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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *ex rel.* MARC SILVER, *Plaintiff-Relator,* v. OMNICARE, INC., et al., *Defendants.*	Hon. Noel L. Hillman Civil Action No. 11-1326 (NLH) (AMD) **UNITED STATES' STATEMENT OF INTEREST IN RESPONSE TO PHARMERICA'S OPPOSITION TO RELATOR'S MOTION FOR LEAVE TO FILE A FOURTH AMENDED COMPLAINT**

The United States submits this Statement of Interest pursuant to 28 U.S.C. § 517, to respond to certain arguments made by defendant Pharmerica Corporation ("Pharmerica") in its opposition to relator's motion for leave to file a fourth amended complaint (ECF No. 520). Even though the United States has not intervened, it remains the real party in interest in this matter. In addition, because the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), is the United States' primary tool to prosecute fraud on the Government, it has a keen interest in the development of the law in this area and in the correct application of that law in this and similar cases.

The United States submits this statement of interest solely to clarify two points regarding the Medicare Part D program and claims made thereunder. First, as set

forth below, Pharmerica advances an unduly narrow view of whether the prescription drug event ("PDE") data that Part D Plan Sponsors ("Plan Sponsors") submit to CMS are "claims" under the FCA. The statutory text, regulations, agency instructions, and case law all compel the conclusion that the submission of PDE data constitutes a "claim" under the FCA. Second, a claim submitted to a Plan Sponsor may be rendered false by the payment of kickbacks in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b. (*See* Def. Opp'n at 18-22.) The United States takes no position on the other arguments made by Pharmerica.

I. STATUTORY AND REGULATORY FRAMEWORK

A. The Medicare Part D Program

Medicare is a federally funded and administered health insurance program that primarily serves the elderly and disabled persons. The Department of Health and Human Services ("HHS") administers the Medicare program through the Centers for Medicare & Medicaid Services ("CMS"). In 2003, Congress established a voluntary prescription drug benefits program for Medicare enrollees known as Medicare Part D. The Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, 42 U.S.C. §§ 1395w-101 *et seq*. Medicare Part D became effective January 1, 2006. 42 U.S.C. § 1395w-101(a)(2).

To implement the Medicare Part D program, CMS contracts with private entities known as Plan Sponsors to administer prescription drug benefit plans. The Part D program, however, is funded with federal dollars. Pursuant to CMS regulations, Plan Sponsors must agree to comply with "Federal laws and regulations

designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(1).

Plan Sponsors typically do not dispense drugs to Medicare beneficiaries. Rather, Plan Sponsors enter into subcontracts with downstream entities to provide drugs to the Part D beneficiaries enrolled in their plans. These entities include pharmacy benefit managers ("PBMs") who provide drugs through mail order operations, retail pharmacy chains, and long-term care pharmacies such as Pharmerica. CMS regulations require that all subcontracts contain language obligating the downstream entity to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. §§ 423.505(i)(3)(iv), (i)(4)(iv).

B. The Prescription Drug Event and Required Certification

When a pharmacy dispenses drugs to a Medicare beneficiary, it submits a claim electronically to the beneficiary's Plan Sponsor (or to a PBM) and receives reimbursement from the Plan Sponsor (or PBM). The reimbursement reflects an amount negotiated with the pharmacy that is not paid by the beneficiary's cost sharing. *See* 42 C.F.R. § 423.104. The pharmacy's claim to the Plan Sponsor is reflected in the Plan Sponsor's submission to CMS of information used to determine payment of federal funds. Specifically, CMS requires the Plan Sponsor to submit a PDE. 42 C.F.R. § 423.343(c). The PDE includes fifty-seven fields of information about a specific drug transaction, including cost and payment fields. *See* CMS PDE Inbound

File Layout.[1] The Plan Sponsor submits the PDE for purposes of determining payment, and CMS bases payment decisions on the PDEs submitted. When the Plan Sponsor submits the PDE claims data to CMS, it becomes the summary record that documents the final adjudication of a dispensing event.

During the benefit year, CMS pays Plan Sponsors estimated payments on a monthly basis. 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 payment." 42 C.F.R. § 423.505(k)(1) ("As a condition for receiving a monthly payment . . . the Part D plan sponsor . . . 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 payment."). The regulation states that "data related to payment" may include enrollment information, claims data, bid submission data and any other data specified by CMS. *Id*. At the end of the payment year, CMS reconciles its advance payments to the sponsor with the costs incurred by the sponsor throughout the year as reflected in the aggregated PDE data. *See* 42 C.F.R. § 423.343.

In the Proposed Fourth Amended Complaint, relator alleges that Pharmerica entered into contracts with Plan Sponsors and/or PBMs acting as agents of sponsors and that those contracts required Pharmerica to certify the accuracy, completeness,

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[1] The CMS PDE Inbound File Layout can be found at: csscoperations.com/internet/csscw3.nsf/DIDC/ETTDDMFAAP~Prescription%20Drug%20Program%20(Part%20D)~File%20and%20Report%20Layouts (last accessed Mar. 5, 2021).

and truthfulness of the PDE data it generated and to comply with all applicable federal laws, including the AKS, regulations, and CMS instructions. (Proposed Fourth Am. Compl. ("FAC") ¶¶ 77-78.) Relator alleges that Pharmerica also was obliged to acknowledge that its submissions in this regard would be used to obtain federal reimbursement. (FAC ¶ 77.) Finally, relator alleges that Pharmerica submits electronic claims to and receives reimbursement from the beneficiary's Plan Sponsor for the costs not paid by the beneficiary. (FAC ¶ 59.)

II. APPLICATION OF THE FALSE CLAMS ACT TO PART D

A. The PDE is a Claim Under The False Claims Act

The FCA defines "claim" broadly to include "any request or demand, under a contract or otherwise for money or property presented to an officer, employee or agent of the United States or made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf to advance a Government program or interest." 31 U.S.C. § 3729(a)(2). In the context of Medicare Part D, the PDE data that Plan Sponsors submit to CMS are "claims" under the FCA. The expansive definition of "claim" reflects Congress' clear intent to provide the FCA with broad reach, and finding that PDEs are claims under the FCA is consistent with that intent.

In addition to the statutory text and legislative intent, CMS regulations and program instructions reinforce that the PDE is a "claim" for this purpose. CMS refers to PDE submissions as "claims data." *See* 42 C.F.R. § 423.505(k); 73 Fed. Reg. 30664, 30664 (May 28, 2008) ("We further note that the Part D prescription drug event data

(hereinafter also referred to as 'Part D claims data') . . . ."). Moreover, in 2011 guidance, CMS states that the submission of PDE data is a condition of claim payment in the context of the Part D program. CMS 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide, pages 1-15 ("As a condition of payment, Part D plans must submit PDE and other data necessary for CMS to carry out these four payment provisions . . . . 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.").[2]

In addition, the purpose and function of PDE data put it squarely within the FCA definition of "claim." CMS uses PDE data for "payment" and "validation" of claims, as well as part of the year-end reconciliation process, which may result in additional money paid by the Government, as well as to determine the Government's monthly payments for the following year. *Id*. ("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. . . . . Much of the data, especially dollar fields, will be used primarily for payment.") (emphasis added). In sum, PDE data is information submitted to CMS for each prescription filled under

[2] The CMS 2011 Regional Prescription Drug Event Data Technical Assistance Participant Guide can be found at: csscoperations.com/internet/csscw3_files.nsf/F/CSSCPDEParticipantGuide%20cameraready%20081811.pdf/$FILE/PDEParticipantGuide%20cameraready%20081811.pdf (last accessed Mar. 5, 2021).

the Part D program and used to determine payment.

Consistent with the statute, regulations, and explicit instructions from CMS, courts have affirmed that a PDE is a claim under the FCA. *United States ex rel. Buth v. Pharmerica Corp.*, 2014 WL 4355342, No. 09-720 (E.D Wisc. Sept. 3, 2014); *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 168 (E.D. Pa. 2012) ("[T]he PDE records submitted by Defendants to CMS are clearly claims for payment."); *see also United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746 (3d Cir. 2017). In *Buth*, the United States alleged in its FCA complaint against Pharmerica that "[t]he PDEs submitted by the plan sponsor are the claims upon which CMS makes payment." *Buth*, 2014 WL 4355342 at *5. In evaluating the sufficiency of the United States' complaint, the district court reviewed how the Part D program works and concluded that "the United States has adequately pled a false or fraudulent claim inasmuch as Pharmerica billed plan sponsors for Schedule II drugs knowing that the drugs were not dispensed upon a valid prescription and caused the plan sponsor, who relied on Pharmerica's electronic claim, to inaccurately represent to the United States (CMS) in the PDE record that the drugs were reimbursable 'covered Part D drugs.'" *Id.*

Pharmerica seeks to discredit *Buth* by pointing out that its holding on PDE has not been cited in any subsequent decision. The absence of citation merely reflects the unremarkability of the proposition that a PDE is a claim for purposes of the FCA. Indeed, in *Spay*, the Third Circuit addressed the use of false prescriber identifiers on

PDEs and treated PDEs as claims under the FCA. 875 F.3d at 765 (dummy Prescriber IDs were intended to prevent denial of "legitimate claims for reimbursement"; "[t]he claims themselves were neither false nor fraudulent"). If Pharmerica were correct that a PDE is not a claim, the Third Circuit presumably would have dismissed the case on that threshold basis rather than proceeding to address the more involved question of whether the false information in the PDE was material to the agency's payment decision.

Acceptance of Pharmerica's unduly narrow and unsupported interpretation of "claim" would undermine efforts by the Government to protect the integrity of the Medicare program by limiting the Government's ability to use the FCA to recover money improperly paid under Part D. The Court should reject Pharmerica's interpretation.

B. PDEs Tainted By Kickbacks Are False Under the FCA

The AKS prohibits the knowing and willful solicitation, receipt, offer, or payment of remuneration in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program. 42 U.S.C. § 1320a-7b(b). Paying kickbacks in connection with prescriptions to Part D beneficiaries renders the claims for such prescriptions false under the FCA. *United States ex rel. Wood v. Allergan*, 246 F. Supp. 3d 772, 816 (S.D.N.Y. 2017) (reversed on other grounds; citing *United States ex rel. Wilkins v. United Health Grp.*, 659 F.3d 295, 313-14 (3d Cir. 2011)). Congress amended the Anti-Kickback Statute in 2010 to

state expressly that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018) (citing 42 U.S.C. § 1320a-7b(g)).

Effectively ignoring that relator has pled a kickback scheme (FAC ¶¶ 108-138, 179-230.), Pharmerica argues that "the [PDE] certifications that relator references are only as to the factual accuracy of the PDE records" and that relator does not allege that "the PDEs are factually false" or "that the Plan Sponsors' payment requests and attendant certifications are rendered false by the allegedly tainted PDE records." (Def. Opp'n at 21.) In essence, Pharmerica contends that so long as the factual information in the PDE is accurate, those claims cannot form the basis of FCA liability.

Pharmerica's argument is wrong for two critical reasons. *First*, CMS regulations required Pharmerica to certify that it was complying with the AKS. "CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, ***including pharmacies***, contain language obligating the pharmacy to comply with all applicable federal laws." *See Allergan*, 246 F. Supp. 3d at 813 (citing 42 C.F.R. § 423.505(i)(4)(iv) (emphasis added)). In *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 337 (S.D.N.Y. 2014), the court held that "[t]he AKS is unquestionably one of the 'applicable Federal laws' governing Medicare Part D that is cited in the subcontract certification." The court continued:

> CMS regulations specifically identify the AKS as one of the 'Federal laws and regulations designed to prevent fraud, waste, and abuse' that apply to Medicare Part D. 42 C.F.R. § 423.505(h)(1). Moreover, the AKS itself states that it applies to any "Federal health care program," which includes Medicare Part D. 42 U.S.C. § 1320a–7b(f).

Id. at 337.

In a recent case in this district, the Court upheld a similar certification as an express representation of compliance with the AKS. In *United States ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 405 (D.N.J. 2019), the court held that submission of Medicare enrollment forms requires, among other things, certification that payment is "conditioned upon the claim and the underlying transaction complying with [the Medicare] laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute)." *Id.* at 405. The court held that this certification is "more than specific enough to make clear that the claims submitted . . . represented that any underlying transactions had not involved third party kickbacks prohibited by the AKS." *Id.* (citing *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 393 (1st Cir. 2011)). Relator alleges that Pharmerica expressly certified under applicable CMS regulations that it would comply with all applicable federal laws, including the AKS.

Second, even if Pharmerica had not made an express certification, "a claimant who requests payment from the Government implies that it has . . . complied with the AKS and other statutes and regulations." *Allergan*, 246 F. Supp. 3d at 816 (citing *Wilkins*, 659 F.3d at 313-14). In *Allergan*, the court upheld kickback claims based on implied certification, holding that "compliance with the AKS is a 'material' condition

of payment." *Allergan*, 246 F. Supp. at 818. Likewise in *United States v. Johnson & Johnson*, No. 12-cv-7758 (MAS) (LHG), 2017 WL 2367050, at *7 (D.N.J. May 31, 2017), the court held that relator adequately pleaded materiality by alleging a kickback scheme causing submission of false claims to the Medicare Part D program.

Relator has alleged that in submitting PDEs, Pharmerica has certified (falsely) that it would comply with all applicable federal laws, including the AKS. (FAC ¶¶ 77-78.) Relator alleges that each of Pharmerica's PDEs was accompanied by a certification that the transaction was not in violation of federal or state statutes, regulations, or program rules and that each of those certifications was false because each claim for payment was tainted by a kickback arrangement. (*See, e.g.*, FAC ¶ 234.) That allegation, if proven, constitutes a violation of the FCA. *See Greenfield*, 880 F.3d at 95. And, in any event, in submitting PDEs, Pharmerica impliedly certified its compliance with the AKS, among other federal statutes.

A violation of the AKS can occur when the items or services furnished are otherwise legitimate and medically necessary. The accuracy of PDE data is thus inconsequential to whether a violation of the AKS occurred. Taking relator's kickback allegations as true, such kickbacks would render legally false all of Pharmerica's PDEs, even if they were factually accurate.

CONCLUSION

If the Court reaches the issue of whether PDEs are "claims" under the FCA, the United States urges the Court to find that PDEs are "claims" under the FCA, and

that the payment of kickbacks in connection with such claims is actionable under the FCA.

Dated: March 5, 2021

Respectfully submitted,

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By: */s/ Daniel W. Meyler*
DANIEL W. MEYLER
Assistant United States Attorney

CERTIFICATE OF SERVICE

I, Daniel W. Meyler, hereby certify that on March 5, 2021, I caused copies of the foregoing statement of interest of the United States to be served by ECF and email to counsel for relator Marc Silver and defendant Pharmerica. I swear that the foregoing statements are true and correct to the best of my ability and knowledge.

Dated: March 5, 2021
Newark, New Jersey

/s/ Daniel W. Meyler
DANIEL W. MEYLER
Assistant U.S. Attorney