to approved Touhy requests[5] and/or orders of this Court: Tom Hutchinson, Tracey McCutcheon, and Jeff Grant.[6] Mr. Hutchinson, deposed on October 17, 2014, is CMS's former Director of the Medicare Plan Payment Group. During the relevant time frame, Mr. Hutchinson led the CMS group "responsible for the payment policy and operations for the Part D plans." Tracey McCutcheon, deposed on October 22, 2014, is a current CMS official who, during the relevant time frame, was CMS's Deputy Director of the Medicare Drug Benefit Group. She led Medicare Part D policy development, including coordinating the development of the Part D regulations, and also took on an operational management role once the Part D program went live in 2006. Jeff Grant, deposed on October 30, 2014, is a senior technical advisor at CMS who, during the relevant time frame, was the Director of the CMS division responsible for processing PDE data and developing a system to run the Part D payment reconciliation process. He worked on the

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[5] In U.S. ex rel. Touhy v. Ragen, 340 U.S. 462 (1951), the United States Supreme Court held that, pursuant to a "housekeeping" statute, 5 U.S.C. § 301, a federal agency may promulgate regulations governing internal affairs and that an agency subordinate could not be held in contempt of court for failing to respond to a subpoena where a supervisor ordered him not to do so in accordance with a Department of Justice policy.

[6] Notably, many other fact witnesses were also deposed, but those depositions shall be introduced as necessary during the legal discussion of the case.

development of operational policies and operational processes to implement those operational policies. These witnesses testified only in their personal capacities and not on behalf of the Government or CMS.

CMS also obtained several expert witnesses. First, CMS retained CMS's former Acting Administrator, Leslie Norwalk. Ms. Norwalk is an attorney, served as CMS's Acting Administrator from October 2006 to July 2007, and served as CMS's Deputy Administrator for four years prior to October 2006. Second, CMS retained Michael Little, former Deputy Inspector General for Investigations within OIG. Third, Caremark designated Annette Gabel, a twenty-one year member of NCPDP, as an expert regarding the NCPDP Version 5.1 Telecommunication Standard, claims processing, and PBM industry practices in 2006–2007. Fourth, Caremark designated Ed McGinley, an executive committee member and President-Elect of the National Association of Boards of Pharmacy ("NABP") and member and former President of the New Jersey Board of Pharmacy, as an expert on the practice of pharmacy issues generally and issues related to Relator's dummy prescriber ID, gender DUR, and expired drugs claims. Fifth, Caremark retained Dr. Sharon Clackum, the current president of the American Society of Consultant Pharmacists, as an expert on the practice of geriatric pharmacy and issues related to Relator's dummy prescriber ID, gender DUR, and expired drugs claims. Finally, Caremark designated Dorothy DeAngelis, a senior managing director in FTI Consulting's Health Solutions Practice, as an expert on the Medicare Part D program, PDE data analysis, and damages.

Plaintiff, on the other hand, designated Mary Wickens, who has specialized in compliance with Medicare and other federal program rules for over thirty-five years. Plaintiff also designated as an expert Dr. Craig Stern, an individual who has spent over thirty years in the

pharmacy industry as director of a pharmacy, a pharmacy auditor, a pharmacist, and a professor. Third, Plaintiff designated William Mahno, who is an independent consultant specializing in health care fraud matters for over twenty-three years. Finally, Plaintiff retained as an expert Jade K. Roberts, who is a Senior Director of Analytic Products for Performant Financial Corporation, an entity which works with private and public payers to analyze data, including health care data claims.

The First Amended Complaint alleges six fraud theories that correspond to the six findings in Pharm/DUR's audit discussed above. The Court individually addresses some of the basic facts underlying each claim.[7]

1. The Dummy Prescriber ID Claim

A substantial portion of the claimed damages and penalties in this case concerns "dummy" prescriber IDs. Plaintiff's expert has identified fifty-six different numbers in the 2006–2007 PDE data generated by Caremark that pass the check-digit algorithm for a DEA number, but which are not unique identification numbers actually assigned to prescribers by the DEA. Out of Caremark's Total PDE Universe (more than 114 million PDEs), Plaintiff identified 2,348,308 PDEs (or 2%) containing one of those fifty-six dummy prescriber IDs.

In early 2006, a number of Caremark employees were important in Defendants' implementation of the Medicare Part D requirements and the resolution of foregoing issue. Lisa Colasacco described herself as an expert on PDE implementation information, the actual PDE file, and PDE transmission to CMS or the Part D Sponsor and, as such, Defendants drew upon

[7] At the risk of redundancy, the Court repeats some of these facts both in this section and the "Discussion" section of this Opinion. Given the length of the Opinion, such repetition was necessary for coherency and comprehensiveness.

her knowledge as the key implementation person for PDEs across all plans and all adjudication platforms. Ms. Colasacco's direct supervisor was Joseph Mulenex, who served as Director of both Eligibility and of Defendants' Electronic Data Delivery Department. He was responsible for the business requirements relating to outbound data for the Part D Program across Caremark's three adjudication platforms. He was described as a "subject matter expert on the submission of prescriber identifier data in the form of PDE submissions." (Raspanti Decl., Ex. 17-11 (Deposition of Dena Rus ("Rus Dep.")), 94:5–12.) From 2005 to 2013, Dena Rus was Defendants' Vice President of Medicare Program Service, the third-highest ranked CVS/Caremark employee with responsibility for Medicare Part D. David Carpenter was an independent contractor who worked on a PDE-related project at Caremark in 2006 and 2007. Finally, Dave Langowski worked in Defendants' IT department and assisted Mr. Carpenter in coding PDE.

In March 2006, Defendants' employees identified approximately 4,500 PDEs—authorized for payment by Caremark, but not yet submitted to CMS—that had "errored out" on the QL platform's pre-submission edits due to the lack of a PDE-compatible prescriber ID. (Raspanti Decl, Ex. 43-3–4.) As a solution to the problem, Caremark used a dummy prescriber identifier—the number AA0000000—in 4,500 PDEs in March 2006 and later programmed it into the QL system as part of the system's "chase" logic. More specifically, when there was any claim on which the underlying pharmacy claim either had no prescriber identifier or had a prescriber identifier that was not in a DEA number format, Defendants' QL adjudication platform was programmed to default populate the prescriber identifier field with the dummy DEA number. The other adjudication platforms—RxClaim and RECAP—only permitted

pharmacies, at the point-of-sale, to submit a prescriber ID that met the check-digit algorithm for a DEA number. QL also populated the Prescriber ID Qualifier with a "12," the qualifier for a DEA number, in certain circumstances. Independent contractor David Carpenter consulted Wikipedia to verify that the AA0000000 number would satisfy the "check-digit" algorithm for a DEA number.[8] The "check-digit" algorithm only ensures that the number is in the proper format, but does not ensure that the number is assigned to any unique prescriber. When Mr. Carpenter completed his verification, Mr. Mulenex approved the insertion of the dummy prescriber ID on the approximately 4,500 PDEs that had already been processed through Caremark's internal PDE edits and still had errors. (Raspanti Decl., Ex. 43-1–4.) Certain Caremark employees knowledgeable about PDE generation knew that CMS's system could not detect a non-unique prescriber ID. (Defs.' Resp. to Pl.'s Statement of Undisputed Facts in Opp. to Defs.' Mot. Summ. J. ¶ 66.) Defendants realized that the use of the dummy prescriber ID eliminated CMS error codes 623 and 624 from the PDE claims they generated on their QL platform for their Part D plan clients. In 2006 to 2007, Caremark generated, from pharmacy claims, PDE records containing fifty-six different dummy prescriber identifiers. None of the fifty-six dummy prescriber identifiers Caremark used on PDE claims in 2006 and 2007 uniquely identified any prescriber.

There is evidence that the use of dummy ID numbers by pharmacies was common both before and after Part D's implementation. Pharm/DUR's 30(b)(6) deponent testified that "push

[8] This algorithm works with the seven numbers in a DEA number as follows: (1) the first, third and fifth digits are added; (2) the second, fourth, and sixth digits are added; (3) the two sums are added to achieve a third sum; and (4) the rightmost digit of the third sum (the number in the ones place) should match the seventh digit of the DEA number. If it does not, the DEA number fails the "check digit algorithm" and is not in the proper format.

numbers," *i.e.*, dummy prescriber IDs, were used in the industry based on her prior experience as an employee of a claims processor, NPA, which instructed pharmacies to use the dummy numbers to adjudicate claims if they could not obtain a unique DEA number from a doctor. (Briggs Dep. 159:13–160:18.) Defendants' expert, Dorothy DeAngelis, opined that in 2007, 83% of all Sponsors participating in the Part D Program had PDE data containing many of the same dummy prescriber DEA numbers found in Caremark's PDE data in this case.

On July 15, 2010, the Federal Financial Management, Government Information, Federal Services, and International Security Subcommittee of the U.S. Senate Committee on Homeland Security and Governmental Affairs held a hearing on "Preventing and Recovering Medicare Payment Errors." Deborah Taylor, CMS's Chief Financial Officer and Director of the Office of Financial Management, and Robert Vito, Acting Assistant Inspector General for the OIG, testified as follows:

> Senator KLOBUCHAR. OK, Mr. Vito, in your testimony, you made recommendations to CMS for subjecting invalid identifiers to further review. It is alarming that just 10 invalid prescriber identifiers account for 17 percent of all the invalid prescriber identifiers. And when I saw this, I thought, shouldn't there be some kind of flagging system in place? And if so, can you describe how our recommendations would add to what is already in place?
>
> Mr. VITO. Well, I think the first thing is that CMS has determined that they want the beneficiaries to be able to get the prescriptions that they were given. So with that in mind, we understand the balancing act that they have to do. But we are suggesting that CMS start looking and doing work in this area to ensure that the claims that come in have valid IDs on them. In addition to that, we are saying that CMS should remind the sponsors or make the sponsors first identify all these invalid prescriber IDs and then review them to ensure that they do not keep coming up. When you see $100 million, $100 million as a regular doctor would cause people to be very concerned. It is just the volume of the claims. And the issue really is that you do not know if the claim is a good one or a bad one until you do more work. It could be that, they just put a number in and they are using that. But you will not know that until you actually go into doing all the work, going back into it and getting the

information. So for us, it is so much more valuable to prevent it up front and to stop it right at that time and make sure that the information is correct.

Senator KLOBUCHAR. That it is correct. And, Ms. Taylor, what do you think about his recommendations?

Ms. TAYLOR. We actually agree with all the OIG recommendations. We actually have looked at what is going on in 2009. We were troubled by seeing some entities with a preponderance of invalid numbers. We did have discussions with them. What we are seeing now is a trend that the pharmacies and the sponsors are using the National Provider Identifiers (NPIs). I think in the early days of the program there was confusion as to whether or not those numbers should be protected. And so, I think we have clarified that, but because they were DEA numbers, people thought they needed some privacy or protection to them. Some sponsors told us they just put in fictitious numbers rather than putting in the actual number. We told them they need to use the NPI. And we are starting to see about 75 percent of the claims now in the PDE database coming in with NPI numbers rather than, these DEA numbers.

Senator KLOBUCHAR. So do you think some of this is not really fraud, it is just them putting in any number? Is that what you are saying?

Ms. TAYLOR. We believe that may be part of the reason. They just put in a number rather than trying to look up for a valid number.

Senator KLOBUCHAR. Because they know they are going to get paid.

Ms. TAYLOR. Correct.

Senator KLOBUCHAR. Of course, that also leads to a lot of fraud, I would think.

Ms. TAYLOR. Right. I mean, so we have several efforts underway now. We are looking at what is going on in 2009. We are going to validate those NPI numbers. We do want to understand if there is a systemic reason for why they cannot get to a valid number. If there is a problem with systems or look-up tables, we need to work on that. But we also want to and have started dialogue with those who seem to be not following our guidance, and we will be discussing that and telling them to cease and desist, that they need to do actual look-ups for valid numbers on the PDE claims.

(Defs.' Mot. Summ. J., Ex. 104, 15–16.)

Within a month of the Senate hearing, CMS issued a memorandum, clarifying that, while it still permitted Sponsors to submit alternative identifiers when an NPI could not be obtained at

the point of sale, "it has always been our intention that whatever type of prescriber identifier . . . is used, it must be a valid number." (Defs.' Mot. Summ. J., Ex. 105, at 1.)

2. The Gender DUR Claim

The First Amended Complaint also alleges that, in order to comply with 42 C.F.R. § 423.153(c)(2)(ii), Caremark was obliged to utilize a "drug-sex edit[]" during its claims adjudication process. (First Am. Compl. ¶ 294). It goes on to assert that Caremark's "nationwide [adjudication] system is intentionally designed not to conduct concurrent DUR for gender contraindications (will not deny claims based on drug-sex edits)." (Id.) An "edit" is an electronic check that utilizes clinical data files purchased from third-parties to compare a prescription against information known about the patient's medical history and the drug being prescribed. A "hard edit" is an edit that triggers rejection of the claim and means that the pharmacy would not receive authorization to dispense the drug without additional necessary information. A "soft edit," on the other hand, supplies an informational alert to the pharmacist, but will not block payment of the claim and will allow the pharmacy to dispense the medication without further authorization from the PBM.

The Medicare Part D regulations expressly mandate that Part D Sponsors must have "[c]oncurrent drug utilization systems, polices and procedures" that include, in part, a review for "[a]ge/gender-related contraindications." 42 C.F.R. § 423.153(c)(2). The Part D Final Rule describes concurrent DUR as one of a number of "quality assurance measures and systems to reduce medication errors and adverse drug interactions . . . ." 42 C.F.R. § 423.153. At least with respect to the twenty Part D Sponsor contracts produced during discovery, Defendants agreed to be consistent with and comply with the Sponsor's obligations to CMS as a Part D plan Sponsor.

Plaintiff's expert analyzed both "accepted" and "rejected" PDE claims for payment generated by Defendants in 2006 and 2009. Of those, he identified 15,083 PDE claims (out of the 114,125,392 unique PDE claims generated by Defendants in 2006 and 2007) that were for drugs that were gender-contraindicated, meaning that those drugs were allegedly used "exclusively" in the gender that was opposite to that of the Medicare beneficiary who received the drug. Each PDE in the gender PDE set involved one of seventeen different drugs that, according to Plaintiff's expert were either "Male Exclusive" or "Female Exclusive." The allegedly Male Exclusive drugs were Avodart, Casodex, Cialis, Finasteride, Flomax, Levitra, Uroxotral, and Viagra. The allegedly Female Exclusive drugs were Arimidex, Climara, Clindamax, Estradiol, Evistra, Femasra, Metrogel-Vaginal, Premarin, and Terconazole. Defendants' expert opines, however, that the seventeen medicines all have medically-accepted uses in both genders according to the drugs' FDA-approved labeling, their entries in Part D-recognized compendia, or published medical literature. (Defs.' Mot. Summ. J., Ex. 8, at App. C.)

Each of Caremark's three adjudication platforms provided a standard package of DUR edits that clients could customize to either add or remove edits, or to make certain edits "hard" and certain edits "soft." (Defs.' Mot. Summ. J., Ex. 97, at 10; Defs.' Mot. Summ., Ex. 13, Caremark 30(b)(6) Rep. Shawn Smith ("Smith Dep."), at 89:8–24, June 23, 2014.) Defendants assert that all three platforms had the capability to perform some form of concurrent gender review across all three platforms. (Smith Dep. 89:8–94:18.) In fact, Caremark had such an edit in place for MCS, and MCS's corporate representative testified that Caremark administered the benefit design as they were directed. (Rodriguez Dep. 64:6–25.) It is disputed, however,

whether the gender DUR edit was available to customers on the RECAP and QL platforms, or whether it was only available on the RxClaim platform.

3. The Expired Drug Claim

The First Amended Complaint alleges that Caremark "intentional[ly] [and] knowing[ly] [had a] practice of paying claims for prescription drugs with expired or obsolete NDC numbers." (First. Am. Compl. ¶ 299.) Plaintiff has since refined his claim to assert that "Defendants' [sic] violated the federal False Claims Act by knowingly approving thousands of Medicare Part D claims for drugs where the information in their possession indicated that those drug[s] (which, like all drugs, are required to be identified using a National Drug Code (NDC) number) had passed the shelf-life expiration date of the last-batch of that drug produced by its manufacturer (referred to as the 'last-batch shelf-life expiration date')." (Pl.'s Resp. Opp'n Defs.' Statement of Facts Supp. Summ. J. ¶ 671.) That operative date is the Health Care Financing Administration ("HCFA") Termination Date. Plaintiff's expert identified 87,803 PDE claims that Defendants generated, in 2006 and 2007, for drugs dispensed to Medicare beneficiaries on a date falling after the HCFA Termination Date value assigned to that drug's NDC. Plaintiff's expert did not opine that any drug associated with those PDEs was actually expired, but, on the other hand, Defendants have not produced any contrary evidence to show that the relevant drugs were not expired.

The HCFA Termination Date is a value provided by CMS to First Databank, Inc., a publisher of drug information databases. (Defs.' Mot. Summ. J., Ex. 112 (First Databank Decl.), ¶¶ 9–10.) In 2006 and 2007, First Databank's MedKnowledge database manual defined the HCFA Termination Date field as follows: "an eight-character numeric column that contains the

shelf-life expiration date of the last batch of product produced, as supplied on the Centers for Medicare and Medicaid Services' (CMS, formerly CFA) quarterly update. The date is supplied to CMS from the drug labeler. The date format is 'CCYYMMDD.' Today, the MedKnowledge documentation manual still defines the data field the same way." (Id. ¶ 12.)

The 1996 Medicaid Drug Rebate Operational Training Guide defined "Termination Date" as being determined:

> [B]y the reason the product is being discontinued. If it is being pulled from the shelf immediately, due to a health or safety reason, whether it be by FDA or labeler directive, the Termination Date is the date it is removed. If, however, it is being replaced by an improved version, or discontinued due to low sale, the Termination Date is the shelf life of the last batch sold. THE TERMINATION DATE IS LEFT BLANK UNLESS AND UNTIL ONE OF THE ABOVE CONDITIONS OCCURS.

(Defs.' Mot. Summ. J., Ex. 66, at F7 (emphasis in original).) One use of the "HCFA Termination Date" is to determine the date on which Medicaid will stop paying rebates for a particular NDC.

The HCFA Termination Date is a data field that currently can be licensed from information vendor First Databank, through its MedKnowledge database. This database currently contains approximately sixty different data elements in the NDC table. The MedKnowledge database does not currently contain, and has not contained at least as far back as January 1, 2006, a data field consisting of the expiration dates on prescription drug products' labels. (Id. ¶ 5.) The FDA, however, requires that all drug products bear an expiration date on their labeling as determined by appropriate stability testing. 21 C.F.R. § 211.137. Section 211.137(g) contains certain exceptions to this requirement. In 2006 and 2007, Caremark calculated an NDC's "obsolete date" on the RxClaim platform by adding two years to the

"inactive date," and, on the QL and RECAP platforms, by adding three years to the NDC's inactive date.

4. The Puerto Rico Claims

The First Amended Complaint also alleges claims related to three other issues cited in Pharm/DUR's Audit: MAC Pricing, prior authorizations, and quantity limits. Unlike the previous three claims, Plaintiff alleges these claims only to the extent Defendants submitted PDEs on behalf of MCS, rather than with respect to all of Caremark's thirty-nine Sponsors in 2006–2007.

a. The Prior Authorization Claim

In 2006, MCS used a Part D formulary created by Defendants. "Tiering," as defined by Defendants, is "[a] coverage determination decision that allows for coverage of a non-preferred drug at the preferred price whenever the plan determines that the drug is medically necessary, consistent with the Part D participant's physician's statement." (Traina Decl., Ex. 144-1 SPCM00000001–004.) Defendants charged MCS a fee to develop and manage the "SilverScript Formulary." This Formulary—developed and managed by Defendants for Part D Sponsors such as MCS—specified that certain medications required a prior authorization before they could be dispensed.

Federal regulations governing the Part D program require concurrent DUR services to avoid overutilization. 42 C.F.R. § 423.153(c)(2). The SilverScript-MCS contract provided that SilverScript agreed to develop and maintain policies and procedures designed to prevent over-utilization and under-utilization of prescribed medications. Under the section addressing "Drug Limitations," the contract stated that "limitations on drug coverage may be established for

specific drugs or drug classes, which are otherwise included in the Plan Design or are subject to coverage override. Claims for these drugs will be rejected if dispensing the drugs would cause any applicable drug coverage limitation to be exceeded." (Raspanti Decl., Ex. 70-31.) Defendants agreed to adjudicate and process pharmacy claims in keeping with the Sponsor's requirements for prior authorizations as follows:

> . . . for certain drugs, it will be necessary for SilverScript to perform prior authorization in order to determine whether the drug in question meets the definition of a "Covered Part D drug," and, therefore, is eligible for coverage under Part D. Customer agrees that it will perform such prior authorization itself. Customer agrees that it will provide to SilverScript a list of drugs to be prior authorized with respect to determining Part D coverage.

(Raspanti Decl., Ex. 70-2–3.)

MCS relied upon Defendants, who provided concurrent review of Part D prescriptions, to identify Part D claims for drugs requiring a prior authorization under the SilverScript Formulary used by MCS during 2006. Defendants agreed that SilverScript would "provide to Customer a monthly report of the Concurrent DUR Services rendered during the month." (Raspanti Decl., Ex. 70-7.) In addition, the contract stated that SilverScript would "implement methods designed to provide cost-effective drug utilization management, such as step therapy, prior authorization and/or tiered cost-sharing, as selected by Customer . . . ." (Raspanti Decl. Ex. 70–8.) Finally, Section 3.5 of the SilverScript-MCS contract required MCS to notify Caremark of any changes to the "prior authorization requirements" of the MCS Part D plan benefit design. (Raspanti Decl., Ex. 70-16.) Caremark's responsibility with respect to prior authorizations consisted of coding its systems with a hard edit instructing the pharmacist to contact a class center run by MCS to obtain a prior authorization. (Smith Dep. 196:23–198:6.) Defendants had the ability to review each

paid Part D pharmacy claim and determine whether a prior authorization was present for that claim.

b. The Quantity Limits Claim

Plaintiff further alleges that Defendants violated the FCA by knowingly failing to conduct required DUR to avoid overutilization and, instead, adjudicated Part D claims for Tier 4 drugs dispensed over the limits in the Sponsor MCS's formulary or exceeding the maximum doses as listed by the manufacturers. Under the MCS-SilverScript contract, Defendants agreed to provide "Utilization Management ('UM') Services" as part of its "Clinical Services and Drug Utilization Review ('DUR')." As part of the UM Services, Defendants agreed to "develop and maintain policies and procedures designed to prevent over-utilization and under-utilization of prescribed medications . . . ." (Raspanti Decl., Ex. 708.) The quantity limits that were approved by MCS, the Part D Sponsor, were detailed in the SilverScript Part D formulary.

c. The Maximum Allowable Cost ("MAC") Prices Claim

Finally, pursuant to Part D regulations, Part D Sponsors (such as MCS) must provide their enrollees with the benefit of "negotiated prices" for all Part D drugs dispensed. 42 C.F.R. § 423.104(g)(1). Under the MCS-SilverScript contract, MCS negotiated for the Maximum Allowable Cost ("MAC") for generic drugs to be dispensed to those enrolled in the MCS Part D plan. MAC pricing, as defined by the contract, states:

> **"Maximum Allowable Cost" or "MAC"** means the unit price that has been established by SilverScript for a generic drug included on SilverScript's MAC list, which may be amended from time to time by SilverScript. A copy of the MAC list shall be provided to Customer, upon Customer's reasonable request, and shall be updated by SilverScript in its sole discretion.

(Raspanti Decl., Ex. 70-28.) Defendants created, and periodically updated, a SilverScript MAC

list that documented the MAC prices charged for generic drugs when adjudicating Part D pharmacy claims between January 1, 2006 and December 31, 2006.

M. Summary Judgment Motions

On April 13, 2015, Defendants filed a Motion for Summary Judgment as to all of Plaintiff's claims and Plaintiff filed a Motion for Partial Summary Judgment as to only his false prescriber identifier claim. Briefing continued over the next few months with the last relevant filing on these Motions being submitted on July 13, 2015. The Motions are now ripe for judicial review.

II. STANDARD OF REVIEW

Summary judgment is proper "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). A factual dispute is "material" only if it might affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). For an issue to be "genuine," a reasonable fact-finder must be able to return a verdict in favor of the non-moving party. Id.

On summary judgment, the moving party has the initial burden of identifying evidence that it believes shows an absence of a genuine issue of material fact. Conoshenti v. Pub. Serv. Elec. & Gas Co., 364 F.3d 135, 145–46 (3d Cir. 2004). It is not the court's role to weigh the disputed evidence and decide which is more probative, or to make credibility determinations. Boyle v. Cnty. of Allegheny, 139 F.3d 386, 393 (3d Cir. 1998) (citing Petruzzi's IGA Supermkts., Inc. v. Darling-Del. Co. Inc., 998 F.2d 1224, 1230 (3d Cir. 1993)). Rather, the court must consider the evidence, and all reasonable inferences which may be drawn from it, in the

light most favorable to the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986) (citing United States v. Diebold, Inc., 369 U.S. 654, 655 (1962)); Tigg Corp. v. Dow Corning Corp., 822 F.2d 358, 361 (3d Cir. 1987).

Although the moving party must establish an absence of a genuine issue of material fact, it need not "support its motion with affidavits or other similar materials negating the opponent's claim." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). It can meet its burden by "pointing out . . . that there is an absence of evidence to support the nonmoving party's claims." Id. at 325. If the non-moving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden at trial," summary judgment is appropriate. Celotex, 477 U.S. at 322. Moreover, the mere existence of some evidence in support of the non-movant will not be adequate to support a denial of a motion for summary judgment; there must be enough evidence to enable a jury to reasonably find for the non-movant on that issue. Anderson, 477 U.S. at 249–50.

Notably, these summary judgment rules do not apply any differently where there are cross-motions pending. Lawrence v. City of Phila., 527 F.3d 299, 310 (3d Cir. 2008). As stated by the Third Circuit, "'[c]ross-motions are no more than a claim by each side that it alone is entitled to summary judgment, and the making of such inherently contradictory claims does not constitute an agreement that if one is rejected the other is necessarily justified or that the losing party waives judicial consideration and determination whether genuine issues of material fact exist.'" Id. (quoting Rains v. Cascade Indus., Inc., 402 F.2d 241, 245 (3d Cir. 1968)).

III. DISCUSSION[9]

As this Court has previously discussed, Plaintiff's lawsuit centers on the False Claims Act ("FCA"), 31 U.S.C. § 3729, et seq, (1994).[10] The False Claims Act enables the government to recover losses it has incurred as a result of fraud. United States v. Educ. Mgmt. Corp., 871 F. Supp. 2d 433, 445 (W.D. Pa. 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 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.

This case alleges 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

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[9] As noted above, the parties have submitted hundreds of pages of briefing on the various legal issues in these case. Within these pages are hundreds of single-spaced footnotes raising new issues and discrete arguments. Given the sheer volume of the briefing and the constraints on a federal court's time and resources, the Court simply cannot address each and every minute point raised by the parties. In an effort to ensure comprehensive consideration of the key legal points, the Court will address primarily those arguments that are material and crucial to the determination of the parties' motions. The Court will only review the ancillary arguments when necessary.

[10] 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.

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). "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.'" U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 304–05 (3d Cir. 2011) (quoting U.S. 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)). 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. Zimmer, 386 F.3d at 242. Finally, "[t]o 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.[11]

The alleged violations of these sections are grounded on the six theories discussed in

[11] For a more thorough discussion of the law underlying Plaintiff's claims, the Court incorporates by reference its lengthy prior opinion in this case, U.S. ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125 (E.D. Pa. 2012).

detail above: dummy prescriber IDs, gender DUR, expired drugs, MAC pricing, prior authorizations, and quantity limits. The Court discusses each theory individually.[12]

A. Dummy Prescriber IDs

As set forth above, Plaintiff asserts that Defendants' use of dummy identification numbers on the PDE records constitutes a violation of the FCA. Specifically, Plaintiff relies on Defendant's alleged non-compliance with 42 C.F.R. § 423.505(k). 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***

[12] As a general note, the Court must remark that Plaintiff's Response to Defendants' Motion for Summary Judgment, while attempting to deliver a few fatal blows, generally takes a "death by a thousand pin pricks" approach. Stated differently, rather than rebutting Defendants' broad defense theories, Plaintiff presents a myriad of minor arguments including, among other things, objections to evidentiary submissions, citations to isolated excerpts from documents, strained interpretations of regulations, and challenges to Defendants' failure to present evidence. The Court does its best to address the bulk of these arguments, in large part by footnote, but, by necessity, disregards some of the most minute points.

purposes of obtaining Federal reimbursement.

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

Section 423.322 discusses the "Requirement for Disclosure of Information" and states, in relevant 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." 42 C.F.R. § 423.322(a). 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 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.
> . . .
> 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.

(Raspanti Decl., Ex. 5-20.) 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. at 5-24.) Finally, Section 2 goes on to list the thirty-seven data elements "that must be submitted on PDE records for payment." (Id. at 5-26.)

One of these thirty-seven elements is the "Prescriber ID." The 2006 PDE Instructions, published in conjunction with these requirements, explicitly stated that the "Prescriber ID" field that "must be submitted on PDE records for payment" required "the prescriber's unique identification number." (Id. at 5-28.) CMS repeated that statement on the written requirements for the "Prescriber Identifier" field on various written iterations of PDE instructions from April 2005 through 2007. (Raspanti Decl., Exs. 5, 8, 11, 12.)

Plaintiff now asserts that Defendants admittedly populated the physician ID field on a large number of its PDE records with a default or dummy identifier and then falsely certified the correct submission of unique physician identification numbers, thereby causing an FCA violation. Defendants respond that this argument fails on four grounds: (1) CMS's knowledge of dummy prescriber IDs bars the claim; (2) Plaintiff cannot prove the "falsity" element because dummy prescriber IDs are not deceptive; (3) Plaintiff cannot prove the FCA's knowledge element; and (4) Defendants did not make a false certification. As the Court finds that Defendants' first argument has merit, summary judgment will be granted on that ground and the Court will not address Defendants' remaining defenses to the false prescriber theory of liability.

1. Law Regarding the Government Knowledge Defense

To establish knowledge under the FCA, a relator must prove that the defendant acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of

information. U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr., 495 F.3d 103, 109 (3d Cir. 2002) (quoting 31 U.S.C. § 3729(b)). The FCA's scienter requirement is satisfied if the defendant: (1) has actual knowledge that the claim is false; (2) acts in deliberate ignorance of the truth or falsity of the claim; or (3) acts in reckless disregard of the claim's truth or falsity. 31 U.S.C. § 3729(b)(1)(A). No proof of specific intent to defraud is required. Id. at (b)(1)(B). Congress has expressed "'its intention that the [A]ct not punish honest mistakes or incorrect claims submitted through mere negligence.'" Hefner, 495 F.3d at 109 (quoting United States ex rel. Hochman v. Nackman, 145 F.3d 1069, 1073 (9th Cir. 1998)).[13] While courts should be hesitant to grant summary judgment when a case turns on a state of mind determination, U.S. ex rel. Taylor–Vick v. Smith, 513 F.3d 228, 232 (5th Cir. 2008), they are not prohibited from doing so in an FCA case when there is no genuine dispute as to whether the defendant acted knowingly. Id. at 233; Hefner, 495 F.3d at 110; see also U.S. Dept. of Transp. ex rel. Arnold v. CMC Eng'g, Inc., 947 F. Supp. 2d 537, 543–44 (W.D. Pa. 2013), aff'd, 567 F. App'x 166 (3d Cir. 2014).

Without more than a relator's subjective interpretation of an imprecise contractual provision, a defendant's reasonable interpretation of its legal obligation precludes a finding that

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[13] The Act defines "knowing" and "knowingly" as follows:

> For purposes of [section 3729], the terms "knowing" and "knowingly" mean that a person, with respect to information—
> (1) has actual knowledge of the information;
> (2) acts in deliberate ignorance of the truth or falsity of the information; or
> (3) acts in reckless disregard of the truth or falsity of the information,
> and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b) (2000).

the defendant had knowledge of its falsity. U.S. ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency, 530 F.3d 980, 983–84 (D.C. Cir. 2008); U.S. ex rel. Wilson v. Kellogg Brown and Rost, Inc., 525 F.3d 370, 378 (4th Cir. 2008); U.S. ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999). Further, if the defendant knew that, despite the government's awareness of the statement's falsity, the government "was willing to pay anyway," the defendant "cannot be said to have knowingly presented a fraudulent or false claim." U.S. v. Southland Mgmt. Corp., 326 F.3d 669, 682 (5th Cir. 2003) (concurring opinion); U.S. ex rel. Thomas v. Siemens AG, 991 F. Supp. 2d 540, 568–69 (E.D. Pa. 2014) (quoting U.S. ex rel. Marquis v. Northrop Grumman Corp., No. Civ.A.09–7704, 2013 WL 951095, at *2 (N.D. Ill. Mar. 12, 2013)) ("'[T]he Government's knowledge and approval of the particulars of a claim for payment before that claim is presented . . . effectively negates the fraud or falsity required by the FCA.'"); Arnold, 947 F. Supp. 2d at 545 (holding that government knowledge of facts underlying an allegedly false claim prior to presentment creates an inference against scienter regardless of the actual falsity of the claim) (citation omitted).

At least six courts of appeal have adopted the "government knowledge inference" doctrine to help distinguish claims submitted with scienter from those submitted without scienter. Id. Under this doctrine, "when the government knows and approves of the facts underlying an allegedly false claim prior to presentment," an inference arises that the claim was not knowingly submitted, regardless of whether the claim itself is actually false. U.S. ex rel. Burlbaw v. Orenduff, 548 F.3d 931, 951 (10th Cir. 2008); accord U.S. v. Southland Mgmt. Corp., 326 F.3d 669, 683–84 (5th Cir. 2003); U.S. ex rel. Becker v. Westinghouse Savannah River Co., 305 F.3d 284, 289 (4th Cir. 2002); U.S. ex rel. Durcholz v. FKW Inc., 189 F.3d 592,

544–45 (7th Cir. 1999); U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp., 985 F.2d 1148, 1157 (2d Cir. 1993); U.S. ex rel. Hagood v. Sonoma Cnty. Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991).

Although the Court of Appeals for the Third Circuit has not addressed the issue,[14] multiple district courts within the Third Circuit have dismissed FCA claims on the basis of the government knowledge inference. See, e.g. U.S. v. Educ. Mgmt. LLC, No. Civ.A.07-461, 2013 WL 3854458, at *11 (W.D. Pa. May 14, 2013) ("There are therefore essentially two elements that must be met for government knowledge to impact scienter: (1) the government must know that the claim is fraudulent; and (2) the defendant must know that the government knows."); Arnold, 947 F. Supp. 2d at 545 (noting that because the Third Circuit has "striven for consistency with other circuits on the interpretation of the FCA generally . . . and the inference is consistent with the Court's holding that the FCA is not designed to punish defendants who make 'honest mistakes' or act with mere negligence," the court would apply the government knowledge inference); U.S. ex rel. Watson v. Conn. Gen. Life Ins. Co., No. Civ.A.98-6698, 2003 WL 303142, at *8 (E.D. Pa. Feb. 11, 2003) ("The government's knowledge of CGLIC and others' possible manipulation of the VMS software if there were evidence of such, negates Watson's argument that CGLIC perpetrated fraud on the government in this effort."). Similarly, district courts outside the Third Circuit have repeatedly applied this doctrine. See, e.g. San Francisco Bay Area Rapid Transit Dist. v. Spencer, No. Civ.A.04-4632, 2007 WL 1450350, at *8 (N.D. Cal. May 14, 2007) (holding that government knowledge is highly relevant and may be

[14] The Third Circuit was presented with this argument in United States Dept. of Transp., ex rel. Arnold v. CMC Engineering, 567 F. App'x 166 (3d Cir. 2014), but the court declined to address it. Id. at 170 n.9.

used to show that a defendant did not "knowingly" submit a false claim); Boisjoly v. Morton Thiokol, Inc., 706 F. Supp. 795, 809 (D. Utah 1998) ("[C]ourts have disallowed FCA claims where the [g]overnment knew, or was in possession at the time of the claim, all of the facts that make the claim false."); U.S. ex rel. Lamers v. City of Green Bay, 998 F. Supp. 971, 988 (E.D. Wisc. 1998) ("Since the crux of an FCA violation is intentionally deceiving the government, no violation exists where the government has not been deceived.").

Given the consistency in the federal case law, and the absence of any jurisprudence suggesting that the government knowledge inference should not be used, this Court will follow overwhelming weight of the cases and likewise recognize this defense. Nonetheless, the Court recognizes that this doctrine is only an inference and does not automatically preclude a finding of scienter. U.S. ex rel. Burlbaw v. Orenduff, 548 F.3d 931, 952–53 (10th Cir. 2008); see also Kreindler & Kreindler, 985 F.2d at 1156 ("[T]he defendant's knowledge of the falsity of its claim . . . is not automatically exonerated by any overlapping knowledge by government officials."). "The proper focus of the scienter inquiry under § 3729(a) must always rest on the defendant's 'knowledge' of whether the claim is false, a knowledge which may certainly exist even when a government agency misinterprets its own regulations and chooses—with full comprehension of the facts—to pay a false claim." Orenduff, 548 F.3d at 953. It remains well-established, however, that "the 'knowing' submission of fraudulent claims is logically impossible when responsible government officials have been fully apprised of all relevant information."[15] Lamers, 998 F. Supp. at 988. Thus, "[w]here the government and a contractor

[15] Plaintiff argues that Defendants have misstated the relevant standard for the government knowledge defense. He asserts that the government knowledge inference only applies where the defendant fully and extensively discloses all material facts to the government

have been working together, albeit outside the written provisions of the contract, to reach a common solution to a problem, no claim arises." U.S. v. Bollinger Shipyards, Inc., 775 F.3d 255, 263 (5th Cir. 2014) (quotations omitted).

2. Defendants Have Established Governmental Knowledge Sufficient to Defeat a Finding of Scienter

In the present case, the Court finds that Defendants have conclusively established, using

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prior to making the false claim. He also asserts that sufficient knowledge exists where the only reasonable conclusion a jury could draw from the evidence was that the defendant and the government had so completely cooperated and shared all information that the defendant could not have knowingly submitted false claims. Moreover, he asserts that government knowledge is only relevant at the time the claim underlying the FCA action was submitted and is not a bar if the knowledge is incomplete or acquired too late in the process.

Plaintiff's interpretation of the relevant standard misunderstands the case law and requires too high a degree of knowledge on the part of the government. The government knowledge inference arises "when the government knows and approves of the facts underlying an allegedly false claim prior to presentment." Orenduff, 548 F.3d at 952; see also Becker, 305 F.3d at 289 ("[T]he government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation."). This jurisprudence seems to suggest that non-material facts related to the alleged fraudulent claims do not need to be disclosed. The cases on which Plaintiff relies do not indicate otherwise. See Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 534 (10th Cir. 2000) (holding that "some level" of government knowledge would negate the intent requirement, but not specifying precisely what level is required); U.S. ex rel. A+ Homecare, Inc. v. Medshares Mgmt Grp., Inc., 400 F.3d 428, 454 n.21 (6th Cir. 2005) (holding that, based on the particular facts of the case, the government had not been apprised of sufficient facts on which to have knowledge of the claim's falsity, but not setting the required level of government knowledge); Orenduff, 548 F.3d at 954 (noting that "neither the directness of the government-contractor communications nor their nexus to an existing contractual relationship constitute an essential predicate for the government knowledge inference. Instead, the focus properly rests upon the depth of the government's knowledge of the facts underlying the allegedly false claim and the degree to which the government invites that claim."); Durcholz, 189 F.3d at 545 (noting, in the context of an individual contract—unlike the regulatory scheme at issue in this case—that "[i]f the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim"); U.S. ex rel. Wang v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992) (holding that government's knowledge of the defendant's mistakes and limitations in performance of a contract undermines the scienter requirement), overruled on other grounds, 792 F.3d 1121 (9th Cir. 2015).

the government knowledge inference, that they did not have the requisite scienter for purposes of Plaintiff's FCA claim as to dummy prescriber identifiers. Specifically, the evidence is clear that (a) CMS officials knew, in 2006–2007, that Sponsors and PBMs were having trouble obtaining the unique physician identifier number necessary to populate the associated field on the PDE; (b) CMS prioritized the filling of valid pharmacy claims over the administrative requirement of populating the physician identifier field and did not want valid claims rejected due to the absence of that number; (c) CMS knew that, in order to submit PDEs for valid pharmacy claims, Sponsors and PBMs were submitting PDEs containing dummy prescriber identifiers, yet never sanctioned any Sponsor, terminated any Sponsor, or required the submission of any PDE from 2006 or 2007 as a result of this practice; (d) although CMS preferred the use of a unique identifier, CMS affirmatively instructed Sponsors and PBMs to submit dummy prescriber IDs when a unique number was not available; (e) only after the 2006–2007 time frame did CMS issue affirmative instructions mandating the use of a unique identifier; (f) Defendants understood that CMS permitted the use of dummy prescriber IDs in 2006–2007; and (g) Defendants' certifications of the accuracy of the data were filed during the period when CMS clearly knew of dummy prescriber usage. The Court reviews such evidence in more detail.[16]

a. CMS Was Aware of the Problems in Obtaining Unique Identifier Numbers

As a primary matter, the evidence reflects that, given the early stages of the Medicare Part

[16] Notably, the parties present competing testimony on this issue from experts that so drastically contradict each other that it is impossible for the Court to determine which expert is more reliable. Recognizing that crediting the appropriate expert is a job for a factfinder and not proper on summary judgment review, the Court generally disregards such expert testimony.

D program and the PDE requirement, CMS was cognizant of a problem faced by pharmacies and PBMs in obtaining a unique physician identifier number. Jeffrey Grant[17] worked at CMS from July 1993 to September 2008, was involved with the development of the operational policies surrounding the reconciliation of Part D payments for risk adjustment, reinsurance and risk corridors, and low-income cost sharing, and was director of the Medicare Part D payment reconciliation division. (Defs.' Mot. Summ. J., Ex. 3, Dep. of Jeffrey Grant ("Grant Dep."), 17:24–18:7, 19:19–21:5, Oct. 30, 2014.) Mr. Grant acknowledged that, in the 2006–2007 time period:

> [T]here were a number of challenges with—you know, the way the process works is sponsors submit PDE records to CMS to reflect a claim that they paid. And some of those PDEs got through our system with no difficulties. Others ran into difficulties, and one of the difficulties was the prescriber ID. And because we had made it a required field and we were unable to change that requirement in the system, the person that—a sponsor that did not have a prescriber ID for a claim that they had

[17] Plaintiff takes great issue with Defendants' use of the testimony from Mr. Hutchinson, Mr. Grant, and Ms. McCutcheon because none of them was officially authorized to speak on behalf of CMS. Rather, they were each testifying in their individual capacities as present or former employees. Under the principles of agency law, however, knowledge in the possession of an agent—here a government employee—who has a duty to transmit or receive the information is knowledge in the possession of the principal—here the United States or an appropriate agency. See Huston v. Proctor & Gamble Paper Prods. Co., 568 F.3d 100, 106–08 (3d Cir. 2009). As indicated by the Restatement (Second) of Agency § 272, "the liability of a principal is affected by the knowledge of an agent concerning a matter as to which he acts within his power to bind the principal or upon which it is his duty to give the principal information." Clearly, these three witnesses were key individuals in the handling of PDE submissions and relevant policies within CMS. Defendants do not ask that the Court accord their testimony the deference normally due to an agency's interpretation of its own regulations. See United States ex rel. Quinn v. Omnicare, Inc., 382 F.3d 432 (3d Cir. 2004). Rather, Defendants simply offer their testimony as a showing of what CMS understood and accepted as a common practice in submission of Medicare Part D claims in 2006 and 2007. To that end, their testimony is relevant and persuasive.

Given the importance of and disputes over these witnesses' testimony, the Court has reviewed all three deposition transcripts in totality. Accordingly, the Court has been able to obtain an accurate sense of what these witnesses stated without influence from the parties' briefing.

already paid was unable to get those claims into our system to be part of the Part D reconciliation.[18] And the only way to do that would be create a dummy number and then send the claim in.

(Id. at 50:13–51:4.)

Thereafter, he elaborated as follows:

Q. And, in fact, you just testified that it—in some cases the only way to get the PDE record through was to submit a dummy ID in the prescriber field; correct?
A. That is . . . correct.
. . .
Q. And—and why is that? Elaborate for me on that, please.
A. The PDE has been paid. The—well, the claim has been paid, so the process is a member theoretically has seen a physician and presents at the pharmacy with a prescription. The pharmacy files a claim with a—usually a pharmacy ban—plan—a pharmacy benefit manager that may or may not be a sponsor as well. And if they're not the sponsor, then either the PBM on behalf of the sponsor or the sponsor themselves created a record of that claim and sent it to CMS. If that claim never had a prescriber ID, a Part D sponsor may or may not have a direct relationship with the prescriber, especially a Part D only sponsor as opposed to an MAPD plan. So they lack any ability to compel the production of a prescriber ID because of the lack of a direct relationship. And in the inability to compel a prescriber ID that accurately reflected who that prescriber was, the only way the PDE would go through the system was with a dummy ID.

(Grant Dep. 65:11–66:18.)

Defendants also deposed Tracey McCutcheon, Deputy Director of the Medicare Drug Benefit Group in 2006 to 2007. (Defs.' Mot. Summ. J., Ex. 2, Dep. of Tracey McCutcheon ("McCutcheon Dep."), 17:13–18:4, Oct. 22, 2014.) Ms. McCutcheon indicated that there was a

[18] Plaintiff repeatedly suggests that, had it wanted to, CMS could have changed its DDPS system so that a physician identifier number was not a requirement for a valid PDE. (Pl.'s Resp. Opp'n Summ. J. 57, 58, 72, 73.) The evidence Plaintiff cites, however, does not support this proposition and Plaintiff points to no evidence to prove that a PDE field could be changed from mandatory to optional. As shown above, Mr. Grant's deposition testimony flatly contradicts Plaintiff's point.

general awareness at CMS that pharmacies oftentimes could not get a prescriber number placed into their claims data. (Id. at 26:20–24.) Indeed, in 2006 and 2007, CMS did not have a requirement for a point-of-sale edit for prescriber ID. (Id. at 37:11–14.) She explained that CMS's "primary policy goal is for beneficiaries to get the drugs that they need when they need them, and we certainly prioritize that over administrative accuracy." (Id. at 61:3–6.)

b. CMS's Policy of Not Rejecting Valid Claims

Facing a problem of valid claims potentially being rejected due to the unavailability of a unique physician identifier, CMS repeatedly reiterated that its policy prioritized beneficiaries' access to drugs over the administrative PDE requirement of physician identifiers. Thomas Hutchinson, former director of the Medicare plan payment group at CMS, testified based on his eighteen-year tenure at CMS and his direct role in the payment policy and operations for the Medicare Part D plans.[19] (Hutchinson Dep. 14:10–14:3.) He explained that, with respect to the implementation of Medicare Part D in 2006 and 2007, there was an overriding policy objective to ensure that beneficiaries got access to the drugs they needed. (Id. at 22:14–23:7.) To his understanding, in 2006 and 2007, CMS did not require the NPI on a PDE. (Id. at 35:24–36:21.) He explained that a decision was made to not add an up-front edit for rejection of prescriber identifiers that were not the NPI because the prescriber identifier field just did not factor into payment or reconciliation. (Id. at 59:13–17.) Ms. McCutcheon further confirmed that CMS

[19] Upon reading this deposition, the Court was somewhat disturbed to see the extreme overuse of objections by Plaintiff's counsel. Indeed, counsel objected after almost every question posed. While the Court understands that parties must preserve their objections during the course of a deposition, Plaintiff's counsel interposed multiple statements incessantly throughout the questioning. The Court disapproves of such a tactic as an effort to disrupt a deposition. When the Court quotes from such depositions, any objections will be omitted with the appropriate ellipses.

prioritized access to care over rejecting claims "on the basis of missing or questionable administrative data." (McCutcheon Dep. 81:11–18.)

During a July 15, 2010 hearing by the Federal Financial Management, Government Information, Federal Services, and International Security Subcommittee of the U.S. Senate Committee on Homeland Security and Governmental Affairs on "Preventing and Recovering Medicare Payment Errors," CMS addressed the ongoing problem of false physician identifiers. Deborah Taylor, CMS's Chief Financial Officer and Director of the Office of Financial Management, reiterated this same policy:

> I think Mr. Vito and certainly the CMS concern is we do not want beneficiaries standing in front of the drug counter not being able to get needed and necessary drugs. So we always weigh that balance of making sure we get the valid information on the claim, but not holding up beneficiaries from getting their needed drugs. So we do not want to stop that. I think the issue here is we need the pharmacies and the sponsors to then, even if they give the information out because the system is slow or whatever, the drugs out, they still go back and validate the number, they do not leave it as a fake number on the PDE. We absolutely do not want that.

(Defs.' Mot. Summ. J., Ex. 104, at 22–23.) In a subsequent CMS response to the OIG's analysis of "invalid" prescriber IDs in 2007 Part D data, CMS informed OIG:

> The CMS concurs with this recommendation, CMS will issue: guidance instructing Part D plans to implement policies and procedures to identify and review invalid prescriber identifiers received on Part D drug claims, which will include a reminder that CMS expects them to have procedures in place outside of their claims processing to address potential non-compliance with NPI prescriber ID requirements on the National Council for Prescription Drug Programs (NCPDP) pharmacy claims transactions. However, CMS must caution that Part D sponsors and CMS strike a balance between ensuring valid prescriber identifiers on all Part D claims and ensuring beneficiary access to legitimate medically necessary Part D prescriptions. Therefore, consistent with our May 1, 2008, guidance on "Prescriber Identifier on Part D NCPDP Pharmacy Claims Transaction" CMS will continue to instruct Part D sponsors not to simply implement point-of-sale edits to reject all Part D claims with "invalid" prescriber identifiers because of the significant potential to interrupt

medically necessary drug therapies.

(Defs' Mot. Summ. J., Ex. 103, at 17.)

Indeed, notwithstanding CMS's knowledge of the difficulties in obtaining prescriber IDs, CMS, in the interest of ensuring access to prescriptions, did not issue any guidance prohibiting the use of dummy prescriber identifiers. Although the 2006 PDE Instructions said the Prescriber ID field required a "unique" identification number, no CMS guidance issued subsequent to September 2006—after CMS realized the difficulty of obtaining the prescriber number—affirmatively required that a unique identifier be used. Remarking about the 2006–2007 time frame, Ms. McCutcheon explicitly noted that, "I can say with the fullness of . . . knowledge now that we would not have felt that that was the appropriate thing to do, as you have seen in—in other pieces of this guidance, because to do so would have denied access to beneficiaries on the basis of missing or questionable administrative data, which I think we're—on record in some of these places as saying that that's not—that that would not have been our priority. Our priority was to maintain access to needed drugs." (McCutcheon Dep. 80:16–81:18.)

c. <u>CMS Knowledge of PBMs' Use of False Physician Identifiers</u>

Given the combined factors of pharmacies and PBMs' inability to obtain unique identifier numbers and the expressed CMS policy of accepting valid claims that lack such numbers, the evidence is abundant that CMS had full knowledge of a general industry use[20] of dummy

[20] Plaintiff asserts that CMS's knowledge of an industry-wide practice is not sufficient. Rather, he claims that Defendants must show that CMS knew of Defendants' specific practices. In support of this interpretation of the government knowledge defense, however, Plaintiff provides no supporting case law. Indeed, it would be illogical for FCA liability to lie against Defendants where CMS knew and accepted that this practice was being done commonly in the

physician identifier numbers in order to comply with the Part D requirement of 100% submission of PDEs on accepted claims. 70 Fed. Reg. 4194-01, 4307.

Mr. Hutchinson expressly testified that he was aware, during his tenure, that different Sponsors and their agents were putting in various dummy or default values in PDE fields, including the prescriber ID field. (Id. at 45:20–46:5.) He went on to indicate as follows:

> Q. And is it fair to say that CMS in the '06–'07 time period accepted PDE records with dummy or default identifiers?
>
> . . .
>
> A. Yes.
>
> Q. And is it fair to say that CMS in the '06–'07 time period made payment on PDE records that contained dummy or default identifiers?
>
> . . .
>
> A. Yes.
>
> Q. Is it fair to say—with respect to payment, is it fair to say that only certain fields were reviewed for the purpose of payment from the PDE record?
>
> . . .
>
> A. It is fair to say that only certain fields in the PDE were used to calculate payment.
>
> Q. Was prescriber ID one of those fields?
>
> . . .
>
> A. No.
>
> . . .
>
> Q. Does the prescriber ID field relate to reconciliation, Mr. Hutchinson?
>
> . . .
>
> A. No.

(Hutchinson Dep. 47:3–50:7.)

He went on to comment as follows:

> Q. So if you picked up a PDE record with that prescriber identifier, AA followed by seven zeros, you would be able to tell that that was a dummy or default prescriber identifier; is that fair?
>
> . . .
>
> A. That's fair.
>
> Q. By the way, I've been using the word "dummy" or "default" prescriber

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industry, but simply may not have known about the specifics of Defendants' practices.

identifiers. Do you view those terms to be interchangeable?

. . .

A. Yes.

Q. And did you understand at the time [the 2006–2007 period] that your—Mr. Hutchinson, that dummy prescriber identifiers were used by many Part D sponsors and PBMs on occasion?

. . .

A. I don't know when it became an issue where I would have known that this is a common practice.

Q. Okay.

A. I don't know if it was 2005–2007.

Q. Sometime in that time period you became aware that it was a common practice to use dummy prescriber identifiers?

. . .

A. Again, I don't know when it was I became aware.

Q. Okay. When you became aware that it was a common practice to use dummy prescriber identifiers, did you do anything about it?

. . .

A. No.

Q. And these dummy/default prescriber identifiers were on claims that CMS—were—excuse me—were on PD—PDE records that CMS accepted; is that correct?

. . .

A. Yes.

Q. And CMS didn't do anything, to your knowledge, to stop accepting PDE records with dummy or default prescriber identifiers [in the 2006–2007 time period]?

. . .

A. CMS did not do anything to stop or to reject PDEs that had dummy or default prescriber IDs in 2006 or 2007.

(Id. at 68:15–71:1.)

Thereafter, upon questioning by Plaintiff's counsel, Mr. Hutchinson admitted that he knew about dummy prescriber identifiers in 2006 and 2007:

> Q. You indicated, I thought, in response to one of [Defendants' counsel's] questions that in '06 or in '07—and tell me if I got your testimony wrong—that you believed there were members of this industry, as she put it, who were submitting dummy prescriber identifiers. Is it your testimony that you have any factual knowledge and possessed it in 2006 or 2007 that other members of the industry were submitting dummy PDE prescriber identifier data?

. . .
A. I had knowledge in 2006 and 2007 that various dummy and default variables were going into PDEs.
. . .
Q. In '06, at that time in that year, identify for me any member of the industry who you claimed learned in that calendar year was submitting dummy prescriber identifiers as part of that PDE submissions. List them for me.
. . .
A. I don't think I can specifically say which PBMs.
Q. You can't identify for me any in 2006 that you had knowledge—
. . .
A. I'm not saying I couldn't identify any. I can't—I'm telling you I can't specifically remember factually who the PBMs were . . . that did that. I'm not saying I don't remember anybody never doing it.
. . .
Q. Can you identify for me any member of the industry who made PDE submissions in 2007 that contained the dummy prescriber identifiers of which you possess knowledge in '07?
. . .
A. Certainly by '07 we had heard an awful lot about this and the issue was around the reconciliation, but, again, I'm not going to be able to tell you who specifically told us we were doing default and dummy values. But I do know certainly by 2007 it was a pretty well-known issue.

(Hutchinson Dep. 233:12–237:5.)[21]

Moreover, Mr. Grant also commented on discussions with PBMs regarding the use of dummy prescriber identifiers, as follows:

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[21] Plaintiff challenges Mr. Hutchinson's testimony on several grounds. First, he attempts to suggest that Mr. Hutchinson has some bias because he "spent the last six years performing work and consulting on Defendants' behalf," after he left CMS in 2010. (Pl.'s Resp. Opp'n Summ. J. 50 n.19.) The simple fact that Mr. Hutchinson now works on the PBM-side of the industry, however, does not cast any doubt on his factual statements—made under oath—about what he knew in his capacity as a CMS-employee prior to 2010.

Moreover, Plaintiff repeatedly argues that Mr. Hutchinson did not have any knowledge of use of dummy identifiers in 2006 and 2007. As indicated above, however, Mr. Hutchinson's initial testimony was that he could not recall exactly when he found out about the use of dummy identifiers. He later clarified that he knew of the common use of dummy or default information on PDEs in 2006 and 2007, but simply could not identify precisely which PBMs were submitting that information.

Q. Did Caremark—in 2006 and 2007, Caremark or any other related entities of Caremark, including SilverScript, did they ever tell you, sir, that they were simply going to skip the step of trying to find a prescriber identifier, and, instead, they were going to make up their own? They were going to make no effort to find whether there actually existed a prescriber identifier and just populate it with whatever they felt like doing. Did they ever tell you that, sir?

. . .

A. I do not recall Caremark specifically. I recall those types of discussions with Part D sponsors, and I recall us saying that was not problematic.[22]

Q. Okay.

A. We needed to get claims through a system that they could not get through, and we did not wish for prescriber ID to be a barrier to that.

(Grant Dep. 189:3–190:2.)[23]

Finally, commenting in a retrospective fashion about practice prior to 2009, Deborah Taylor testified before Congress that although it was not happy about the use of dummy identifiers, it was well aware of the practice:

> Ms. TAYLOR. We actually agree with all the OIG recommendations. We actually have looked at what is going on in 2009. We were troubled by seeing some entities with a preponderance of invalid numbers. ***We did have discussions with them.*** What we are seeing now is a trend that the pharmacies and the sponsors are using the National Provider Identifiers (NPIs). I think in the early days of the program there was confusion as to whether or not those numbers should be protected. And so, I

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[22] Citing to his experts, Plaintiff attacks this portion of Mr. Grant's testimony by arguing that there is no such thing as CMS "verbal guidance." Mr. Grant, however, indicated that although CMS's preferred method for doing anything was to put it ins writing, there were, nonetheless, many verbal directives given by high level administrators to Part D Sponsors about how to handle things. (Grant Dep. 206:10–207:5.) Plaintiff points to no clear regulations to support its contention that CMS could not issue verbal guidance. Moreover, whether CMS preferred to not issue verbal guidance is irrelevant to the fact that it did issue verbal guidance in this situation.

[23] Notably, Ms. McCutcheon testified that, prior to 2008, she was aware that dummy identifiers were being submitted on PDE records and such dummy identifiers were easily recognizable. (McCutcheon Dep. 24:3–25:12, 26:20–24.) Ms. McCutcheon later testified, however, that in 2006 and 2007, she did not know that PDE records were being submitted with an invalid prescriber identifier and did not find out about the issue until the OIG report was issued in June 2010. (Id. at 206:15–207:11.)

think we have clarified that, but because they were DEA numbers, people thought they needed some privacy or protection to them. ***Some sponsors told us they just put in fictitious numbers rather than putting in the actual number.*** We told them they need to use the NPI. And we are starting to see about 75 percent of the claims now in the PDE database coming in with NPI numbers rather than, these DEA numbers.

Senator KLOBUCHAR. So do you think some of this is not really fraud, it is just them putting in any number? Is that what you are saying?

Ms. TAYLOR. We believe that may be part of the reason. They just put in a number rather than trying to look up for a valid number.

Senator KLOBUCHAR. Because they know they are going to get paid.

Ms. TAYLOR. Correct.

Senator KLOBUCHAR. Of course, that also leads to a lot of fraud, I would think.

Ms. TAYLOR. Right. I mean, so we have several efforts underway now. We are looking at what is going on in 2009. We are going to validate those NPI numbers. We do want to understand if there is a systemic reason for why they cannot get to a valid number. If there is a problem with systems or look-up tables, we need to work on that. But we also want to and have started dialogue with those who seem to be not following our guidance, and we will be discussing that and telling them to cease and desist, that they need to do actual look-ups for valid numbers on the PDE claims.

. . .

[W] are not happy that there were invalid numbers, certainly dummy numbers that on the face of the claim were not valid to begin with. I think Mr. Vito has alluded—we have asked our contractors for some of these top 10 to go back to the entity and find out why they were putting those numbers in there. We certainly are focused on the high-risk claims, meaning those where controlled substances were part of the claim. We will work closely with the OIG if we find any real underlying issues. ***We believe that because it was in the beginning of the program, there may have just been a misunderstanding of whether or not they could put the DEA number on the face of the PDE claim. Some of the sponsors have told us they thought that was a protected number, that they would not be allowed to put it on the claim. So we certainly want to work and figure out what is going on there.*** Again, we have seen a substantial shift moving away from the DEA number to the NPI. We are going to be looking at the 2009— we do not have all of 2010 yet, but we will look at 2010 also to see whether or not, we are just substituting invalid numbers from DEA to NPI. We want to understand that. We want to be able to give these plans and pharmacies

> information and guidance about how to get to a valid NPI number. We do not know if there is a systems issue. We do not know if all pharmacies and plan sponsors have the ability to get into the NPI database. We do not know if there are problems with slowness of the database, whatever. So we want to figure out what is causing some of the underlying reasons why they are just putting a number on there.

(Defs.' Mot. Summ. J., Ex. 104, 16–17, 22–23 (emphasis added).)

Defendants also offer evidence of direct communications between PBMs and CMS regarding this issue. Defendants initially cite to an email from SilverScript to a Mr. Jones and a Ms. Haley at CMSPartD_FWA_Comments@cms.hhs.gov, regarding comments on CMS's Medicare Part D Rules. (Defs.' Mot. Summ. J., Ex. 80.) In that email, Defendants informed CMS as follows:

> Regarding the edits mentioned in this section, CMS states that Sponsors should have the system capability to "establish an edit on a given provider and use that edit to automatically deny a claim or suspend payment on a claim "when appropriate." However, many claims processing systems, including ours, do not independently verify or authenticate prescriber IDs entered into the system by pharmacies. Instead, they use a check digit algorithm, which validates the format of the prescriber ID. ***Thus, pharmacists could potentially enter dummy or incorrect prescriber IDs without the system being able to detect this.*** As such, we cannot and do not attempt to determine if the prescriber is dead, suspended, or otherwise excluded.

(Id. at SPCM00762839 (emphasis added))[24]

[24] Plaintiff lodges multiple objections to Exhibit 80. He argues that Defendants have failed to authenticate or lay foundation for it as there is no evidence that it was ever submitted to CMS, received by CMS, or reviewed by anyone at CMS. He asserts that Defendants obtained no testimony from either their own employees or CMS employees to authenticate it. Moreover, he claims that CMS did not produce a copy of this document from its records and it appears to have been sent to the wrong e-mail address. Finally, Plaintiff argues that Exhibit 80 does not disclose Defendants' practices including PDE claims, Defendants' own use of "dummy" prescriber identifiers, or Defendants' own "fix."

The Court finds no merit to any of these arguments. As a primary matter, Defendants present evidence that (1) CMS's production was minimal and did not include any Sponsor's or PBM's comment letter on the draft Chapter 9 despite testimony that CMS received such letters; (2) the email address was proper for receiving comment letters. (Defs.' Third Statement of Facts, Ex. 157, Decl. Of Kevin Lovecchio ¶ 3; Ex. 156, Decl. of Russell Ring ("Ring Decl.") ¶ 7); and

Defendants also point to an email from Anthem, a Part D Sponsor, from February 2007. (Defs.' Mot. Summ. J., Ex. 89.) Originally, Anthem notified CMS—in particular, Mr. Jeffrey Grant and one other CMS official—that it noticed dummy prescriber IDs in its PDE data and that it was receiving "781" error codes.[25] (Id.) It remarked that either pharmacies or Anthem's claims processor were "forcing in a value" in order "to bypass th[e] requirement" that the Prescriber ID field be populated. (Id.) CMS's simple response was, "PBM practice varies. We believe some PBMs use default numbers." (Id.) Notably, no mention was made that this practice was prohibited or that CMS was pursuing action against such PBMs.[26]

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(3) Caremark's practice was to also mail a hard copy to CMS. (Ring Decl. ¶¶ 8–9.) Moreover, the Third Circuit has "repeatedly noted that the burden of proof for authentication is slight," Lexington Ins. Co. v. W. Pa. Hosp., 423 F.3d 318, 328 (3d Cir. 2005) (quotations omitted), and that courts have authenticated emails by relying on the email addresses in the headers, explanations in the body of the emails, conduct after receiving the emails, and other circumstantial evidence. U.S. v. Vahari, No. Civ.A.08-693-01-02, 2009 WL 2245097, at *8 (E.D. Pa. July 27, 2009). Relying on such evidence in this case, the email in Exhibit 80 is properly authenticated for purposes of summary judgment.

As to Plaintiff's argument that the email does not fully disclose Defendants' specific practices, the Court finds this point to be of no moment. Caremark clearly informed CMS of the crucial fact—that it was not screening for, and therefore was submitting, dummy physician identifiers in the PDEs. While the Court agrees that Defendants could have been more direct by affirmatively stating that Caremark was submitting dummy identifiers on its own when the prescriber ID was not available, their failure to do so does not undermine the existence of CMS's knowledge regarding the use of dummy identifiers.

[25] As Plaintiff correctly points out, a "781 error" is a DDPS error related to the pharmacy where the prescription was filled and does not relate to the prescriber identifier on PDE claims. Nonetheless, Anthem clearly remarked that it believed it may have been receiving the error because its pharmacy system required the "DET PRESCRIBER ID" field—*i.e.,* the physician identifier field—to be populated with a dummy identifier "just to bypass this requirement." (Id.)

[26] Notably, CMS may terminate a Sponsor's contract for, *inter alia*, ailing to comply with the terms of the CMS-Sponsor contract, carrying out its contract in a manner that is "inconsistent with the effective and efficient implementation" of the Part D Program, or where there is credible evidence that the Sponsor "committed or participated in false, fraudulent or abusive activities affecting the Medicare program, including submission of false or fraudulent data, or where the

Faced with this overwhelming evidence of CMS's knowledge of PBMs' use of dummy physician prescribers in their PDE records during the 2006–2007 time period, Plaintiff attempts to render the appearance of genuine issues of fact by arguing that Defendants did not disclose any of the following facts to CMS:

- That, in 2006 and 2007, Defendants generated and certified PDE claims containing 56 different dummy prescriber identifiers;
- That Defendants' claims adjudication systems did not accept two of the four PDE-compatible prescriber identifiers (state license numbers and UPINs) on pharmacy claims at any time in 2006 and 2007;
- That Defendants' claims adjudication systems did not accept the NPI number in the prescriber identifier field on the pharmacy claims until February 26, 2007;
- That Defendants' claims adjudication systems would "disregard" any additional identifying information about the prescriber, including the prescriber's name and phone number, sent by the pharmacy during the adjudication process;
- That Defendants adjudicated and approved payment for thousands of pharmacy claims without any prescriber identifier whatsoever in 2006 and 2007;

Sponsor "[f]ails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329." 42 C.F.R. § 423.509(a). CMS may sanction a Sponsor for, *inter alia*, "[f]ail[ing] substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual," or for misrepresenting or falsifying information presented to CMS. 42 C.F.R. § 423.752(a)(1), (a)(5)(i).

Despite CMS's knowledge of the use of dummy identifiers—and notwithstanding its dissatisfaction with their use—CMS never sanctioned or terminated a contract with a Part D Sponsor for submitting dummy prescriber IDs on PDEs in 2006–2007, or for certifying that PDEs containing dummy prescriber IDs were "true, accurate, and complete." In fact, although CMS reopened reconciliation for Plan Years 2006 and 2007 on multiple occasions, Plaintiff has produced no evidence that CMS ever asked Sponsors to correct dummy prescriber IDs on PDEs.

- That Defendants knew that CMS would reject PDE claims created from these pharmacy claims because they lacked a prescriber identifier;

- That Defendants' employees with direct responsibility for the company's PDE generation process devised a plan, later known as "the fix," to populate PDE claims with a dummy prescriber identifier;

- That Defendants' third-party contractor, David Carpenter, created a dummy prescriber identifier by researching the check-digit algorithm on Wikipedia;
- That Defendants specifically designed the dummy prescriber identifier of AA0000000 to blend in with and be indistinguishable from valid DEA registration numbers;

- That it did not matter to Defendants whether any prescriber identifier included on PDE claims generated for submission to CMS was "valid or not;"

- That Defendants used "the fix" across all three of their claims adjudication platforms for all of 2006 and 2007;

- That Defendants' claims adjudication systems recognized when dummy numbers were submitted by pharmacies on the pharmacy claim;

- That, when a pharmacy submitted a dummy prescriber identifier, Defendants did not take any steps to identify the actual prescriber and simply passed on the dummy prescriber identifier on the PDE claim; and

- That Defendants certified as true, accurate, and complete the PDE claims containing dummy prescriber identifiers.

(Pl.'s Resp. Opp'n Summ. J. 43–44.)

At first glance, a failure by Caremark to disclose all of these facts to CMS might seem to undermine any government knowledge inference. On closer review, however, these facts—assuming them to be true—are simply a red herring distracting from the simple point that CMS knew of the commonplace use of dummy identifiers by PBMs, regardless of how they were developed. As set forth above, "when the government knows and approves of the facts underlying an allegedly false claim prior to presentment," an inference arises that the claim was

not knowingly submitted or purposes of FCA liability, regardless of whether the claim itself is actually false. Orenduff, 548 F.3d at 952. The crucial facts underlying the false claims here are that (1) CMS was well aware of the difficulty many pharmacies and PBMs were having obtaining a proper physician identifier; (2) CMS was concerned with filling valid prescriptions and did not want claims rejected at the point of service for absence of a valid identifier; (3) PDE records could not be submitted without some type of number that satisfied the requisite algorithm in the physician identifier field; (4) CMS knew that many PBMs were submitting PDEs with dummy numbers in the physician identifier field in the 2006 and 2007 time period; (5) CMS could easily recognize dummy prescriber identifier numbers; and (6) CMS took no action to deny payment on such claims during the 2006–2007 time period. Whether Defendants used fifty-six different identifiers, whether Defendants purposely created an algorithm to ensure their ability to submit PDEs when it did not have a prescriber identifier, or whether their system did not check for other identifying information about the prescriber is irrelevant to CMS's ultimate knowledge about this practice. Plaintiff has not established that his list of facts enumerated above would have had any impact on CMS's knowledge of the use of dummy identifiers.

d. CMS Affirmatively Authorized the Use of Dummy Identifiers

Aside from just being aware of the use of dummy identifiers in the 2006–2007 time period, the evidence demonstrates that CMS expressly condoned the use of such numbers. Of key importance is a memorandum, issued directly from CMS on May 1, 2008,[27] to All Part D Plan Sponsors regarding "Prescriber Identifier on Part D NCPDP Pharmacy Claims

[27] The parties appear to agree that this memorandum was misdated as May 1, 2009.

Transactions." (Defs.' Mot. Summ. J., Ex. 99.) In the body of the Memorandum, CMS stated:

> CMS requires a prescriber ID for all Prescription Drug Events (PDEs), which means that Part D plans must obtain prescriber IDs on all pharmacy claims. CMS emphasizes that plans should make all reasonable efforts to obtain NPIs in the prescriber ID field. Nevertheless, given the guidance provided by the FAQ, Part D plans cannot justify putting enrollees at risk of service interruption by establishing point-of-sale edits that reject pharmacy claims that do not include the NPI in the prescriber ID field. ***Part D plans must avail themselves of the claims processing flexibility allowed by the FAQ by ensuring that their systems continue to accept non-NPI prescriber IDs (e.g. DEA number, State License number) on NCPDP pharmacy claims transactions. Part D plans should establish alternative policies and procedures outside of their claims processing that address potential non-compliance with NPI prescriber ID requirements on NCPDP pharmacy claims transactions.***

(Id. (emphasis added).)

In the FAQs attached to the Memorandum, CMS went on to provide guidance as follows:

> Question: After May 23, 2008, is an NPI required for the prescriber ID field on the NCPDP pharmacy transaction? If the prescriber's NPI is not available, or if the prescriber doesn't have an NPI, but the payer requires the prescriber ID, what alternatives, if any are available for pharmacies to use to avoid having the transaction and the claim rejected?
>
> Answer: The prescriber identifier field on an NCPDP transaction is a provider identifier field and, as such, should carry an NPI in almost all cases when populated. It is expected that most prescribers will be covered entities and will therefore have an NPI assigned for use on all HIPAA transactions, where required. However, if the prescriber is not a covered entity, s/he may not be required to have an NPI, and may not opt to obtain one voluntarily. If a health plan or other payer rejects a (pharmacy) claim because it does not have prescriber ID, and one is not available to the pharmacy, this presents a potential service disruption problem in point of service billing, which must be avoided when possible.
>
> In the rare cases when either a prescriber does not have an NPI or the pharmacy cannot obtain an NPI, and where the prescriber ID is required by the payer, non-NPI individual identifiers may be substituted if allowed by the payer. ***In keeping with past practice, if no identifier is available a default identifier may be substituted; providers and pharmacies are encouraged to work with their payers for such default alternatives.***
>
> This guidance is expected to be used to cover exceptions. It is not intended to allow

> routine use of non-NPI identifiers or default identifiers in place of individual prescriber NPIs. Pharmacies are expected to make all reasonable efforts to obtain and utilize the appropriate individual NPIs for prescribers. ***Payers that elect to utilize the flexibility allowed under this Q&A should monitor pharmacy use of non-NPI and default identifiers to ensure that pharmacies comply with the requirements to use NPI whenever available.***

(Id. (emphasis added).)

Mr. Hutchinson reviewed the May 1, 2008 CMS memo on prescriber ID on Part D NCPDP pharmacy claims transactions, together with the FAQ section attached to the memo, and agreed that it essentially stated that if a Sponsor did not have a prescriber identifier, it was to use a default or dummy identifier. (Hutchinson Dep. 97:8–16.) Likewise, Mr. Grant was asked to comment on the CMS memorandum, which he significantly authored alongside Tracey McCutcheon. (Defs.' Mot. Summ. J., Ex. 99; Grant Dep. 161:12–20.) When asked what he wanted Part D plan Sponsors and others to take away from the memo and FAQs, Mr. Grant stated:

> A. What we wanted them to take away from this memo was that—really, two main points: that if there was an NPI, you could not continue to use outdated identifiers. But if the NPI did not exist, was not available to the sponsor, et cetera, and you paid a claim in good faith, you could submit that claim with an alternate identifier.
> Q. And could an alternative identifier include, if necessary, a dummy identifier?
>
> . . .
> A. Oh, yes. Absolutely it did. We actually are very specific in that.
> . . .
> Q. Is it fair to say that if an NPI or other prescriber identifier such as a DEA number, for example, was not available, that CMS was directing that a default or dummy ID could be utilized?
> A. We did not direct something could be—we were allowing it to be utilized, and also very clearly said it was not supposed to be a routine; that this was the exception rather than the rule.
> Q. And by "it" you mean dummy—
> A. The use of—

Q. —identifier?
A. —a dummy identifier would—was intended to be the exception, not the rule. The primary rule was use of an NPI. An alternate identifier was the second most important identifier to get. And if neither was available and the claim was still paid and was a legitimate claim on all other merits, a default identifier could be used.
Q. Okay. Given that we're focused on the frequently asked question now, I'll draw your attention to the third paragraph, last sentence, which reads as follows: In keeping with past practice, if no identifier is available, a default identifier may be substituted. Providers and pharmacies are encouraged to work with their payers for just—for such default alternatives. Does that sentence essentially indicate that if no other identifier is available, a default or dummy ID can be utilized?
A. Yes.

(Grant Dep. 164:16–165:20, 166:13–167:19.) Mr. Grant further testified:

Q. And until there could be a universal identifier put into place, was the use of a dummy ID as a last resort acceptable to you?
. . .
A. It would have been acceptable, as were many other accommodations we needed to make to process a complete set of PDEs in time for the 2006 reconciliation which occurred in mid-2007.

(Id. at 65:11–69:6.)[28]

[28] Plaintiff repeatedly takes issue with whether Mr. Grant was aware of the use of dummy identifiers in the 2006–2007 time period. Plaintiff argues, based on isolated sections of Mr. Grant's testimony, that Mr. Grant did not recall if dummy identifiers were used in 2006 and 2007 and did not recall any specific discussions with members regarding their use of dummy identifiers.

This argument, however, misrepresents the full extent of Mr. Grant's testimony. When first asked if dummy identifers were used on PDE records in 2006 and 2007, he did not say that they were not, but rather testified that "[t]hey may have been. They certainly could have been. I don't have direct knowledge that I—that I remember now." (Grant Dep. 39:11–17.) As noted above, Mr. Grant later stated that in the 2006–2007 time period, use of dummy identifiers was acceptable to CMS. Moreover, when asked if he recalled having discussions with Mr. Hutchinson about the need to use dummy identifiers in the prescriber ID field, Mr. Grant stated, "I am certain they occurred. I do not recall a specific discussion. They most certainly occurred because they materially impacted the Part D payment reconciliation, and anything that materially impacted the Part D payment reconciliation would have been a matter for discussion with Tom Hutchinson." (Id. at 69:16–23.) Finally, when later asked whether in years prior to May 23, 2008, he knew that default or dummy identifiers were utilized, he explicitly answered, "[y]es."

Finally, Ms. McCutcheon indicated that the Memorandum effectively recognized that there were circumstances in which, when the NPI was not available, CMS expected that claims would not be denied for the absence of an NPI. (McCutcheon Dep. 73:19–74:13.) She went on to state that the memo gave "permissive guidance" that "in keeping with past practice, if no identifier is available a default identifier may be substituted." (Id. at 74:16–75:1.) Moreover, she admitted that CMS never—for the 2006 to 2007 time period— issued a written directive prohibiting the use of dummy or default identifiers, even though, as of 2013, it put such a prohibition in place. (Id. at 81:20–25, 82:9–20.)[29]

(Id. at 168:4–17.)

[29] Plaintiff argues that the May 1, 2008 Memorandum relates to NCPDP pharmacy claim transactions (*i.e.*, point-of-sale transactions), and not to PDEs, which are usually created weeks after a claim is submitted b a pharmacy. More specifically, Plaintiff avers that both the Memorandum and the FAQ permit, in rare cases, the use of a dummy identifier on pharmacy claims, but does not permit the use of dummy identifiers on PDE claims. He goes on to assert that CMS expected that PDE claims would contain a valid prescriber identifier regardless of the information submitted on the pharmacy claim. This inference is obvious from CMS's August 2010 memorandum that "it has always been [CMS's] intention that whatever type of prescriber identifier is used . . . it must be a valid number" and that CMS was not sure "why [Sponsors] were submitting [dummy prescriber identifiers] in [their PDE submissions]." (Defs.' Mot. Summ. J., Ex. 105.)

Plaintiff's suggested interpretation of the May 1, 2008 Memorandum is simply not supported by a plain reading of the document, or the explanatory testimony. The Memorandum is addressed to Part D Sponsors and specifically allows for use of a dummy identifier on the pharmacy transaction. As described above, Mr. Grant clearly testified that if the pharmacy claim never had a prescriber ID, "a Part D Sponsor may or may not have a direct relationship with the prescriber . . .[s]o they lack any ability to compel the production of a prescriber ID because of the lack of a direct relationship. And in the inability to compel a prescriber ID that accurately reflected who that prescriber was, the only way the PDE would go through the system was with a dummy ID." (Grant Dep. 65:11–66:18.) Caremark made this same point in its letter to CMS when it noted that if pharmacists enter dummy or incorrect prescriber IDs, Caremark's system does not attempt to determine if that ID is valid. (Defs.' Mot. Summ. J., Ex. 80.) (Grant Dep. 65:11–66:18.) Finally, both Mr. Grant and Ms. McCutcheon made clear that the May 1, 2008 Memorandum was affirmatively permitting the use of dummy identifiers on PDE records in the event no unique identifier was available.

e. CMS's Post-2007 Efforts to Prohibit Use of Dummy Identifiers

Defendants next present evidence of CMS's actions post-2007 efforts (after the relevant time period in this case) to expressly prohibit the use of the dummy physician identifiers as probative of the fact that no such proscription existed in the past. First, in August 13, 2010, CMS issued a memorandum to all Part D Sponsors indicating that:

> [A]lthough HIPAA requires pharmacies to use the NPI on HIPPA covered transactions, we recognize that pharmacies cannot always obtain the prescriber NPI at the time of dispensing. Therefore, to ensure Part D enrollees do not experience service interruptions, CMS guidance permits Part D sponsors to accept alternative prescriber identifiers, such as DEA registration numbers or state license numbers. However, we ***clarify*** in this memorandum that it has always been our ***intention*** that whatever type of prescriber identifier (i.e., NPI, DEA number, unique provider identification number (UPIN) or state license number) is used, it must be a valid number.

(Defs.' Mot. Summ. J., Ex. 105 (emphasis added).).

Thereafter, in September 2011, CMS issued a revised Chapter 5 of the Prescription Drug Benefit Manual. This document stated as follows:

> Sponsors must report on PDE records one of the following four prescriber identifiers:
> - NPI
> - DEA number
> - UPIN
> - State license number

To the extent Plaintiff relies on the August 2010 Memorandum from CMS to all Part D Sponsors, his reliance is misplaced. This Memorandum also addressed pharmacy point-of-sale claims and is reflective of post-2007 efforts to eliminate the use of dummy identifiers in favor of specific and unique identifiers in the prescriber ID field. The 2010 Memorandum focused only on the PDE data in the last six months of 2009 and indicated displeasure with the fact that some invalid numbers continued to appear on PDE records. It further discussed an initiative to improve compliance with use of the NPI as a unique prescriber ID. Nothing in that Memorandum undermines the express statement in the May 1, 2008 FAQ that dummy identifers were permitted.

> ***Beginning January 1, 2012***, sponsors must ensure these identifiers are active and valid. Sponsors may not reject a pharmacy claim solely on the basis of an invalid prescriber identifier in order to not impede Medicare beneficiary access to needed medications unless the issue can be resolved at point of sale. In other words, sponsors may not reject a pharmacy claim at point of sale without prompt follow-up to ensure that the claim has been resubmitted with a corrected and valid prescriber identifier, or new information has been otherwise received to correct the sponsor's information. If this is not possible, pharmacies can fill prescriptions and sponsors can pay the associated drug claims with an unvalidated prescriber ID at the point of sale. However, sponsors are then responsible for verifying and reporting a valid prescriber ID on the PDE record and, whichever type of identifier is reported on the PDE, the identifier must be valid. Therefore, if an active and valid prescriber ID is not included on the Part D claim, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire a valid ID of one of the four acceptable types before the PDE is submitted to CMS.

(Defs.' Mot. Summ. J., Ex. 108, § 90.2 (emphasis added).) On October 11, 2011, CMS published a proposed rule to require an "active and valid" individual NPI on each PDE record beginning on January 1, 2013, and CMS promulgated the Final Rule on April 12, 2012. This Final Rule stated that in light of the administrative burden on Part D Sponsors:

> [W]e are ***revising our policy and the regulation text*** to require a Part D sponsor to ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug. Sponsors will be required to so ensure in the following manner: (1) A sponsor must communicate at point-of-sale whether or not the prescriber NPI is active and valid; (2) if the sponsor communicates that the prescriber NPI is not active and valid, the sponsor must permit the pharmacy to confirm that the NPI is active and valid, or in the alternative, to correct it; (3) if the pharmacy confirms that the prescriber NPI is active and valid or corrects it, the sponsor must pay the claim if it is otherwise payable; and (4) if the pharmacy cannot or does not correct or confirm that the prescriber NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

77 Fed. Reg. 22072-01, 22146 (emphasis added).

Considered collectively, this evidence creates the sole reasonable inference that CMS did

not previously have a clear prohibition on the use of dummy identifiers. By first "clarifying" its policies, then implementing a *prospective* rule regarding unique physician identifiers, and finally "revising" its prior policy and regulation text, CMS effectively indicated that, prior to these efforts, dummy identifiers were permissible.

f. Defendants Understood that CMS Permitted Dummy Prescriber IDs in 2006–2007

Having thus established government knowledge, Defendants still must prove that they knew of CMS's knowledge and acceptance of dummy identifiers. See U.S. v. Educ. Mgmt. LLC, No. Civ.A.07-467, 2013 WL 3854458, at *11 (W.D. Pa. May 14, 2013). The Court finds that the unequivocal guidance issued by CMS supports Defendants' general knowledge that dummy prescribers were permissible. Moreover, Joe Mulenex, Caremark's manager directly responsible for the PDE submission process, expressly testified that he was not aware of any guidance preventing Caremark from using dummy DEA numbers, and that he had conversations with CMS officials indicating that CMS would consider "valid" any prescriber ID value that met the check-digit algorithm. (Defs.' Mot. Summ. J., Ex. 119, Dep. of Joe Mulenex ("Mulenex Dep."), 76:3–23; Traina Decl., Ex. 8-1.) Given his conversations with CMS, he approved the use of a dummy identifier when no other unique identifier was available. (Mulenex Dep. 72:2–14.)

In an effort to refute this argument, Plaintiff offers isolated citations from various pieces of evidence to suggest that, notwithstanding CMS's knowledge, Caremark believed that use of dummy identifiers on PDE records in 2006 and 2007 was improper and contrary to CMS regulations. Closer review of this cited evidence in context, however, reveals nothing that

would indicate Caremark's belief that the use of dummy identifiers was wrongful, fraudulent, or violative of what was required by CMS. Indeed, quite to the contrary, the evidence reflects Caremark's struggle to deal with the identical problem identified by CMS—processing claims where the pharmacy did not have a prescriber ID in order to avoid withholding valid prescriptions. For example,

- *Plaintiff argues that, in a March 15, 2006 email, David Carpenter, a third-party consultant hired by Defendants to develop a dummy identifier that would satisfy the check digit algorithm, wrote an email saying, "Hopefully, there will not be an edit [by CMS] to say that a number with all zeroes are [sic] not allowed." (Raspanti Decl., Ex. 43-2–4.)* Taken in the context of the whole email chain, however, this statement shows only that Carpenter was working with Caremark to develop a solution for the situation where valid claims had already been processed through the pharmacy without a physician number, but Caremark was not able to go back and get the correct ID—precisely the problem identified by CMS in its own statements. (Id. at 43-3–4.) His statement does not indicate any nefarious behavior.

- *Plaintiff argues that, in a protocol entitled "Retail Prescriber ID Requests" attached to an August 25, 2006 email among Defendants' employees, Defendants stated "We are not to use the 'Dummy DEA#' under any circumstance!" (Raspanti Decl., Ex. 7–2.)* The document, however, was attached to an August 2006 email from a representative of MCS asking if MCS could do a mailing to all the pharmacies in their network stating that if they do not have the Prescriber ID available, they can use a dummy ID. (Id.) There is no date on this document. The email indicates that Defendants were attempting to discourage pharmacy use of dummy identifiers in order to comply with CMS's preference for a unique identifier.

- *Plaintiff cites to an October 16, 2006 email among Caremark employees, wherein a Ms. Benson wrote, in part, "Okay, sounds good. I'm afraid to say boo to IT at this point anyway. Hopefully CMS is silent on the dummies knowing that every provider is not issued one." (Traina Decl., Ex. 8–1.)* The email, however, was in direct response to both the problem of what to do when a pharmacy cannot get a DEA number and CMS's statement that restricting claims to the DEA number was not acceptable. Melanie Benson of Caremark suggested that pharmacies just submit a "dummy DEA." (Id. At 8-2.) Dena Rus of Caremark agreed and noted that "Joe [Mulenex] isn't aware of any guidance that prevents us from putting in a dummy DEA that

passes DEA check digit to get the PDE record to go through." (Id. at 8-1.) Thus, in context, this email affirmatively shows Caremark's belief that this practice was acceptable and Caremark's hope that CMS would not change its position on the issue.

- *Plaintiff refers to a November 16, 2006 email from Michael McNelis, an adviser in Defendants' Medicare Program Services Group, in which he stated, "We definitely shouldn't be submitting a dummy DEA number . . . no idea how we came up with that idea." (Raspanti Decl. Ex. 57-2.) Dena Rus responded that Defendants would use dummy prescriber identifiers "until a client or CMS hollers specifically at us." (Id.)* In his deposition, however, McNelis explained that he had no "concerns from a regulatory perspective" regarding dummy prescriber IDS, because "there's no subterfuge . . it's patently clear that it is not a prescriber ID assigned to any human being." (McNelis Dep. 146:10–147:15.) Rather, he only felt that dummy identifiers "introduced operational risk and create[d] the opportunity for things to go sideways such as loss or deletion [of data]." (Id. at 270:1–22.)

- *Plaintiff cites a January 17, 2007 email from Emerson Carvalho, a CMS employee, who wrote to Christina Compton, one of Defendants' employees, that if a prescriber did not have a DEA number, Defendants "should not deny these Rx filling [at the point-of-sale], [but] instead should kick the Rx back requesting a state license number." (Traina Dec., Ex. 11-2.)* This email is also taken out of context. The email was sent in connection with a complaint received by CMS from an optometrist association that indicated that PDPs were not filling prescriptions because there was no DEA number, which most optometrists did not have. Mr. Carvalho simply remarked that Defendants should not deny the prescriptions, but should request the state license number, emphasizing that "[t]he plan ought to avoid denying the prescription altogether if possible." (Id.) Ms. Compton merely indicated that she would check out the problem internally. (Id. at 11-2.) Nothing in this email chain offers any revelation regarding the dummy prescriber ID problem.

- *Plaintiff points to an email from Dena Rus to Emerson Carvalho, dated January 22, 2007, stating, "It is our understanding that CMS will continue to allow processing and acceptance of, via the PDE filed process, prescription drug claims that are submitted with a valid DEA, State License Number (and those specific identifiers currently defined) for prescribers beyond the May 23, 2007 NPI effective date." (Traina Decl., Exs. 12-1, 13-1.)* Mr. Carvalho simply noted that "a memo will be release [sic] regard." (Id.) The Court fails to see how this email even remotely reflects Caremark's lack of awareness of CMS's acceptance of dummy prescriber identifiers.

- *Finally, Plaintiff relies on the testimony of Patrick Jeswald, who was at the relevant time Chief of Compliance for Silverscript Insurance Company. Mr. Jeswald testified that he was unaware of Defendants' generation of PDE claims with dummy prescriber identifiers and, had he been aware, he would have reported it to CMS, launched an internal investigation, and may have fired those responsible.* Crucially, however, Mr. Jeswald did not become Director of Compliance for Silverscript until January 2008, and, during the relevant 2006–2007 time period, he had no involvement with the rollout of Medicare Part D. (Defs.' Mot. Summ. J., Ex. 131, Dep. of Patrick Jeswald ("Jeswald Dep."), 29:25–30:9.) He admitted that prior to January 2008, he knew nothing about PDE data and its submission to the government. (Id. at 102:24–103:22.) He further conceded that although current use of dummy identifiers is prohibited, he was not aware, in 2006-2007, of the Part D rules or if dummy identifiers were a violation of those rules. (Id. at 113:5–114:5.) He even stated that "the guidance around what's allowed to be submitted for a prescriber ID have [sic] changed several times over the last few years." (Id. at 114:10–12.)[30]

In short, the evidence Plaintiff cites not only fails to support the proposition that Caremark believed that use of dummy identifiers was improper, but actually highlights the ongoing problem faced in the industry of how to fill prescriptions where an identifier was not available. It further shows that, in 2006–2007, Caremark believed, at minimum, that dummy identifiers were not expressly prohibited by CMS, and, at maximum, that dummy identifiers were an acceptable solution in the face of a missing prescriber identifier. Plaintiff's isolated and out-of-context citations simply suggest to this Court an effort to create a genuine issue of material fact where one does not actually exist.

g. Defendants' Certifications About the Validity of Their PDE Records Were Made, At the Earliest, on July 30, 2007

[30] Plaintiff also argues that in response to the audit conducted by Pharm/DUR, Defendants did not make any reference to CMS's knowledge, awareness, or approval of the use of dummy prescriber identifiers. Pharm/DUR's audit, however, reviewed pharmacy claims, not PDE submissions and, as such, Defendants would have had no reason to raise the government knowledge defense.

Finally, even assuming some question remained as to when CMS knew of the dummy prescriber records, the Court notes that the relevant issue is not CMS's knowledge in 2006–2007, but rather CMS's knowledge as of Defendants' certifications beginning on July 30, 2007. As noted in this Court's Memorandum Opinion on the Motion to Dismiss, the crux of Plaintiff's FCA allegations focus on the express false certification theory. "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." U.S. ex rel. Wilkins v. United Health Grp., 659 F.3d 295, 305 (3d Cir. 2011) (citations omitted). Plaintiff alleges that 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," "based on best knowledge information and belief." 42 C.F.R. § 423.505(k)(1) and (3).

CMS expected certifications of PDE data "on an annual basis after the end of each coverage year, in preparation for final reconciliation." (Defs.' Mot. Summ. J., Ex. 75, at SPCM00716172.)[31] CMS set July 30, 2007 as the submission deadline for 2006 PDE records

[31] Plaintiff asserts that Defendants certified each and every PDE claim they generated at the time those claims were submitted to CMS. He goes on to argue that Chapter 9 of the Prescription Drug Benefit Manual indicated that, "[w]hen 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. (Raspanti Decl., Ex. 4-68.)

Notably, however, CMS's 2006 Prescription Drug Event Data Training Participant Guide made clear that "[c]ertification of PDE and claims data or payment is not the same as the certification for data submission which is described in the module Data Format. The two 'certification' processes are separate requirements that are both incumbent on the plan sponsor and any third party submitter." (Defs.' Mot. Summ. J., Ex. 75, at SPCM00716172.) Certification for data submission means that a submitter not previously certified must complete

for inclusion in 2006 reconciliation.[32] (Defs.' Mot. Summ. J., Ex. 123.) Plaintiff has not produced any evidence that would establish that Defendants submitted such certifications at an earlier time. Mr. Hutchinson expressly testified that "[c]ertainly by '07 we had heard an awful lot about this and the issue was around the reconciliation, but, again, I'm not going to be able to tell you who specifically told us we were doing default and dummy values. But I do know certainly by 2007 it was a pretty well-known issue." (Hutchinson Dep. 236:24–237:5.) Thus, by the time Caremark would have certified the veracity of its 2006 PDEs under § 423.505(k)(3), CMS obviously knew of the use of dummy prescriber identifiers. Moreover, by the time Caremark would have submitted its PDEs for 2007 and reached the July 30, 2008 certification date, CMS clearly had knowledge of the practice and had affirmatively condoned it in its May 2008 memorandum.

h. Summary of the Uncontradicted Evidence

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testing and certification. (Id. at SPCM00716018.) The annual certification, discussed above, is the certification of PDE and claims data for payment, as set forth under 42 C.F.R. § 423.505(k)(3). See also id. As this latter certification under 42 C.F.R. § 505(k) makes proper certification of data a "condition of payment," it is the failure of a Part D Sponsor or its subcontractor to submit such certification that properly indicates the accuracy, completeness, and truthfulness of data related to payment that gives rise to an FCA claim. The actual submission of such data and the certification of the entity submitting the data do not constitute certifications to obtain payment for a claim.

[32] In order to suggest that Defendants submitted its final reconciliation and certification prior to July 30, 2007, Plaintiff points to an email from Chris Risher of Caremark to one of Caremark's clients, Coventry. Upon careful review of this email, the Court finds nothing to indicate—as Plaintiff argues—that Caremark made its final certification of its 2006 PDE data to CMS prior to July 30, 2007. (Declaration of Ian P. Samson ("Samson Decl."), Ex. 10-1.) The reference to "prior certifications" does not even remotely indicate that any previous certification was made to CMS, but rather appears to be a simple disclaimer. Indeed, this email reflects that Caremark was attempting to ensure that Coventry corrected all errors in PDE records prior to Caremark making its own final certification to CMS. (Id.)

Considering all of the foregoing in conjunction, the Court finds that there is no genuine issue of material fact regarding CMS's knowledge or approval, albeit reluctant, of Defendants' use of dummy identifiers in the prescriber ID field of the PDE records. Indeed, the evidence tells a clear and logical story that reflects a climate of uncertainty in the early days of the Medicare Part D Program and requirement for the submission of PDEs.

The original written instructions for Medicare Part D PDE submissions stated that a "unique identifier" was required for prescribers as one of the multiple fields. Nonetheless, CMS officials made it abundantly clear that their primary objective was ensuring that valid claims got paid and that technical compliance with some of the primarily administrative fields was trumped by that objective. PBMs, however, faced the competing obligations of a 100% submission policy for PDE records—*i.e.*, they were required to submit PDE records for *all* claims submitted and paid under Medicare Part D—and an inability to obtain all the required information to fill the PDE records. Specifically, in order to submit such claims, the PBMs had to populate all fields, including the physician identifier field. As demonstrated by the evidence, a unique physician identification number was not always available at the point of sale. As such, in order to comply with their 100% submission obligation and to avoid rejecting valid pharmacy claims at the beneficiary's expense, many PBMs, including Defendants, implemented the use of dummy physician identifiers.

Given the relative infancy of both the Medicare Part D program and the PDE requirement, CMS quickly recognized the obvious problems that many pharmacies and PBMs had in obtaining the proper physician identifier. CMS repeatedly and clearly expressed its concerns that the inability to populate this field could impact valid claims, and it indicated that it

did not want these problems to become an obstacle to filling valid prescriptions. As such, although CMS preferred that the physician ID field be populated with the requisite NPI number and did not want to encourage widespread use of a false identifier, it repeatedly acknowledged and condoned the use of dummy identifiers to ensure that PBMs could comply with the 100% PDE submission policy and prevent blockages of valid claims without valid IDs.[33] Indeed, CMS issued explicit, written guidance to PBMs on this subject and remarked that, in keeping with this well-known *past* practice, it would accept dummy identifiers on the rare occasions when a unique physician number was unavailable. Defendants were aware of CMS's position on this issue and clearly took this guidance to heart, as only 2% of their approximately 114 million PDEs submitted in the 2006–2007 time frame contained dummy physician identifiers. Plaintiff has offered no evidence that Defendants ever submitted a claim with a dummy identifier when it was in possession of a prescriber's unique identification number.

The evidence revealed that CMS was not deceived by the use of a dummy identifier and could easily detect when one was being submitted. Only after the 2006–2007 time period did CMS decide to disallow the use of dummy identifiers and require the use of a unique physician identifier number. In testimony given in 2010 before Congress, CMS acknowledged that it was unhappy with the use of dummy identifiers, but recognized that there was confusion in the industry regarding what number to use, combined with the general consensus that claims should

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[33] See U.S. ex rel. Englund v. Los Angeles Cnty., No. Civ.A.04-282, 2006 WL 3097941, at *15–16 (E.D. Cal. Oct. 31, 2006) ("[W]hile the County's [Defendant's] practices were not necessarily popular with Congress and CMS, there was a common understanding that the practices were legal. For this reason, the court finds that there is a want of evidence from which a jury could infer that the County knowingly asserted a false claim to the Federal government and summary judgment must be entered for the County.").

not be denied at the point of sale based on the absence of a physician identifier number. CMS expressly noted that it knew PBMs were using dummy identifiers and had conversations with such PBMs about that practice. Even then, however, it was not until January 1, 2013, that CMS officially mandated that PBMs ensure that the physician ID field was populated with the NPI number, suggesting that, prior to that time, such a requirement was not in place.

As explained in detail above, the crux of an FCA violation is intentionally deceiving the government. Where the government has not been deceived, no violation can exist. In 1986, Congress clarified the scope of "knowing" conduct that would give rise to liability under the FCA. Specifically, the House Judiciary Committee explained that the FCA is intended to reach "persons who ignore 'red flags' that the information [submitted in a claim] may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim. . . . This definition, therefore, enables the Government not only to effectively prosecute those persons who have actual knowledge, but also those who play the 'ostrich.'" H.R. Rep. No. 99-660, 99th Cong. 2d Sess. (1986), at 20–21. The Committee further provided that, while "individuals and contractors receiving public funds have some duty to make a limited inquiry so as to be reasonably certain they are entitled to the money they seek," a "rigid definition of that duty . . . would ignore the wide variance of circumstances under which the Government funds its programs." Id. at 20. Consequently, "[o]nly those who act in 'gross negligence' of this duty will be found liable under the False Claims Act." Id.

Far from showing deception, the unequivocal evidence in this case shows that CMS knew that PBMs were having trouble complying with the need to use a unique physician identifier, recognized that many PBMs were using dummy identifiers to ensure that prescriptions were not

being rejected at the point of sale, and condoned—albeit with some reluctance— the use of such dummy identifiers in keeping with its policy of ensuring access to prescriptions for its beneficiaries during these early stages of the Medicare Part D program. Indeed, Caremark was open with CMS about its problems and, although it may have been groping for potential solutions, it was not knowingly presenting a false claim. Ultimately, CMS, with full knowledge of the practice at issue, paid out on all the PDEs and, even upon reopening of these claims, has never sought repayment from Defendants for those claims submitted with dummy identifiers. There can be no falsity where "[t]he government knew what it wanted, and . . . got what it paid for." U.S. ex rel. Durcholz v. FKW, Inc., 189 F.3d 542, 545 (7th Cir. 1999). Given such evidence, the Court concludes that no jury could reasonably find that Defendants acted with the requisite scienter of falsely submitting a claim. Accordingly, the Court grants Defendants' Motion for Summary Judgment as it relates to Plaintiff's False Claims Act violation based on dummy prescriber identifiers.

B. Gender DUR

Plaintiff's second claim asserts that Caremark's failure to perform concurrent DUR for gender-related contradictions violates the FCA under a "worthless services" theory. As explained in the Court's prior opinion in this case, "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). 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). "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 overall 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 the particular gender DUR claim at issue, Plaintiff asserts that Defendants were required, in 2006 and 2007, to personally perform concurrent DUR for gender-related contraindications before each Part D prescription was dispensed because: (1) the Part D regulations expressly required such concurrent DUR; and (2) Defendants agreed to perform such services in their contracts with their Part D Sponsor clients. As a result of Defendants' failure to perform these required services, Plaintiff asserts that Defendants submitted claims for drugs not covered by Part D and then collected payment for DUR services not provided in their dispensing of these drugs.

Defendants now respond that they are entitled to summary judgment because Plaintiff cannot establish a knowing violation of the law given Defendants' full compliance with both the actual requirements of Section 423.153(c) for gender DUR and their contracts with Part D Sponsors. The Court first considers what Defendants' obligations were under both (a) the Medicare regulations and (b) their contracts with Part D Sponsors. The Court then turns to an analysis of whether Defendants' actions fulfilled their obligations such that a worthless services claim is viable.

1. The Regulations

The pertinent regulations in this case 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.
>
> . . .
> (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.

42 C.F.R. § 423.153 (emphasis added).

Plaintiff avers that section 423.153(c) makes clear that merely maintaining "policies and procedures" for concurrent DUR alone is not sufficient, but rather the Part D Sponsor must ensure that concurrent DUR review for "gender-related" contraindications is "performed before each prescription is dispensed." Plaintiff then spends multiple pages of his Opposition brief arguing that concurrent DUR for gender-related contraindications was part of "quality assurance

measures and systems," and that a Part D Sponsor's "comprehensive quality assurances system will ensure enrollees receive access to high quality prescription drug coverage." (Pl.'s Resp. Opp'n Summ. J. 100–103.) He reasons that CMS expected that Sponsors would utilize PBMs to adjudicate Part D claims and perform the mandated concurrent DUR. As such, he avers that Caremark's failure to have its own edits in place on their adjudication platforms for gender contraindications constituted a disregard of its statutory obligations.

Upon close review of the regulation and its legislative history, however, the Court finds nothing that would mandate that Defendants themselves—as opposed to any of their contracting pharmacies—perform the requisite DUR. As noted above, the regulation itself states only that the Part D Sponsor "must have established quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use" and that those measures must include both a (1) "[r]epresentation that network providers are required to comply with minimum standards for pharmacy practice as established by the States" and (2) "[c]oncurrent drug utilization review *systems, policies, and procedures*[34] 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*." 42 C.F.R. § 423.153. With the recognition that Part D Sponsors would not be performing all such tasks themselves, the regulations provided:

> Each and every contract governing Part D sponsors and first tier, downstream, and related entities, must contain the following:

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[34] Plaintiff suggest that "systems, policies, and procedures" has a meaning beyond mere concurrent DUR, but fails to explain exactly what else "systems, policies, and procedures" requires. (See Pl.'s Resp. Opp'n Summ. J. 31.)

> (i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit pharmacies or other providers from holding an enrollee liable for payment of any fees that are the obligation of the Part D plan sponsor.
>
> (ii) Accountability provisions that indicate that ***the Part D sponsor may delegate activities or functions to a first tier, downstream, or related entity only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.***
>
> (iii) A provision requiring that any services or other activity performed by a first tier, downstream, and related entity in accordance with a contract are consistent and comply with the Part D sponsor's contractual obligations.
>
> (iv) ***Each and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.***
>
> (v) A provision requiring prompt payment of clean claims by the Part D sponsor, consistent with § 423.520.
>
> (vi) A provision that establishes timeframes, consistent with § 423.505(b)(20), for long-term care pharmacies to submit claims to the Part D sponsor for reimbursement under the plan.

42 C.F.R. § 423.505(i)(3) (emphasis added).

While the language of these provisions contains some ambiguity as to precisely how the "systems, policies, and procedures" should be implemented so as to fulfill their purpose, the legislative history more clearly indicates that the regulation intends to offer only general guidelines for the Part D Sponsor/PBM and does not specify that the Sponsor/PBM personally perform the required DUR. In the Final Part D Rule's legislative history, CMS states:

> As with the proposed regulations for drug utilization management programs, the proposed rule for quality assurance measures and systems provided ***minimum standards*** for quality assurance measures and systems, while for the most part ***giving plans flexibility to design such measures and systems***. Proposed § 423.153(c) required Part D sponsors to include quality assurance measures and systems for: (1) reducing medication errors; (2) reducing adverse drug interactions; and, (3) improving

> medication use. It also proposed to require plans to establish requirements for: (1) drug utilization review (DUR); (2) patient counseling; and, (3) patient information record-keeping.

70 Fed. Reg. 4194-01, 4278 (emphasis added). The Final Rule goes on to note:

> The overwhelming majority of comments confirmed our understanding that the relevant parts of OBRA 90 for DUR, patient counseling, and patient information record-keeping generally describe widely accepted standards of pharmacy practice for both Medicaid and Non-Medicaid patients. We find that almost all of the State boards of pharmacy have adopted regulations for pharmacy practice that, at a minimum, generally reflect these relevant parts of the OBRA 90 requirements. However, upon reconsideration, ***since our intent was to ensure that plans provided access to network providers that are required to comply with contemporary pharmacy practice standards, and not to create a new Federal standard for pharmacy practice, we agree with commenters that recommended that we defer to existing authority for regulating pharmacy practice.*** In fact, this is consistent with the Department of Health and Human Service's (HHS) general position of deferring to States for regulating the practice of pharmacy. ***Therefore, our requirement at § 423.153(c)(1) in the final rule states that plans must provide us with representation that their network providers are required to comply with minimum standards for pharmacy practice established by the States.***

Id. As to concurrent DUR, the final rule remarks that its mandates go only to the minimum requirements for what must be done, not how it should be done or who should do it. Specifically, it states:

> we agree that concurrent and retrospective DUR must be components of the quality assurance systems and measures ***to be implemented*** by Part D plans. Accordingly, we have specified requirements for concurrent and retrospective DUR systems, policies, and procedures at § 423.153(c)(2) and § 423.153(c)(3), respectively.

Id. (emphasis added).

This general acknowledgment that CMS expected pharmacies to continue the long-standing practice of engaging in the prescription-by-prescription quality control review of claims, including conducting the requisite concurrent DUR, is further supported by CMS's recognition in 42 C.F.R. § 423.100 that pharmacies are entitled to "dispensing fees." These fees

"[i]nclude only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee," and include, among other things, reasonable costs associated with a pharmacist's time "***performing quality assurance activities consistent with § 423.153(c)(2)***." 42 C.F.R. § 423.100 (emphasis added). In other words, CMS recognized that pharmacies would be performing some of the DUR required under § 423.153(c)(2) and were entitled to be reimbursed for their time.[35]

In an effort to rebut this obvious interpretation, Plaintiff contends that the "systems, policies, and procedures" required by this section were part of essential quality assurance measures that were designed to ensure that the Part D Sponsors *themselves* conducted the requisite DUR. This contrary interpretation, however, finds no support in either the plain language of the regulation, the legislative history, or any materials cited by Plaintiff. First, nothing in the record supports the proposition that the phrase "systems, policies, and procedures" expressly requires that Sponsors and their PBMs perform the requisite DUR themselves. Plaintiff cites to the 2010 Prescription Drug Benefit Manual, which states that "Part D sponsors should be able to demonstrate how information obtained from their DUR program is used in their overall quality assurance system and improves their enrollees' quality of care." (Traina Decl., Ex. 146-5–6.) Plaintiff does not establish, however, how that phrase can be construed to mean that the Sponsor/PBM must run the DUR program itself. Moreover, this citation disregards the early portion of this paragraph, in which CMS stated "Part D Sponsors

[35] Plaintiff asserts that this definition does not serve "as evidence that CMS required pharmacies to perform the mandated concurrent DUR." (Pl.'s Resp. Opp'n Summ. J. 35.) Notably, however, Defendant only cites to this provision as evidence that pharmacies could, under the regulations, perform DUR, not that pharmacies were required to perform the mandated DUR.

should maintain written concurrent DUR policies and procedures that explain the level of DUR checks (i.e., ***whether they are imposed at the pharmacy and/or plan level)***, systems logic for establishing the edits, thresholds used to trigger the edits, and accompanying pharmacy messaging." (Id. (emphasis added).) In other words, this Manual explicitly demonstrates that CMS contemplated that some Sponsors would require the DUR checks to be done at the pharmacy level instead of at the plan level.

Second, Plaintiff illogically argues that the clear language of the regulation prohibited Caremark—as the PBM—from delegating the concurrent DUR to a downstream entity in lieu of performing the DUR itself.[36] A plain reading of the regulation, however, imposes the obligation of instituting "established quality assurance measures and systems" including "[c]oncurrent drug utilization review systems, policies, and procedures" on the ***Part D Sponsor***. Thus, Plaintiff's argument that the obligations in the regulation cannot be delegated would necessarily mean that Part D Sponsors could not have delegated such obligations to Caremark—since it was only a PBM—and Caremark could not logically be bound by such regulation. As noted above, CMS clearly did not contemplate such a regime.

In short, the regulations state only that Part D Sponsors and their downstream entities must put into place 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*." Nothing in these regulations indicates, as Plaintiff bears the burden of proving, that DUR—including the gender contraindication review—must be done by the Part D Sponsor or the PBM itself.

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[36] (See Pl.'s Reply Br. 34.)

2. Caremark's Contracts With Part D Sponsors

The second source of Defendants' potential obligations for the gender DUR are Defendants' contracts, in 2006 and 2007, with thirty-nine different Part D Sponsors for Defendants' provision of PBM services to their Part D plans. Plaintiff argues that provisions within Defendants' PBM contracts explicitly obligated them to perform concurrent DUR services that complied with their Part D Sponsors' obligations to CMS, including the express mandate for concurrent DUR for gender-related contraindications set forth in 42 C.F.R. § 423.153(c)(2). (Pl.'s Resp. Opp'n Summ. J. 103.)

In its PBM contracts, Caremark explicitly agreed to "participate as a subcontractor to Customer [Part D Sponsor], in the management of Customer's Part D Plan, and understands that its activities in this capacity must, to the extent these are communicated to SilverScript, be consistent and comply with Customer's contractual obligations to CMS as a Part D Plan Sponsor." (See, e.g., Defs.' Mot. Summ. J., Exs. 35–37, § 1.1.) Further, it agreed to "comply with all Laws applicable to its prescription drug benefit plan, including but not limited to all requirements and conditions of a PDP Sponsor under Part D. . . . Customer has no responsibility to advise SilverScript regarding SilverScript's compliance with any applicable law." (Id. § 6.4.)

As to the DUR services, the Part D contracts generally provided that Caremark "will provide its automated concurrent DUR Services for point of sale (POS) Claims." (Id. ¶ 1.8(b).) The contracts noted, however, that "DUR Services are highly automated and any focused professional review is based upon automated analysis of Plan Participant's profiles. Therefore the DUR Services are necessarily limited by the amount, type and accuracy of Plan Participant Information made available to SilverScript" and "SilverScript will have no obligation to acquire

information concerning any Plan Participant beyond the information that is included in SilverScript's eligibility file or the Claims submitted by Participating Pharmacies in connection with the Plan." (Id. § 1.8(e).)

In addition, these Contracts included a provision that "SilverScript will provide its automated concurrent DUR Services for point of sale (POS) Claims. In certain instances, a Claim that is denied or otherwise rejected by the system may actually represent appropriate drug therapy as determined by the applicable physician or pharmacist in his/her professional judgment." (Defs.' Mot. Summ. J., Ex. 48 (Harris Am. Contract); Ex. 33 (Arta Contract); Ex. 53 (MCS Contract).) The contract with Sponsor Neighborhood Health Providers was more specific and stated that, "SilverScript will provided its automated concurrent DUR Services including but not limited to (i) drug to drug interactions; (ii) therapeutic duplications; (iii) known drug sensitivity; (iv) over-utilization; (v) insufficient or excessive drug usage; and (vi) early or late refills." (Defs. Mot. Summ. J., Ex. 60 § 2.13.) Only Caremark's contract with Sponsor Coventry actually specified that the DUR services would include a drug-gender check.

> CAREMARK shall perform a concurrent DUR analysis of each prescription filled through the Mail Service Pharmacy or submitted for adjudication on-line by a Participating Pharmacy in order to assist the pharmacist in identifying potential drug interactions, incorrect prescriptions or dosages and certain other conditions that may be indicative of inappropriate prescription drug usage including, but not limited to, overuse checks, underuse checks, drug-age check, drug-gender check, therapeutic duplication, formulary non-formulary check, drug allergy check, high dose check and low dose check. If a Participating Pharmacy is able to insert an outcome code in response to the DUR edit using industry accepted formats, CAREMARK shall be able to accept it.[37]

[37] Oddly, neither party seems recognize that Defendants' contract with Sponsor Coventry specified that Caremark would perform drug-gender edits. When Plaintiff cites this contract in both his statement of facts and his Opposition brief, he inexplicably omits the language "drug-age check, drug-gender check, therapeutic duplication, formulary non-formulary check." (Pl.'s

(Defs.' Mot. Summ. J., Ex. 38, § 4.2.)

For the most part, however, the contracts clearly that Caremark's DUR capability was limited, as follows:

> **b. DUR Limitations.** The information generated in connection with DUR Services is intended as an economical supplement to, and not as a substitute for, the knowledge, expertise, skill, and judgment of physicians, pharmacists, or other health care providers in providing patient care. Providers are individually responsible for acting or not acting upon information generated and transmitted through the DUR Services, and for performing services in each jurisdiction consistent with the scope of their licenses. Except as set forth in paragraph (b) above, in performing DUR Services, SilverScript will not, and is not required by this Agreement to, deny Claims or require physician, pharmacist, or patient compliance with any norm or suggested drug regimen, or in any way substitute SilverScript's judgment for the Professional judgment or responsibility of the physician or pharmacist.

(See, e.g., Defs.' Mot. Summ. J., Exs. 35 § 1.8(b), 36 § 1.8(b), 37 § (1.8(b), 41 § 1.8(d), 43 § 1.8(e), 45 § 1.8(e).) In other words, Defendants expressly informed their Sponsor-clients that in performing DUR, it would defer to the judgment of the providers/pharmacies.

At their core, these contracts obligated Defendants to comply with the applicable regulations, as set forth above, and indicated that Defendants would, in fact, perform some concurrent DUR. For the most part, these contracts did not specify precisely which DUR edits had to be done by Caremark and did not prohibit Caremark from requiring that some DUR be done at the point of sale by the pharmacies themselves. Indeed, the contracts expressly indicated

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Separate Statement of Undisputed Facts in Opp. to Defs.' Mot. Summ. J. ¶ 248.) Although Defendants correct this error in their Response to Plaintiff's Statement, they go on to argue, in their Reply Brief, that Caremark's contracts with Sponsors never promised particular edits, and the only one that did promise particular DUR edits "conspicuously *omitted* a drug-gender edit from what was to be provided." (Defs.' Reply Supp. Summ. J. 36.) As neither party acknowledges the existence of this provision, neither party explains its implications on Defendants' precise obligations under this contract. Absent some explanation about how this one seemingly anomalous contract impacts the issues in this case, the Court disregards it.

that Defendants' DUR was highly automated and that, in large part, they would defer to the judgment of the pharmacies and the physicians. As such, to the extent the Sponsor contracts imposed greater obligations on Defendants than those required by CMS, violations of such contracts would not automatically amount to a violation of the False Claims Act.[38]

3. Caremark's Actions to Fulfill Its Responsibilities Both to CMS and to its Sponsor Clients

Having established the scope of Defendants' obligations under CMS regulations, the Court must now determine whether there is any evidence to support a claim that Defendants

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[38] Plaintiff's evidentiary citations in support of their argument that both Defendants and their Sponsor-clients interpreted the Part D Regulations as requiring Defendants to perform all concurrent DUR are inapposite. Primarily, Plaintiff argues that "[i]n multiple emails from April 2007 to Mr. Jeswald, who was then Defendants' Manager of Pharmacy Performance, discussing Caremark's concurrent DUR edits, 'Age/gender related contraindications' is identified as one of the 'CMS Required Concurrent DUR Edits.'" (Pl.'s Reply Br. 33.) Nothing in that email, however, indicates that Caremark believed that it had to personally perform such required DUR. Indeed, in that same email, it is noted that Caremark must "[p]rovide communication to participating pharmacies ensuring Drug-Allergy contraindications are reviewed as per the CMS 'musts' for concurrent DUR requirements" because it was difficult to do at the PBM level, thereby acknowledging that some edits are, in fact, performed at the pharmacy level. (Id. at Exs. 3-2, 4-1.)

Plaintiff also relies on a September 2006 email from Jeff Lawson, Defendants' Clinical Director, wherein he asked multiple Caremark employees: "Can either of you help us respond to the client [Sponsor MCS] to help them assure CMS that they are in compliance with the rules regarding patient safety and medication error prevention by using our current POS DUR system that is made up of primarily soft edits." (Samson Decl., Ex. 2-2.) Alan Martin, Defendants AVP of Pharmacy Professional Practice responded, in part: "In talking with Patty Milazzo, we went through our QL DUR system with Coventry and whether they satisfied the CMS rules." (Id., at 2-1.) Although Plaintiff asks that this Court take this evidence as supporting the proposition that MCS contracted with Defendants to perform concurrent DUR including patient safety, a complete review of the documents show that MCS was concerned with whether Defendants' use of primarily soft edits instead of hard edits was in compliance with CMS rules. (Id. at 2-2.) Notably, after Defendants went through the full QL DUR system edits with Coventry, "[i]t was found to be compliant with CMS rules." (Id. at 2-1.) This document therefore suggests that Defendants' own concurrent DUR, which did not include the drug gender edit, was sufficient to meet CMS rules.

rendered worthless services for purposes of a False Claims Act claim. Upon thorough consideration of the parties' briefs and the cited evidentiary submissions, the Court finds that no genuine issue of material fact remains to preclude a summary judgment ruling in Defendants' favor.

In advance of the January 1, 2006 implementation date of Medicare Part D, Defendants sent out an Addendum to each of its participating pharmacies to "enable [them] to participate as a Part D dispensing pharmacy." (Defs.' Mot. Summ. J., Ex. 70, at SPCM00309194.) The Addendum stated, in pertinent part, that "[t]o the extent that Provider shall provide Pharmacy Services to a Part D Enrollee, Provider agrees to comply with any applicable Part D requirements for participation in Part D as a dispensing pharmacy." (Id. at SPCM00309195.) Among the obligations accepted by pharmacy were the following:

> Provider agrees to perform its services under this Addendum in a manner that is consistent with Part D and in compliance with the contractual obligations of a Part D Plan Sponsor to CMS.
> . . .
> Provider ***agrees to comply with*** all applicable Federal and State laws, CMS guidance or instructions relating to Part D, and ***any minimum standards for Provider practice established by the States in which Provider is licensed.*** Pharmacy agrees to comply with all applicable State and Federal privacy and security requirements, including the requirements set forth in 42 C.F.R. § 423.136, the Privacy Rule, Security Rule, and Transactions Standards.
> . . .
> Pharmacy agrees to submit Claims to Caremark's real-time claims adjudication system.
> . . .
> Provider ***agrees to implement such utilization management and quality assurance programs, including concurrent drug utilization review, generic substitution and/or therapeutic interchange programs, as Caremark may require, and as consistent with and in compliance with 42 CFR § 423.153(b), (c) and (d).*** Pharmacy agrees to offer patient counseling to Part D Enrollees, where appropriate and/or required by law.

(Id. (emphasis added).) In addition, the Pharmacy agreed that Caremark, on its own behalf and on behalf of any Part D plan Sponsor, could monitor the performance of Provider on an ongoing basis. (Id.) In 2007, Caremark released an updated Provider Manual containing these same terms. (Defs.' Mot. Summ. J., Ex. 71.)

By imposing such obligations on the pharmacies, Defendants intended to—and did in fact—explicitly delegate the responsibility for conducting DUR as specified under 42 C.F.R. § 423.153(b), (c), and (d) to the contracting pharmacy. Vice President of Network Business Services at CVS Health Incorporated (f/k/a CVS Caremark Corporation), Brian Correia, indicated that compliance with the terms of the Part D Addendum was a condition of pharmacies' participation as dispensing pharmacies within the Part D Network and that this Addendum was a document through which Caremark imposed Part D-specific obligations on its network pharmacies. (Defs.' Mot. Summ. J., Ex. 154, Decl. of Brian Correia ("Correia Decl.") ¶¶ 6, 10.) Caremark understood this Part D Addendum as imposing two distinct DUR-related requirements: (1) a requirement that before each Part D prescription was dispensed, the dispensing pharmacy would perform the DUR specified in 42 C.F.R. § 153(c)(2), including, at a minimum, each component of the review listed in subsections (i)–(vii) of the regulation; and (2) a requirement that before each Part D prescription was dispensed, the dispensing pharmacy also would perform any additional DUR required by Caremark on behalf of its client Part D Sponsors that exceeded the minimum standards of 42 C.F.R. § 423.153(c)(2).[39] (Id. ¶ 11.) Mr. Correia

[39] Plaintiff offers a tortured interpretation of the sentence in the Addendum requiring the pharmacies to implement concurrent drug utilization review. First, Plaintiff contends that, by its plain language, this sentence only requires pharmacies to implement DUR "as Caremark may require," which, according to Plaintiff, is permissive and does not mandate that network pharmacies perform concurrent DUR. Simple rules of grammar, however, suggest otherwise.

also indicated that, in 2006 through 2007, Caremark routinely audited its network pharmacies to monitor the pharmacies' compliance with regulatory standards and contractual obligations, including compliance with the Part D Addendum, and these audits showed that the pharmacies generally were performing DUR in accordance with their contractual obligations, Part D requirements, and state pharmacy standards. (Id. ¶¶ 13, 15.) Dena Rus, the Senior/Vice President of Medicare Program Services for Caremark from 2005 until 2013, likewise concurred that Caremark intended, through this Addendum, to comply with any obligation it assumed from its Sponsors under Section 423.153(c)(2), and that participating pharmacies that agreed to this Addendum were at all times obligated to perform Part-D compliant DUR without the need for any further instruction or action by Caremark.[40] (Defs.' Mot. Summ. J., Ex. 155, Decl. of Dena

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Taking out the modifier phrase separated by commas, the sentence reads that "Provider agrees to implement such utilization management and quality assurance programs . . . as Caremark may require, ***and***, as consistent with and in compliance with 42 C.F.R. § 423.153(b), (c), and (d)." A plain interpretation of the well-drafted language indicates that the pharmacies had to provide utilization management and quality assurance programs (such as DUR) both (a) as Caremark may require and (b) as required by the regulation. To read the phrase "as Caremark may require"—as Plaintiff urges—as modifying the entire provision is simply inconsistent with any grammatical interpretation.

Plaintiff also contends that requiring pharmacies to "implement" concurrent DUR is not the same as the requirements of § 423.153(c)(2), which requires that the pharmacies "perform" DUR. Again, a plain reading of this language leaves no room for a pharmacy to simply not perform the mandated DUR, particularly given the fact that it would have no entity to which to delegate it.

[40] Plaintiff argues that Mr. Correia and Ms. Rus do not cite a single document to support the statements in their Declarations. At the summary judgment stage, however, Defendants need only show that Plaintiff has not produced any evidence to create a genuine issue of material fact as to the veracity of his FCA claims. Defendants do not need to support the Declaration with any underlying evidence. Rather, the burden falls on Plaintiff to produce evidence that would allow a reasonable jury to find in his favor. He has not done so.

In addition, Plaintiff claims that Defendants must offer an explanation as to why there is no documentation showing that Defendants advised their Sponsor clients that the pharmacies were performing the requiring concurrent DUR as specified in 42 C.F.R. § 423.153(c)(2).

Rus ("Rus Decl."), ¶ 6.)

In addition to imposing obligations on the pharmacies through the Addendum, Defendants did, in fact, implement their own automated concurrent DUR Services for point of sale claims as part of the claims adjudication process. The evidence reveals that Caremark delivered DUR Services through a standard package of electronic safety edits on three adjudication platforms (RECAP, RxClaim, and QL), and allowed Sponsors to customize those edits, either adding additional ones or removing some of the standard ones. During the relevant period in this case, each of the three platforms purported to offer edits for drug-to-drug interaction, therapeutic duplication, high drug doses, low drug doses, drug-age contraindications, and early refills. (Defs.' Statement of Undisputed Facts ¶ 416; Pl's Resp. Defs.' Statement of Undisputed Facts ¶ 416.) These categories correspond with most of the categories listed in 42 C.F.R. § 423.153(c)(2)(i)–(vii), with the obvious exclusion of the drug-gender contraindications edit. In addition, every client on the RxClaim platform actually included, as part of its standard package, a "soft" drug-gender edit,[41] except for MCS, which included a hard-edit.[42] (Defs.' Mot.

Plaintiff, however, points to no evidence showing that Defendants should have or were required to inform their Sponsor clients precisely how they were ensuring compliance with the regulations. Indeed, it does not seem odd that Caremark did not attempt to shift blame for any errors to its participating pharmacies, but rather attempted to resolve quality control issues on its own.

[41] Plaintiff disputes this fact, citing to audit communications between Sponsor client Harris Corporation and Caremark, wherein Harris noted that Caremark adjudicated some "claims that may be inappropriate" for the patient's gender. (Traina Decl., Ex. 53–8.) Caremark responded that "[Caremark] does not apply sex/gender edits as a standard edit." (Traina Decl., Ex. 106-17.) Whether or not Caremark included sex/gender as one of its standard edits on the RxClaim platform, however, has no bearing on whether all of Caremark's clients on that platform actually had that edit, either as a soft edit or a hard edit.

Plaintiff also asserts that a "drug-sex" edit is not the same as a "drug-gender" edit. As Plaintiff does not explain the difference, and the Court cannot discern any, the Court disregards

Summ. J., Ex. 113, at ex. 1.)

4. Summary of Gender DUR Claim

Given these undisputed facts, the Court must find that Defendants fully complied with their obligation, under 42 C.F.R. § 423.153(c)(2), to ensure concurrent DUR for gender contraindications. By its plain terms, the regulation applies specifically to Part D Sponsors—*i.e.*, Defendants' clients. Yet, CMS explicitly recognized that Part D Sponsors needed only to "implement," not perform, these quality assurance systems including concurrent DUR; that they would delegate many of these functions to downstream entities; and that pharmacies were often in the best position—given their direct contact with the prescribers and their expertise—to perform these quality assurance measures. In keeping with these mandates, Defendants' Part D Sponsor clients contracted with Defendants to administer the Part D prescription drug benefits and required Defendants to comply with all CMS requirements imposed on Part D plan Sponsors. Although those contracts also required that Defendants provide some automated concurrent DUR services, they did not specify—except in extremely limited circumstances—precisely what DUR edits would apply. When doing so, Defendants expressly informed the Part D Sponsors that Defendants' highly automated systems would rely on pharmacies to perform prescription-specific reviews and would not override the pharmacies'

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this argument.

[42] Interestingly, as Defendants point out, the RxClaim platform processed the prescriptions for the majority of Caremark's Sponsor-clients and adjudicated thirty-nine percent of the prescriptions that Plaintiff contends were improperly given to the wrong gender. This fact would indicate that Defendants personally provided the concurrent DUR for gender contraindications on many of the alleged false claims, but that the pharmacies overrode the soft edit at the point of sale.

judgment

Thereafter, under a reasonable reading of both the regulation and their Sponsor contracts—and operating under the CMS-recognized fact that pharmacies are in the best position to provide quality assurance measures—Defendants issued an Addendum to their participating pharmacies explicitly requiring them to implement concurrent DUR as mandated by CMS. In addition, Defendants audited their pharmacies for compliance, and then supplemented the pharmacies' review with its own concurrent DUR, which included most of the items in the CMS regulations, but for (in most cases) the drug-gender edit. In the final analysis, the approach was generally effective to ensure the drug-gender edits were being performed. Plaintiff's expert identified only 0.014% of 114 million prescriptions filled that involved a gender-specific drug being prescribed to the opposite gender.[43] Among those claims, Plaintiff has not identified any PDE where the drug dispensed, albeit gender-specific in nature, was improperly prescribed to the particular patient for a medically-acceptable purpose or was against the professional judgment of both the physician and the pharmacist.

Ultimately, it is well established that to establish a prima facie case under the FCA, the plaintiff must prove, among other things, that "the defendant knew the claim was false or fraudulent." U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr., 495 F.3d 103, 109 (3d Cir. 2007) (quotations omitted). Yet, Plaintiff has produced no evidence to suggest that any

[43] Plaintiff identifies 15,083 PDE claims (out of the 114,125,392 unique PDE claims generated by Defendants in 2006 and 2007) that were for drugs that were gender-contraindicated, meaning that those drugs were allegedly used "exclusively" in the gender that was opposite to that of the Medicare beneficiary who received the drug. Each PDE in the Gender PDE Set involves one of seventeen different drugs that, according to Plaintiff's expert were either "Male Exclusive" or "Female Exclusive."

submission of gender contraindicated claims by Defendants was done knowingly or even with reckless disregard of its obligations. CMS specifically remarked that it was only providing "minimum standards" for quality assurance measures and systems, while "giving plans flexibility to design such measures and systems." 70 Fed. Reg. 4194-01, 4278. The Part D Sponsors, in this case, delegated that responsibility to Defendants, who, in turn, implemented such measures and systems in a multi-faceted manner through a combination of re-delegating the required concurrent DUR to its participating pharmacies, auditing those pharmacies for compliance with CMS's regulations, and conducting its own, broad-based DUR. In light of the lack of specificity in the regulations as to how the requisite quality assurance and safety measures were to be implemented, the Court cannot find that Caremark's method of conducting its concurrent DUR obligations under the regulations constitutes a violation of any federal rule. As the evidence of record would simply not allow any reasonable juror to find that Defendants rendered worthless services by failing to personally conduct concurrent DUR for gender contraindications,[44] Defendants' Motion for Summary Judgment on this ground is granted.

C. Expired Drugs

Plaintiff's third and final "nationwide" claim concerns Defendants' approval of claims that were for allegedly expired drugs. Specifically, Plaintiff alleges that Defendants violated the False Claims Act by knowingly approving thousands of Medicare Part D claims for drugs where the information in their possession indicated that those drugs had passed the shelf-life expiration date of the last-batch of the drug produced by its manufacturer, *i.e.* the "last-batch shelf-life

[44] In light of this finding, the Court does not address Defendants' argument that any failure by Caremark to provide a drug gender edit rendered its entire bundle of services "worthless."

expiration date" or the HCFA Termination date.[45]

This claim is premised on 42 C.F.R. § 423.153(c)(1), which, aside from imposing concurrent DUR obligation on Sponsors and their PBMs, requires that Sponsors and their PBMs create "quality assurance measures and systems" that include the "representation that network providers are required to comply with minimum standards for pharmacy practice as established by the states." Based on that provision—and some of the interpretive statements from CMS—Plaintiff now draws the broad inference that, in 2006–2007, Defendants were required to deny claims for drugs that had passed the shelf-life expiration date of the last-batch of that drug produced by its manufacturer—thereby presenting a safety risk to Medicare beneficiaries. He asserts that, in that time frame, Defendants had the tools, experience, and capability to identify Part D claims for drugs that had passed their last-batch shelf-life expiration date, and then to act upon that information to protect the safety of Medicare beneficiaries whose drug-benefit they managed. According to Plaintiff, notwithstanding Defendants' use of the First Databank NDDF file for claims processing and their obligation to provide a quality assurance program, Defendants did not deny claims for drugs that had passed their last-batch shelf-life expiration date, but rather focused on whether the drug being dispensed was past its so-called "obsolete date"—which was an internal date created by Defendants by adding two or three years to the drug's "inactive date" (when the drug manufacturer stopped producing the drug using a particular NDC number). As a result, Plaintiff claims that, in 2006 and 2007, Defendants

[45] As described above, the HCFA Termination Date is "an eight-character numeric column that contains the shelf-life expiration date of the last batch of produce produced, as supplied on the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) quarterly update. The date is supplied to CMS from the drug labeler. The date is CCYYMMDD." (Defs.' Mot. Summ. J., Ex. 112, ¶ 12.)

approved 87,083 Part D claims for drugs that were dispensed after their last-batch shelf-life expiration date. Such approvals, according to Plaintiff, violate the FCA under a worthless services theory by neglecting to manage the prescription drug benefit for their Part D Sponsor clients, which included, but was not limited to: (1) establishing and operating a pharmacy network; (2) adjudicating Part D claims submitted by pharmacies within their network; (3) performing concurrent DUR before every Part D prescription was dispensed; (4) establishing the quality assurance program mandated by the Part D regulations; and (5) complying with all laws applicable to its contracts and the services it provided.

Plaintiff's claim, however, fails on multiple grounds. **First**, the applicable regulation—42 C.F.R. § 423.153(c)(1)—merely requires that a Sponsor, and its PBM, "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. . . . [and] (2) Concurrent drug utilization review systems, policies, and procedures." Id. As to the latter requirement, Plaintiff concedes that he does not rest his claim on DUR screening for expired drugs, (Pl.'s Sur-reply Br. 53)—nor could he, given the absence of any such edit in the regulations or other guidance from CMS.[46]

[46] Indeed, Plaintiff's own expert, Craig Stern, stated that "expired drugs are not part of drug utilization review; they're part of standard pharmacy practice. . . . Concurrent drug utilization review is not the same as looking at expired drugs. One is a service—drug utilization review is a service that has to deal with specific areas and in drawing the scope of problems." (Defs.' Mot. Summ. J., Ex. 18, Dep. of Craig Stern ("Stern Dep."), 82:3–19.) Rather, Mr. Stern conceded that pharmacies and pharmacists have a responsibility to screen for expired drugs, as imposed upon them by the state pharmacy laws. (Id. at 85:20–23.)

To the extent Plaintiff relies on this Court's statements in the Memorandum denying Defendants' Motion to Dismiss, it is crucial to note that the Court was bound to accept Plaintiff's

With respect to the first requirement of the regulation, Defendants, as set forth in detail above, expressly required—through their Part D Addendum—that their network pharmacies "comply with . . . minimum standards for Provider [pharmacy] practice established by the States." Such a contractual obligation satisfies in full 42 C.F.R. § 423.153(c)(1), since it not only tracks the language of the regulation, but it comports with CMS's desire "not to create a new Federal standard for pharmacy practice," and to defer to the States for regulating the practice of pharmacy. 70 Fed. Reg. 4194-01, 4278. In other words, by requiring its participating pharmacies to comply with state law, Defendants were effectively ensuring that the screening for expired drugs was performed at the pharmacy level.[47]

Second, Plaintiff's reliance on Chapter 9 of the Prescription Drug Benefit Manual as imposing some sort of obligation on PBMs to deny claims based on the HCFA Termination Date is inapposite. Plaintiff cites to the section entitled "Claims Processing System

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well-pled allegations as true. The Court also went on to remark that, "[u]ltimately, 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." U.S. ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 166 (E.D. Pa. 2012).

[47] Plaintiff argues that one of the examples of "Pharmacy Fraud" highlighted by CMS, in § 70.1.3 of Chapter 9 of the Medicare Drug Benefit Manual, from the start of the Part D Program was "Pharmacies dispensing drugs that are expired . . . ." (Raspanti Decl., Ex. 4-45.) He reasons that as a Part D PBM, Defendants were responsible for monitoring that problem.

The provision cited by Plaintiff, however, involves "Pharmacy Fraud, Waste and Abuse"—as distinct from § 70.1.2 involving "PBM Fraud, Waste and Abuse"—thus indicating that CMS expected that pharmacies would be the entities screening for expired drugs and any failure to do so was their burden. Moreover, by mandating pharmacy compliance with both state law and federal regulations, Defendants effectively obtained a contractual promise that their pharmacies would not commit such fraud, waste, and abuse.

Recommendations," which states as follows:

> Claims processing systems can be an effective tool for plans to monitor the delivery of the prescription drug benefit. Sponsors should use claims processing systems that can be programmed to recognize various claims components and respond to each recognized component. ***Sponsors should have systems capability to establish an edit on a given provider and use that edit to automatically deny a claim or suspend payment on a claim when appropriate.***
>
> Examples of edits include but need not be limited to:
> - Controls on early refills outside of long-term care settings.
> - Limits on the number of days before a refill is permitted outside of long-term care settings.
> - Edits to prevent payment for statutorily excluded drugs.
> - Limits on the number of times a prescription can be refilled.
> - Brand name versus generic drugs.
> - Number of prior authorizations.
> - Real time contraindication (e.g. drug-drug interactions).
> - Sex and age edits compared to the drug prescribed.
> - Therapeutic edits.
> - Excessive claims for controlled substances.
> - Insufficient or excessive dosage edits.
> - Step therapy edits.
> - Identifying drugs provided outside of the Part D benefit by Patient Assistance Programs.
>
> System edits may be used to trend billing practices in a certain region by reviewing providers, beneficiaries, etc. within that zip code. Also, editing should be used to review how a provider is prescribing the same drug or very similar drugs by utilizing name brand versus generic and to review utilization patterns to trend the types of prescriptions being used by beneficiaries.

(Defs.' Mot. Summ. J., Ex. 81, at 44 (emphasis added).)

Aside from the fact that this section was aptly entitled, "Claim Processing System *Recommendations*" as opposed to "Requirements," denial of claims with an expired HCFA Termination Date is not even given as an example of an "appropriate" edit. Indeed, the November 2010 OIG report suggests precisely the contrary. At the outset of that report, OIG

noted that "[s]tate pharmacy practice statutes and regulations generally prohibit or limit dispensing drugs after their expiration dates. Although CMS has issued guidance to States prohibiting payment for terminated drugs under Medicaid, ***no guidance or regulation prohibits payment for terminated drugs under Medicare Part D***." (Defs.' Mot. Summ. J., Ex. 106, at I (emphasis added).) As such, the Report makes clear that, during the time period relevant to this case, there was no CMS prohibition on dispensing terminated drugs. When OIG proposed that CMS issue regulations to prohibit Medicare Part D coverage of terminated drugs, CMS responded that it believed this issue was well handled by state law and at the pharmacy level, denied that terminated drugs were actually dispensed to Medicare beneficiaries, and noted that use of the HCFA Termination date was "flawed." (Id. at Appendix.) Ultimately, it disagreed with OIG's proposal that CMS issue a regulation prohibiting the payment for drugs past their HCFA Termination Date.[48] (Id.)

Third, Plaintiff's suggestion that Defendants' Sponsor contracts somehow mandated that Defendants screen for drugs past their HCFA Termination date is inaccurate. He asserts that these Sponsors "turned to Defendants, one of the largest and most experienced PBMs in the United States, to 'participate in the management of their Part D Plans,'" . . . and "[i]n turn,

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[48] Plaintiff suggests that because the CMS comments were not made until 2010 that: (1) they were not reflective of CMS's position in 2006–2007 and (2) Defendants were not aware of this position. Neither of these concerns are valid. CMS's comments suggest that they have never deemed the HCFA an appropriate indicator of expiration and have always relied on pharmacies to screen for expired drugs; they make no suggestion that their comments represent a change in position. As to Caremark's knowledge, Plaintiff points to no guidance that would indicate that CMS ever told PBMs or Sponsors that screening should be done on the basis of HCFA numbers. In fact, Defendants have submitted evidence that CMS was accepting PDEs involving drugs with NDCs that had been deemed obsolete before January 2002. (Defs.' Mot. Summ. J., Ex. 147.) CMS appeared to recognize that as long as the NDC accurately described the dispensed drug, it was not as concerned with whether the NDC itself was obsolete. (Id.)

Defendants expressly promised that they would: establish and operate a pharmacy network; adjudicate all claims (using First Databank information); perform concurrent DUR on all Part D claims; generate PDE claims for submission to CMS; establish a quality assurance program to prevent medication errors; and comply with applicable CMS laws and regulations." (Pl.'s Sur-reply Br. 55.) Plaintiff goes on to argue that, based on such provisions, it is clear that Defendants had an obligation to screen for expired drugs.

This argument, however, falters in Plaintiff's inability to point to any requirement in any of the pertinent contracts showing that Part D Sponsors expected that Caremark, as a PBM, would deny claims for drugs past their HCFA Termination Date. Plaintiff does not attempt to argue that Defendants utterly failed in their duties, such as by not participating in the management of the Part D plan or not establishing and operating a network of pharmacies, but rather simply claims that Defendants have not performed a specific task that Plaintiff believes is subsumed within such contractual duties. Yet, Plaintiff does not identify any evidence—such as emails, documents, or deposition testimony—indicating that any Part D Sponsor ever intended that screening for expired drugs be included as part of Caremark's contractual obligations. Given this absence of evidence, Plaintiff has failed to meet his burden of establishing a genuine issue of material fact as to Defendants' obligation to screen for HCFA numbers.[49]

[49] Plaintiff makes much of the fact that, in 2006 and 2007, Defendants approved more than 87,000 claims where the First Databank information in their possession indicated that their network pharmacies were dispensing drugs to Part D beneficiaries after the shelf-life expiration date of the last-batch of drugs ever produced. Aside from the fact that this number represents only 0.076% of the total adjudicated claims in 2006–2007, Plaintiff fails to produce any evidence that any of the drugs dispensed in those claims were actually expired or, in any way, a health risk—thereby lending support to general understanding that the HCFA Termination date was not necessarily a reliable indicator of expiration. Indeed, looking retrospectively in 2010, CMS affirmatively stated that it did not believe that "pharmacies dispensed, and Medicare beneficiaries

Finally, even to the extent Defendants could be found to have had an obligation to screen for expired drugs, Plaintiff has failed to put forth any evidence indicating that Defendants *knowingly* submitted claims with expired HCFA Termination dates. Plaintiff points to no evidence that Defendants believed that they had such an obligation. Nor does Plaintiff identify evidence showing that Defendants should have understood that this obligation existed..

Plaintiff makes much of the disputed fact that Defendants' QL platform edited, in real time, mail service and retail pharmacy claims that were "Filled after termination date" and "Filled after expiration date." (Traina Decl., Ex. 51-10.) Inferring from this document that Defendants had the capability to detect a potential problem with the expiration of the drugs, Plaintiff asserts that Defendants effectively adopted a "head in the sand" approach by failing to screen for this problem. The document on which Plaintiff relies, however, purports to have been last updated in October 2003, and does not clearly reflect the QL platform's capabilities in 2006 and 2007. Even if Defendants had the capability to screen for expired HFCA codes, however, it is undisputed that Caremark understood "from industry experts and CMS, themselves" that the HCFA date was "not to be relied upon in terms of an expiration date of products on a shelf. It is a Medicaid rebate reimbursement date." (Smith Dep. 153:22–154:5.) Caremark's Rule 30(b)(6) representative went on to note that, in 2006 and 2007, the industry did not have a reliable product for a PBM to determine, at the point of adjudication, if there was expired product on the

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received, outdated drugs" and it "rarely [saw] evidence to indicate that pharmacies are dispensing outdated drugs to Medicare beneficiaries and [it] believe[d] that pharmacists generally adhere to the practice of dispensing drugs that are not outdated." (Defs.' Mot. Summ. J., Ex. 106, Appendix.) Absent a showing that at least some of those drugs were expired, Plaintiff cannot create an issue of fact as to whether Defendants have failed in their duties to establish quality assurance programs.

shelf. "It is the responsibility of the pharmacist." (Id. at 158:15–22.) This understanding is supported by CMS's own understanding in 2010 that use of the reported expiration date of the last lot of drugs produced does not correlate with the actual expiration date of the drug and that these dates are often subject to change, often by more than a year. (Defs.' Mot. Summ. J., Ex. 106, App. A.) CMS further noted that use of that data to determine if outdated drugs are being dispensed is "flawed" and simply did not reflect that outdated drugs were being dispensed. (Id.)

In sum, the evidence of record clearly establishes that screening for expired drugs was not part of a Part D Sponsor or PBM's role. Rather, as CMS itself repeatedly made clear, that process was to be done at the pharmacy level since there was no reliable way for it to be done at the PBM level as part of the PDE record. To the extent the PBMs and Sponsors had access to the NDC codes or HCFA Termination dates, those dates were not deemed reliable indicators of a drug's expiration date and CMS opposed any use of those dates as a basis for denying beneficiaries' access to prescriptions. Consistent with this understanding, none of Defendants' Sponsor contracts mandated that Defendants perform any type of screen for obsolete HCFA Termination dates and made no suggestion that Defendants' responsibility for quality and safety included this type of screening. Finally, Plaintiff has not produced any evidence that any of the alleged problematic claims—wherein the drug dispensed was past its HCFA Termination date—involved drugs that were actually expired. Accordingly, the Court finds no genuine issue of material fact that precludes the entry of summary judgment in favor of Defendants on this claim.[50]

[50] Having dismissed this claim for Plaintiff's failure to show that Defendants' knowingly violated any CMS regulation, the Court need not address Defendants' argument that they did not provide "worthless services."

D. MAC Pricing

Plaintiff's remaining three FCA claims center only on PDEs submitted by Defendants with respect to Defendants' contract with MCS, and are not alleged on a nationwide basis. With respect to the first claim—MAC pricing—Plaintiff alleged that Caremark "intentional[ly] and fraudulent[ly] failed to provide MCS the benefit of maximum allowable cost , , , pricing that MCS and Caremark had negotiated, which allegedly caused Part D beneficiaries to pay a higher co-pay and MCS to report higher Part D costs to CMS on the PDE record." (First. Am. Compl. ¶ 318.)

As noted above, pursuant to Part D regulations, Part D Sponsors (such as MCS) must provide their enrollees with the benefit of "negotiated prices" for all Part D drugs dispensed. 42 C.F.R. § 423.104(g)(1). Under the MCS-SilverScript contract, MCS negotiated for the Maximum Allowable Cost ("MAC") for generic drugs to be dispensed to those enrolled in the MCS Part D plan. Pharm/DUR's audit found that SilverScript fraudulently failed to apply MAC pricing to all of the MAC drugs, affecting 3,658 pharmacy claims on behalf of MCS. 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.) Plaintiff's sole evidence in support of this argument is the Pharm/DUR updated Audit Report detailing 3,658 claims that were allegedly adjudicated by Defendants during 2006 without applying the proper MAC pricing.

Defendants now claim that they are entitled to summary judgment on this claim for several reasons. First, Defendants contend that Caremark did not overcharge MCS, which is the factual premise of Plaintiff's pricing theory. Absent an overcharge, Defendants assert that

Plaintiff cannot possibly prove a "false" claim. The Court agrees. As discussed in detail above, Pharm/DUR's Initial Report claimed that Caremark failed to provide MCS the benefit of MAC pricing for 33,400 paid pharmacy claims, and valued the finding at $704,392.08 owed to MCS. Caremark's Initial Response stated that "Pharm/DUR utilized the MAC list provided by MCS to perform their analysis, not the Caremark MAC list. Additionally, drugs are frequently added and removed from the MAC list." (Defs.' Mot. Summ. J., Ex. 26, at SPCM00165796.) Caremark went on to note that although it was not provided claim level detail, a high level review of the discrepancies determined that 3,235 or 10% of the samples were claims adjudicated at the Usual and Customary (U&C) amount. (Id. at SPCM00165797.) On April 20, 2007, counsel for Defendants provided the SilverScript Part D MAC list to MCS who, in turn, provided it to Pharm/DUR. Thereafter, in its Amended Report, Pharm/DUR reprocessed its MAC finding and reduced the claimed discrepancies by 89%, from 33,400 claims (for $704,392.08) to 3,658 claims (for $105,141.80). In its Final Audit Response, Caremark reviewed the top 25 NDCs involved in the 3,658 claims and concluded that the company had charged MCS the appropriate price. In its Final Updated Audit Report, MCS stated the following regarding the MAC issue: "MCS will not pursue further action related to this finding" and it considered the issue "closed." (Defs.' Mot. Summ. J., Ex. 29, at MCS-000056319–330.) When asked to explain MCS's decision to not pursue any further actions, MCS's corporate designee testified as follows:

> A. MCS review[ed] the files provided by Pharm/DUR and we encountered two errors. Number one, we provide[d] Pharm/DUR the incorrect MAC list. We have different MAC list[s], one for commercial business and one for Medicare. So that was the first error. We provide[d] the commercial MAC list instead of the—the Medicare MAC list.

> The second error is that we did not provide the updates that [the] MAC list could be subjected [to] on a monthly basis.

(Rodriguez Dep. 443:3–16.) She further indicated as follows:

> Q. Is it fair to say that MCS chose to not pursue further action related to MAC pricing?
> A. That's correct.
> Q. What was the basis for that decision?
> A. The MAC list is a very complex process. It contains a lot of NDCs. And for reviewing that, you need to consider a lot of things, such as that the MAC software changes constantly, month by month, and you can be doing assumptions of incorrect pricing if you do not review the updated list.
> . . .
> Q. Was it MCS's understanding, Ms. Rodriguez, as of October 2008 that Caremark had appropriately administered MAC pricing in the context of the existing Caremark MCS contract for the 2006 time period?
> A. Correct, yes.

(Id. at 65:7–66:12.)

Pharm/DUR's Rule 30(b)(6) designee[51] concurred and testified that Pharm DUR miscalculated its MAC finding based on a truncation error from a missing digit in the prices on the MAC list. (O'Brien Dep. 101:1–106:24.) She agreed that this error significantly impacted the amount of recoverable funds from the audit. (Id.) Plaintiff, Anthony Spay, also indicated that the error resulted from Pharm/DUR "[leaving] off a couple of numbers before the decimal point." (Spay Dep. 222:17–223:15.)

Plaintiff now asserts that genuine issues of material fact exist because he believes that Pharm/DUR in fact used the correct "Caremark Part D MAC list," which was provided by

[51] Plaintiff has argued that Pharm/DUR's Rule 30(b)(6) deponents had "limited" knowledge of Pharm/DUR's business. Both of these witnesses, however, personally participated in a significant manner in the Pharm/DUR audit of MCS in 2007. (O'Brien Dep. 32:20–33:3, 40:5–24; Briggs Dep. 23:2–24:15, 46:8–20.) Moreover, under Rule 30(b)(6), their testimony is binding on Pharm/DUR as a matter of law.

Caremark's attorney.[52] He goes on to note that after Defendants were alerted by MCS and Pharm/DUR in September of 2007 that Pharm/DUR had used the correct Caremark MAC list for Part D, Defendants responded in December of 2007 to the Pharm/DUR audit, but never refuted that Pharm/DUR had used the correct MAC list. During the course of this litigation, Defendants then resurrected the idea that Pharm/DUR used the wrong MAC list in 2007 when it concluded its audit. Therefore, Plaintiff asserts that summary judgment on the MAC pricing issue is not appropriate because an issue of material fact remains as to whether Plaintiff's allegations are based on the correct Part D MAC list.

Plaintiff's argument misunderstands his burden of proof. Plaintiff cannot simply create a genuine issue of material fact by his mere beliefs—refuted by testimony from Pharm/DUR and MCS employees—that (1) a correct list *might* have been used; (2) the missing monthly updates to the list had no impact on the audit; or (3) the truncation errors by Pharm/DUR were inconsequential.[53] Rather, in response to a motion for summary judgment, he must produce

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[52] Plaintiff makes much of the fact that, on April 20, 2007, in connection with the audit, it was Caremark's attorney that provided Pharm/DUR with "a SilverScript MAC list for Med D pricing and drugs." (Traina Decl., Ex. 35.) She represented that "[t]he list is for the timeframe of 1/1/2006 to 4/19/2007. This list should be the information that you need to verify that GER was correctly and accurately calculated." (Id.) As the above testimony makes clear, however, that list did not include any of the monthly "updates" that were so common. Moreover, as Pharm/DUR admitted that it made a "clerical error" that impacted its findings, the burden now falls on Plaintiff to establish that Defendants still made overcharges notwithstanding that error.

[53] Plaintiff asserts that the simple fact that both MCS and Pharm/DUR acknowledged that Caremark properly adjudicated claims in accordance with CMS's pricing terms is "not relevant to whether Plaintiff, Anthony Spay, disputes such facts." (Pl.'s Resp. Opp'n Mot. Summ. J. 160 n.93.) Plaintiff, however, cannot simply avoid summary judgment by disputing such facts without the support of some viable evidence, particularly in the face of the substantial contrary evidence produced by Defendants. Despite Plaintiff's protestations otherwise, the record does not involve competing evidence requiring credibility determinations; rather the record reflects undisputed evidence that no MAC pricing errors were made.

evidentiary proof that shows that Pharm/DUR used the correct MAC list and that, based on that list, Defendants failed to charge the MAC pricing on some claims. Plaintiff's sole evidence of improper MAC pricing, however, is the Pharm/DUR audit report, which, by all accounts, was based on both the use of an incorrect list without the proper monthly updates and Pharm/DUR's improper truncation of numbers on that list. Contrary to Plaintiff's belief, there is no question of fact remaining for a jury to decide.

Moreover, even if Plaintiff had produced some evidence that Defendants failed to apply the proper MAC price to the 3,658 claims identified in the Pharm/DUR report, Plaintiff neglects to establish the third element of an FCA claim: that Defendants knowingly presented a false or fraudulent claim. U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011). As noted previously, the FCA's scienter requirement is satisfied if the defendant: (1) has actual knowledge that the claim is false; (2) acts in deliberate ignorance of the truth or falsity of the claim; or (3) acts in reckless disregard of the claim's truth or falsity. 31 U.S.C. § 3729(b)(1)(A). In the present case, Plaintiff's only evidence that Defendants acted with knowledge is "Defendants' denial that they applied the prices reflected in Plaintiff's MAC claims report as a result of a mistake or negligent conduct." (Pl.'s Reply Br. 64.) In other words, he asserts that Defendants' denial of wrongdoing automatically creates the inference that Defendants knowingly committed wrongdoing. This allegation, however, would allow an inference of knowledge to be presumed every time a defendant maintained its innocence in the face of FCA charges, even where that defendant held a genuine belief that it had not acted wrongfully. In the context of this case, Defendants' firm denials that they failed to apply MAC pricing—especially in light of the record evidence clearly indicating that they did not commit

any violation—allow only for the inference that they did not knowingly avoid their pricing obligations. Given Plaintiff's failure to adduce a single piece of evidence reflecting Defendants' knowledge in this regard, the Court cannot find that Plaintiff has met his summary judgment burden.

Ultimately, the undisputed facts of record reveal that Pharm/DUR's audit as to MAC pricing was based on faulty data and clerical errors. This fact was expressly admitted both by Pharm/DUR employees involved in the audit and employees of MCS, on whose behalf the audit was performed. To the extent an error by Defendants could be found—which it cannot—the record is devoid of evidence that Defendants had the requisite scienter for purposes of an FCA claims. Accordingly, Defendants' Motion for Summary Judgment on this claim is granted.[54]

E. Prior Authorizations

Plaintiff's fifth claim—which also involves only PDEs filed on behalf of MCS—asserts that Defendants improperly submitted claims for drugs that required prior authorizations. CMS's Instructions for submitting prescription drug event data define 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***." (Raspanti Decl., Ex. 5-35.) 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

[54] As this claim is dismissed on other grounds, the Court need not discuss Defendants' argument that Plaintiff has failed to produce any evidence that any Caremark or MCS certification was ever presented to CMS.

formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal.").

According to Plaintiff's Amended Complaint, the MCS formularies at issue required prior authorization before dispensing Tier 2 and Tier 4 drugs, yet Defendants permitted participating pharmacies to dispense drugs without required prior authorizations and illegally paid these claims. 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.

As set forth above, in its Initial Report of July 11, 2007, Pharm/DUR indicated that there was no "MCS intervention to preauthorized payment" for 819 "Tier 2" Formulary claims and 14,840 "Tier 4" Formulary claims, in a total amount of $2,857,529.52. (Defs.' Mot. Summ. J., Ex. 25, at SPCM00089904-5.) Caremark responded as follows:

> [Caremark] responded to 510 (over sixty percent) of the Tier 2 discrepancies and noted the following:
> - Three Hundred Twenty Five (325) of the samples determined the plan did not require a prior authorization.
> - One hundred seventy (170) of the samples indicate a prior authorization was obtained for the drug.
> - Fifteen (15) of the samples were filled under a transition plan which has no prior authorization limits.
>
> These edits are in place for Tier 2 and Tier 4 drugs. [Caremark] will provide the sample responses and support under separate cover. It is our view that we are in compliance with the plan design, these claims adjudicated correctly and there is no material financial discrepancies related to this finding.

(Defs.' Mot. Summ. J., Ex. 26, at SPCM00165178.) Caremark provided no comment as to any of the Tier 4 claims.

Pharm/DUR's Rule 30(b)(6) representative testified that Caremark's Initial Response was

correct with respect to the 170 claims that had received prior authorization from MCS and the 15 claims filled under a transition plan. When MCS and Pharm/DUR issued the Amended Report in September 2007, the Report verified Caremark's response and removed the 170 claims that had received prior authorization and the 15 claims filled under beneficiaries' transition plans, thereby reducing the Tier 2 prior authorization finding from 819 claims to 633 claims, but not addressing any of the Tier 4 prior authorization findings.

Caremark's final response reviewed 571 of the 633 Tier 2 claims cited in MCS's and Pharm/DUR's Amended Report and concluded that there were no financial discrepancies related to this finding. (Defs.' Mot. Summ. J., Ex. 28, at SPCM00225809.) MCS sent Caremark a Final Report on September 30, 2008 confirming that MCS had authorized payment for all but eighty-seven Tier 2 claims, and asking Caremark for further information about those claims. (Defs.' Mot. Summ. J., Ex. 29, at MCS-000056325.) No further information was exchanged on these claims and MCS did not seek payment or recoupment relating to the prior authorization issue.

Defendants now assert that they are entitled to summary judgment on this claim for two independent reasons. Primarily, they contend that the record forecloses a finding of "worthless services." To succeed on a worthless services theory of falsity, Plaintiff must establish that Caremark's performance of its services was "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); see also Mikes v. Straus, 274 F.3d 687, 703 (2d Cir. 2001). Recently, the Seventh Circuit noted that "it is not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for. That is, a 'diminished value' of services theory does not satisfy this

standard. Services that are 'worth less' are not 'worthless.'" U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 710 (7th Cir. 2014).

The factual record of this case does not lend itself to any reasonable inference that Defendants' performance of their DUR services with respect to Tier 2 prior authorizations was worthless. Defendants reviewed 90% of the Tier 2 claims identified by the Pharm/DUR audit as improperly approved without prior authorization. Of those, all but eighty-seven were confirmed to have been properly approved for payment by Caremark. The remaining eighty-seven were inconclusive and MCS ultimately did not seek recoupment for these claims. Even assuming, however, that some of the remaining eighty-seven claims were improperly paid by Caremark without seeking prior authorization, that assumption would allow only the inference that Defendants provided services that are worth some amount less than the services paid for, but were not "worthless." Given that Defendants clearly required prior authorization for most of the Tier 2 claims at issue, no reasonable jury could find that Caremark's performance of this obligation was "so substandard as to be tantamount to no service at all."[55]

This conclusion, however, is not quite as clear cut with the Tier 4 drugs. As noted above, the Pharm/DUR audit alleged that Defendants failed to provide prior authorization services with respect to 14,840 claims during 2006 with a total paid amount of almost $2.8 million. At no point—either during the progression of the Pharm/DUR audit or during this litigation—have

[55] Plaintiff asserts that Defendants must provide a "coherent description of the prior authorization services they allegedly provided." (Pl.'s Sur-reply Br. 65.) This is incorrect. Defendants need only show that Plaintiff has an absence of evidence to support his claims. By demonstrating an absence of evidence establishing Plaintiff's allegations of failure to obtain prior authorizations on Tier 2 claims—and by affirmatively proving that they did obtain such prior authorization— Defendants have met their summary judgment burden.

Defendants ever reviewed any of those claims to prove either their validity or their falsity. To that end, the only evidence of record is Plaintiff's audit asserting that 14,840 claims for Tier 4 drugs did not receive prior authorizations. To the extent Defendants' prior authorizations obligations can be divided by the types of drugs, the Court finds that a genuine issue of material fact remains regarding whether Defendants provided worthless services on Tier 4 drugs.

Nonetheless, analysis of this issue does not end at this juncture. As repeatedly set forth above, the FCA's scienter requirement is satisfied if the defendant: (1) has actual knowledge that the claim is false; (2) acts in deliberate ignorance of the truth or falsity of the claim; or (3) acts in reckless disregard of the claim's truth or falsity. 31 U.S.C. § 3729(b)(1)(A). Congress specifically amended the FCA in 1986 to include this definition of scienter, to make "firm . . . its intention that the [A]ct not punish honest mistakes or incorrect claims submitted through mere negligence." S. Rep. No. 99-345, at 7 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5272. Because Plaintiff bears the burden of proof in establishing the elements of a prima facie FCA cause of action against Defendants, Plaintiff must identify evidence that establishes the existence of all three essential elements of an FCA claim in order to withstand Defendants' motion for summary judgment. U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr., No. Civ.A.01-4078, 2005 WL 3542471, at *4 (D.N.J. Dec. 23, 2005). As such, Plaintiff "must provide the court with evidence demonstrating that Defendants acted knowingly, recklessly or with deliberate ignorance in submitting or causing to be submitted to the government a false or fraudulent claim for payment that caused the government economic loss." Hefner, 2005 WL 3542471, at *4 (citing U.S. ex rel. Watson v. Conn. Gen. Life Ins. Co., No. Civ.A.98-6698, 2003 WL 303142, *4 (E.D. Pa. Feb. 11, 2003)). "If [Plaintiff] is unable to provide evidence sufficient

to establish the existence of each of these elements, Defendants will be entitled to summary judgment on [Plaintiff's] FCA claim." Id.

It is at this element that Plaintiff fails to meet his burden. Defendants contend that even to the extent they erroneously approved payment for a prescription that should have received a prior authorization, Plaintiff has no evidence that this error occurred because of an intentional disregard of Defendants' obligations. Rather, according to Defendants, these mistakes—if any—are attributable to mere negligence, which is not actionable under the FCA.

In response, Plaintiff simply contends that:

> As an initial matter, this question of Defendants [sic] intent is a material issue to be resolved by the jury. However, Defendants' argument is undermined by the absence of any record evidence that Defendants admitted to mistakes or errors in performing Concurrent DUR related to prior authorizations. In addition, during the Pharm/DUR audit process, Defendants overtly denied that their concurrent DUR services for Tier 2 and Tier 4 drugs were impacted by "errors." "These edits are in place for Tier 2 and Tier 4 drugs . . . these claims adjudicated correctly." PUFO ¶¶ 444, 461. Thus, at best, genuine issues of material fact remain regarding whether Defendants knowingly failed to ensure that prior authorizations for Tier 2 and Tier 4 drugs, as required by the formulary Defendants created for MCS, were in place before Defendants dispensed Tier 2 and Tier 4 claims as payable Part D drugs.

(Pl.'s Resp. Opp'n Summ. J. 153–54.) Plaintiffs' Sur-reply Brief goes on as follows:

> Plaintiff's Opposition sets forth admissible record evidence demonstrating that Defendants knowingly failed to perform both Tier 2 and Tier 4 prior authorization services. Prior authorizations were a core PBM service and Defendants had superior ability (as well as the sole opportunity) to identify Tier 2 and Tier 4 claims on the MCS formulary (which Defendants created, maintained, and charged MCS). Moreover, Defendants acknowledged that they were supposed to have "edits in place" as part of these services. . . . Defendants' Reply again ignores Plaintiff's admissible record evidence of their knowing conduct in favor of a simple denial of any wrongdoing. . . . Of course, this is not the standard on summary judgment. At best, Defendants' arguments simply acknowledge the existence of genuine issues of material fact as to Plaintiff's prior authorization claims.

(Pl.'s Sur-reply Br. 67.)

These arguments fail to rescue Plaintiff's claim. As a primary matter, Plaintiff's contention that the question of intent is a material issue to be resolved by a jury only rings true if Plaintiff presents some form of evidence from which a reasonable jury can infer that Defendants acted knowingly, with reckless disregard, or with deliberate indifference. See Watson, 2003 WL 303142, at *8 (E.D. Pa. Feb. 11, 2003) ("Because [plaintiff], the part with the burden of proof in establishing a prima facie FCA claim, has not provided the court with any evidence that [defendant] engaged in any wrongful behavior or that, if it did, it did so with the requisite knowledge for imposing FCA liability, there is no basis on which a rational jury could find that [plaintiff's] allegations of [defendant's] software manipulation are actionable under the FCA."). Plaintiff has not done so. Moreover, Plaintiff's suggestion that Defendants' denial of any wrongdoing somehow constitutes sufficient evidence of scienter to defeat summary judgment is simply incorrect. Plaintiff does not put forth evidence of a singular claim wherein Defendants failed to obtain the required prior authorization and knew or should have known of its failure. Indeed, quite to the contrary, Defendants denied wrongdoing with respect to the Tier 2 claims and then clearly established that it was properly adjudicating those claims. The sole inference to be drawn from this fact is that Defendants held the same belief with respect to the Tier 4 claims, thereby negating any inference of scienter.

In short, Plaintiff has failed to convince the Court that the *possible* submission of Tier 4 claims without the required prior authorization was done either with deliberate ignorance or with reckless disregard of the truth or falsity of the information. While Defendants may potentially—but certainly not clearly—have been negligent in performing their DUR responsibilities to ensure prior authorization, the fact that a substantial number of the allegedly

erroneous claims identified by Pharm/DUR were, in fact, not erroneous at all is more evidence of mistake than knowing or recklessly indifferent submission of false claims. As such, the Court finds that Plaintiff has failed to establish the third element of a prima facie case for filing of false claims under the FCA.

F. Quantity Limits

Plaintiff's final theory of fraud is that Defendants "fraudulently processed" pharmacy claims involving "drugs or days supply over the approved limit." (First. Am. Compl. ¶ 308.) By not denying payment for claims that exceeded the quantity limits, Defendants allegedly caused MCS to report to CMS more costs than appropriate. This claim is also brought under a worthless services theory.

As discussed in detail both in this opinion and the Court's prior opinion, it is well-settled that the MCS-Caremark Agreement required Defendants to perform concurrent DUR services in accordance with federal and state laws. Under CMS's regulations

> 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--
> . . .
> 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.

42 CFR § 423.153 (emphasis added). As this Court previously found, the combination of this regulation and the MCS-Caremark contract mandating that Caremark comply with CMS regulations makes screening for prescriptions filled over plan limits part of the statutorily-mandated DUR services.

As with the prior authorization claim, Defendants assert that this claim fails for two independent reasons. First, Defendants contend that the Pharm/DUR audit chronology demonstrates that Caremark was not ignoring the quantity limit restrictions imposed by MCS's contract and, thus, did not render "worthless services." The Initial Audit Report indicated that Caremark allegedly erroneously adjudicated 14,886 pharmacy claims for Tier 2 and Tier 4 drugs in which a specified quantity limit was exceeded. The claimed amount owed to MCS was $1,263,188.66. Caremark responded that it checked approximately 60% (450) of the cited Tier 2 claims and concluded that quantity limits had not been exceeded because ninety-day supplies were allowed. In the Amended Audit Report, Pharm/DUR admitted that its original finding had erroneously included three particular drugs in the Tier 2 report. After removing those drugs,

there were no remaining discrepant claims in the Tier 2 category and Pharm/DUR admitted that it made a data processing error. (Traina Decl., Ex. 32-1.) Pharm/DUR also reissued its Tier 4 finding, dropping the cited discrepancies from 14,109 claims to 1,875 claims. (Id.) In its Final Response, Caremark responded to 1221, or 65%, of the quantity limit/days supply Tier 4 discrepancies and noted that (1) 1,106 of the samples passed the therapy protocol which limits the amount of a specific medication to be taken in a particular time frame; (2) seventy-seven of the samples were filled under a transition plan which has no quantity/days supply limits; and (3) thirty-eight of the samples indicated a that prior authorization was obtained for the drug. As such, Caremark remarked that it believed the claims were being adjudicated accurately. (Defs.' Mot. Summ. J., Ex. 28, at SPCM00225810.) Pharm/DUR's Rule 30(b)(6) designee acknowledged that Pharm/DUR had no reason to doubt that Caremark's information was correct. (O'Brien Dep. 88:4-15.) Thereafter, in its Final Updated Audit Response of October 2008, MCS did an internal validation of most of the Tier 4 revised claim original count of 1,875 and removed a total of 1,115 claims, but requested that Caremark validate the remaining 760 claims, with a total paid amount of $93,851.02, and provide a response and support documentation. (Defs.' Mot. Summ. J., Ex. 29 (MCS Final Updated Audit Resp.), MCS-000056326–27.) No further documentation was exchanged on these remaining claims. Although MCS sought recoupment related to the quantity limits issues through November 2007, it did not do so after December 2008. (MCS 30(b)(6) Dep. 78:2–79:22.)

As noted above, the Third Circuit has recognized that "[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). Again, "[i]t is not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for," *i.e.*, a "diminished value" of services theory is insufficient. U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 710 (7th Cir. 2014); See also U.S. ex rel. Sanchez-Smith v. AHS Tulsa Reg'l Med. Ctr., 754 F. Supp. 2d 1270, 1287 (N.D. Okla. 2010) ("in order to reach a jury on a factual falsity theory in the context of 'bundled' per diem Medicaid billing, a plaintiff must present facts amounting to (1) the provision of entirely 'worthless services,' . . .; or (2) at a minimum, the provision of grossly negligent services with regard to a particular standard of care or regulatory requirement.") (internal quotations omitted).

Applying this standard here, Plaintiff has failed to demonstrate the provision of worthless services or anything amounting to gross negligence with respect to the required DUR. Plaintiff's evidence is limited to a cursory assertion that "[t]he record here contains significant evidence that Defendants did not perform the core required service of obtaining a prior authorization before dispensing the Part D drug in excess of quantity limits," as reflected in the Part D formulary. (Pl.'s Resp. Opp'n Summ. J. 155.) The sole evidence on which Plaintiff relies, however, is the Pharm/DUR audit finding, which was substantially disproven. As set forth earlier, Caremark submitted a total of 114 million PDEs in 2006 and 2007. Of those, Plaintiff identified 14,886 claims as improperly filled without adherence to quantity limits. Plaintiff does not dispute that, of that number, Caremark had, in fact, properly adjudicated 13,011, or 87%, of them. Nor does Plaintiff dispute that MCS's own internal analysis indicated that, of the

remaining 1,875 claims, 1,115 claims were improperly flagged by Pharm/DUR.[56] Pharm/DUR's audit findings as to the remaining 760 claims have never been reviewed and either confirmed or rejected. Even assuming those remaining claims reflect instances wherein Caremark improperly filled claims over the mandated quantity limits without prior authorization, such a minute number of errors out of the extensive number of prescriptions filled by Caremark in the 2006–2007 timeframe does not reflect that services were not provided, that the service was so substandard as to be tantamount to no service at all, or that Caremark acted with gross negligence in performing its duties. In other words, no reasonable jury could find that Caremark caused MCS to bill the government for services not rendered.[57]

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[56] Plaintiff asserts that, in August 2007, Caremark recognized that the Pharm/DUR finding on quantity limits was "critical;" that it would likely result in "additional conversations and allegations from MCS and PharmDUR;" and that Caremark's response should be supported by documents. (Traina Decl., Ex. 77-1.) Yet, when responding to the MCS-Pharm/DUR audit finding regarding quantity limits claims for a total paid by MCS of $1,233,450.99, Defendants did not analyze the Tier 4 claims, and merely replied that there were no material discrepancies.

This email is probative of no material facts and certainly creates no genuine issue of fact as to whether the majority of Pharm/DUR's audit findings as to quantity limits were erroneous. Pharm/DUR itself admitted to errors and reduced the number of problematic claims from 14,886 to 1,875. Thereafter, MCS's own internal validation of most of the remaining Tier 4 claims resulted in a removal of 1,115 claims from the list, with a request that Caremark validate the remaining 760 claims. Although Caremark did not do so, it is notable that MCS did not pursue the issue further, particularly given Caremark's belief that MCS would fight for reimbursement of any funds to which it believed it was entitled given MCS's ongoing financial issues. (Id.)

[57] Plaintiff asserts that it is somehow Defendants' responsibility to (a) offer a description of the precise edit they had in place to screen for overutilization; (b) provide their own analysis of their pharmacy claims; and (c) provide other evidence that they performed required DUR services related to quantity limits for these claims.

To accept Plaintiff's argument would be to flip the burden of proof and Rule 56 standard on their heads. The burden rests with Plaintiff to establish that Defendants were paid for "worthless services." On summary judgment, Defendants need only point to an absence of evidence supporting that element. Defendants in this case have actually gone further and submitted affirmative proof that almost all of the allegedly problematic claims were, in fact, properly paid. Plaintiff's failure to produce any evidence creating a genuine issue of material fact

Finally, as with the prior authorization claim, even to the extent the Court could find that Defendants rendered worthless services with respect to review for overutilization, the record is devoid of evidence showing that Defendants acted knowingly, with deliberate ignorance, or in reckless disregard of their duties. Plaintiff simply alleges that:

> [T]here is substantial evidence that Defendants acted intentionally in failing to conduct DUR to avoid dispensing Tier 4 drugs for a quantity or days' supply over the limits contained in the MCS Part D formulary. Defendants agreed to provide for MCS, in keeping with Regulations, concurrent DUR services to avoid over-utilization and to implement the limits on drugs in the Sponsor's formulary by rejecting Part D claims for over-limits drugs. . . . The formulary used for MCS Part D plans, which detailed the approved limits for Tier 4 drugs, was created and maintained by Defendants – and they charged MCS for that service. . . . MCS was relying on Caremark to ensure that quantity limits for Tier 4 drugs (contained in a formulary that Caremark both created and controlled) were not exceeded. . . .
>
> Defendants argue, without any record support, that they did not act knowingly in failing to provide concurrent DUR for quantity limits. . . . Defendants have not cited any record evidence relating to Defendants' purported mere mistakes or errors in performing Concurrent DUR regarding to [sic] quantity limits. As they did with Tier 2 and Tier 4 prior authorizations, during the Pharm/DUR audit process, Defendants overtly denied that they acted negligently or made errors in performing concurrent DUR services related to quantity limits: ". . . we are in compliance with the plan design, these claims adjudicated correctly." . . . At best, Defendants' argument highlights that a genuine issue of material fact exists regarding whether Defendants knowingly and intentionally failed to ensure that concurrent DUR was performed to avoid dispensing Part D drugs in excess of quantity limits for [Tier] 4 drugs as proscribed in the formulary Defendants created for MCS.

(Pl.'s Resp. Opp'n Summ. J. 156–57.)

> [T]he admissible record evidence shows that Defendants acted knowingly in failing to conduct DUR to avoid dispensing nearly 1,900 claims for Tier 4 drugs for a quantity or days' supply over limits. Defendants' core PBM services included concurrent DUR to avoid overutilization, they had superior ability and the sole opportunity, during the pharmacy claims adjudication process, to identify Part D pharmacy claims for Tier 4 drugs on the MCS formulary (created and maintained by Defendants), and they represented to Part D sponsors that DUR overutilization edits

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now entitles Defendants to a summary judgment ruling in their favor.

> were hard edits. . . . Defendants' Reply ignores Plaintiff's record evidence of their intentional conduct, and again argues that Defendants' mere denial of any wrongdoing affords Defendants the inference that, if they did not perform required concurrent DUR services for quantity limits, their conduct was not intentional.

(Pl.'s Sur-reply Br. 68–69.)

Contrary to Plaintiff's belief, this argument creates no genuine issue of material fact on the element of scienter. At most—if at all—only a minute percentage of pharmacy claims processed by Defendants were over the contractual limits, meaning that 95 to 99% of the time (depending which numbers are used), Defendants accurately and properly screened submitted pharmacy claims for overutilization. To the extent some claims were filled despite being out of compliance with quantity limits, Plaintiff has not met his burden of putting forth any evidence that such errors were the result of some intentional plan or reckless disregard of duties as opposed to mere negligent failure to catch discrepancies. Absent evidence of scienter, these discrepancies are more appropriately the subject of a breach of contract action between MCS and Caremark, not a False Claims Act lawsuit. Moreover, Defendants' denial that it did anything wrong does not, as Plaintiff argues, suggest that Defendants knowingly and intentionally failed to perform their requisite DUR. To the contrary, it evidences Defendants' consistent belief that it was accurately performing its required duties. Absent evidence of scienter, the Court grants summary judgment in favor of Defendants on this claim as well.

IV. CONCLUSION

" Qui tam" is part of a Latin phrase," qui tam pro domino rege quam pro se ipso in hac parte sequitur," which means "who as well for the king as for himself sues in this matter."

Black's Law Dictionary (9th ed. 2009.) "Qui tam actions are authorized by a variety of statutes as a means of encouraging insiders (i.e., whistle-blowers) to come forward with information of fraud and/or prosecute defrauders." U.S. ex rel. Waris v. Staff Builders, Inc., No. Civ.A.96-1969, 1999 WL 179745, at *1 n.1 (E.D. Pa. Mar. 4, 1999). "They, like private causes of action generally, assist the government by enlisting the aid of citizens in enforcing statutes." Marra v. Burgdorf Realtors, Inc., 726 F. Supp. 1000, 1012 (E.D. Pa. 1989). "Under the False Claims Act, a qui tam plaintiff may win anywhere from 10% to 30% of the proceeds of the suit (including civil penalties and trebled damages), as well as reasonable expenses, attorney fees, and costs, depending on such factors as whether the qui tam plaintiff or the government prosecuted the suit and the significance to the suit of the qui tam plaintiff's information." Waris, 1999 WL 179745, at *1 n.1.

Despite the present case proceeding through years of discovery, Plaintiff's qui tam suit against Defendants will reap him no such rewards as it falls short of surviving summary judgment standards. First, with respect to Plaintiff's claim regarding false physician identifiers, the evidence is clear that the government was well aware of the use of such identifiers and, while not happy with the practice, condoned their use as a way of ensuring that valid prescriptions were filled during the early roll-out stages of Medicare Part D and the use of PDEs. Plaintiff's lengthy briefing and tangential attacks on every form of evidence cited by Defendants reveals Plaintiff's claim to be nothing more than a game of smoke and mirrors designed to detract from the obvious factual backdrop. Second, as to Plaintiff's claim regarding DUR for gender contraindications, the record reflects that Defendants fully complied with their obligations—indeed successfully so—by delegating this portion of DUR to the participating

pharmacies. Third, with regards to the expired drugs claim, the evidence establishes that screening for expired drugs was not part of a Part D Sponsor or PBM's role, but rather was to be done at the pharmacy level. Moreover, Plaintiff has failed to identify any problematic claims wherein prescriptions were filled with drugs that actually expired. Finally, as to the three MCS-specific claims—MAC pricing, prior authorizations, and quantity limits—Plaintiff has not adduced sufficient evidence either that Defendants provided worthless services or that Defendants possessed the requisite scienter required for a valid FCA claim.

In short, the Court finds no remaining issues of material fact that preclude an entry of summary judgment in favor of Defendants. At base, this case appears to be nothing more than an effort to convert an unprofitable private audit—performed at a time when Part D regulations were new and not as explicit in their instructions—into a successful recovery of funds under the guise of a qui tam action. The Court finds that no reasonable juror could determine that Defendants knowingly presented a false or fraudulent claim for payment or approval, knowingly used a false record or statement to get a false or fraudulent claim paid, or knowingly made or used a false record statement to conceal or avoid an obligation to pay or transmit money to the Government. Accordingly, summary judgment is entered in favor of Defendants on the entirety of this action.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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

AND NOW, this *22nd* day of *September*, 2015, upon consideration of **(1)** the Motion for Summary Judgment by Defendants CVS Caremark Corporation, Caremark Rx, LLC (f/k/a Caremark Rx, Inc.); Caremark, LLC (f/k/a Caremark, Inc.), and Silverscript, LLC (f/ka SilverScript Inc.) (collectively "Defendants") (Docket Nos. 181, 182), the Response of Plaintiff Anthony R. Spay (Docket No. 193), Defendants' Reply Brief (Docket No. 201); and Plaintiff's Sur-reply Brief (Docket No. 207); **(2)** Plaintiff's Motion for Partial Summary Judgment (Docket No. 177); Defendants' Response (Docket No. 191); Plaintiff's Reply Brief (Docket No. 198); and Defendants' Sur-reply Brief (Docket No. 211); **(3)** Plaintiff's Motion to Strike Defendants' Exhibit 126 (Declaration of Beth Brinati) (Docket No. 197) and Defendants' Response (Docket

No. 206); and **(4)** Defendants' Motion for Oral Argument (Docket No. 214) and Plaintiff's Response (Docket No. 215), together with the parties' numerous statements of facts, responses and objections to statements of facts, declarations, and exhibits, it is hereby **ORDERED** as follows:

1. Defendants' Motion for Summary Judgment (Docket Nos. 181 & 182) is **GRANTED** in its entirety. **JUDGMENT IS ENTERED** in favor of Defendants and against Plaintiff on the entirety of the Complaint.

2. Plaintiff's Motion for Partial Summary Judgment (Docket No. 177) is **DENIED**.

3. Plaintiff's Motion to Strike Defendants' Exhibit 126 (Docket No. 197) is **DENIED AS MOOT**.[58]

4. Defendants' Motion for Oral Argument (Docket No. 214) is **DENIED**.

This case shall be marked **CLOSED**.

It is so **ORDERED**.

BY THE COURT:

s/ Ronald L. Buckwalter
RONALD L. BUCKWALTER, S.J.

[58] The Court did not cite to or rely on this exhibit when ruling on the summary judgment motions. Accordingly, a ruling on the Motion to Strike is unnecessary.