JUDGE KOELTL

18 CV 3047

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

**United States of America *ex rel.* Azam Rahimi;**
**State of California *ex rel.* Azam Rahimi;**
**State of Colorado *ex rel.* Azam Rahimi;**
**State of Connecticut *ex rel.* Azam Rahimi;**
**State of Delaware *ex rel.* Azam Rahimi;**
**District of Columbia *ex rel.* Azam Rahimi;**
**State of Florida *ex rel.* Azam Rahimi;**
**State of Georgia *ex rel.* Azam Rahim;**
**State of Hawaii *ex rel.* Azam Rahimi;**
**State of Illinois *ex rel.* Azam Rahimi;**
**State of Indiana *ex rel.* Azam Rahimi;**
**State of Iowa *ex rel.* Azam Rahimi;**
**State of Louisiana *ex rel.* Azam Rahimi;**
**State of Maryland *ex rel.* Azam Rahimi;**
**Commonwealth of Massachusetts *ex rel.* Azam Rahimi;**
**State of Michigan *ex rel.* Azam Rahimi;**
**State of Minnesota *ex rel.* Azam Rahimi;**
**State of Montana *ex rel.* Azam Rahimi;**
**State of Nevada *ex rel.* Azam Rahimi;**
**State of New Jersey *ex rel.* Azam Rahimi;**
**State of New Mexico *ex rel.* Azam Rahimi;**
**State of New York *ex rel.* Azam Rahimi;**
**State of North Carolina *ex rel.* Azam Rahimi;**
**State of Oklahoma *ex rel.* Azam Rahimi;**
**State of Rhode Island *ex rel.* Azam Rahimi;**
**State of Tennessee *ex rel.* Azam Rahimi;**
**State of Texas *ex rel.* Azam Rahimi;**
**State of Vermont ex rel. Azam Rahimi;**
**Commonwealth of Virginia *ex rel.* Azam Rahimi;**
**State of Washington *ex rel.* Azam Rahimi,**

**Plaintiffs,**

**v.**

**CVS Pharmacy, Inc.,**

**Defendant.**

**COMPLAINT**

**Civil Action No.**

**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)**

**Jury Trial Demanded**

## COMPLAINT
(False Claims Act)

Table of Contents

SUMMARY STATEMENT ..................- 3 -
JURISDICTION AND VENUE ..................- 6 -
THE PARTIES..................- 7 -
Relator..................- 7 -
Plaintiff United States of America..................- 8 -
State Plaintiffs..................- 8 -
The Defendant..................- 9 -
TAXPAYER COVERAGE OF PRESCRIPTION DRUG SUBSIDIES..................- 10 -
Medicare Part D - Overview ..................- 10 -
Medicare Part D – Federal Reimbursement..................- 13 -
TRICARE/CHAMPUS ..................- 15 -
VA Health Benefits Programs ..................- 16 -
The Federal Employee Health Benefits Program ..................- 16 -
Medicaid – Federal Coverage Requirements..................- 16 -
Medicaid - State Coverage Requirements..................- 18 -
State Medicaid Programs – Claims Submission Requirements..................- 21 -
THE FRAUDULENT SCHEME..................- 23 -
Insulin Pens..................- 23 -
Reimbursement for Insulin Pens..................- 25 -
Determining Quantity to Dispense..................- 26 -
CVS's Dispensing of 15 ml Cartons..................- 27 -
CVS's Falsifying "Days' Supply" on Claim Form..................- 28 -
CVS's Dispensing and Billing for Premature Refills ..................- 31 -
CVS Management's Knowledge of Pervasive False Claims for Insulin Pens..................- 34 -
Examples of False Claims..................- 36 -
DAMAGES..................- 39 -
COUNT ONE..................- 40 -
COUNT TWO..................- 40 -
COUNT THREE..................- 41 -
COUNT FOUR ..................- 41 -
COUNT FIVE..................- 42 -
COUNT SIX ..................- 43 -

COUNT SEVEN ........................................ - 43 -
COUNT EIGHT ........................................ - 44 -
COUNT NINE ........................................ - 44 -
COUNT TEN ........................................ - 45 -
COUNT ELEVEN ........................................ - 45 -
COUNT TWELVE ........................................ - 46 -
COUNT THIRTEEN ........................................ - 47 -
COUNT FOURTEEN ........................................ - 47 -
COUNT FIFTEEN ........................................ - 48 -
COUNT SIXTEEN ........................................ - 48 -
COUNT SEVENTEEN ........................................ - 49 -
COUNT EIGHTEEN ........................................ - 49 -
COUNT NINETEEN ........................................ - 50 -
COUNT TWENTY ........................................ - 50 -
COUNT TWENTY-ONE ........................................ - 51 -
COUNT TWENTY-TWO ........................................ - 52 -
COUNT TWENTY-THREE ........................................ - 52 -
COUNT TWENTY-FOUR ........................................ - 53 -
COUNT TWENTY-FIVE ........................................ - 53 -
COUNT TWENTY-SIX ........................................ - 54 -
COUNT TWENTY-SEVEN ........................................ - 54 -
COUNT TWENTY-EIGHT ........................................ - 55 -
COUNT TWENTY-NINE ........................................ - 55 -
COUNT THIRTY ........................................ - 56 -
PRAYER FOR RELIEF ........................................ - 57 -
DEMAND FOR JURY TRIAL ........................................ - 57 -

## **SUMMARY STATEMENT**

1. This lawsuit involves hundreds of millions of dollars in claims for insulin pens that the Defendant pharmacy chain, CVS Pharmacy, Inc. ("CVS"), has submitted to federal and state health insurance programs knowing full well that it was charging for significantly larger quantities

of insulin than what physicians had prescribed for its customers. The claims are false because government health programs pay for prescription medication only when medically necessary and dispensed upon a prescription.

2. Insulin pens are pre-filled devices typically containing 3 milliliters (ml) of insulin that patients use to self-inject insulin. They are typically sold by the manufacturers in cartons that contain five 3 ml pens each. Insulin is the medication that is used on a daily basis for blood sugar control by most of the 30.3 million Americans with diabetes. Since many of these diabetics are elderly or indigent, the federal Medicare Part D program ("Medicare") and the federal-state Medicaid program ("Medicaid") pay for gargantuan quantities of insulin: in 2015, for example, Medicare paid more than $6.9 billion for insulin products. CVS, as the largest pharmacy chain in the country, is one of the top, if not the number one, biller of insulin pens.

3. Federal and state health care programs such as Medicare, Medicaid, the Federal Employees Health Benefits Program ("FEHBP"), the United States Department of Veterans Affairs ("VA") health care program, and the TRICARE/CHAMPUS program contain limits on the days' supply that a pharmacy may bill to the government program on each fill or refill of insulin. Typical payer days' supply limits are 30, 34, 90 or 100 days. To cover specific situations in which the payer agrees that is preferable to dispense a larger days' supply, most payers provide a procedure for "days' supply limit overrides" in which a pharmacy may contact the payer and request permission to bill for a larger days' supply.

4. The daily dose of insulin prescribed for diabetics varies widely and is usually dependent upon the patient's weight, with typical daily doses ranging from 10 to 80 units per day. For example, the recommended dose is 0.5 to 1 unit per kilogram per day for Apidra and Novolog, 1 to 80 units a day for Toujeo, and up to 10 units per day for patients with type 2 diabetes (the

most common type of diabetes) who are starting on Lantus or Levemir for the first time. 100 units of insulin is the equivalent of 1 ml of insulin. Each insulin pen contains 300 units, or 3 ml of insulin, and each 5-pen carton contains 1,500 units, or 15 ml of insulin.

5. CVS pharmacies routinely dispense insulin pens in their manufacturer-provided 5-pen cartons regardless of the customer's daily dose requirements – even though the pens are individually sealed to protect the integrity of the insulin, marked with their expiration date and all other key product information, and include bar codes for scanning at the register so that they can be dispensed on an individual basis. The result of this practice is that CVS frequently dispenses, and charges payers for, quantities of insulin that exceed the government payer's usual days' supply limit for insulin. For example, when the payer's usual days' supply limit is 30 days, dispensing a full box will exceed that days' supply limit whenever the prescribed daily dose is 40 units or less; and when the payer's usual days' supply limit is 90 days, dispensing a full box will exceed the days' supply limit whenever the prescribed daily dose is 10 units or less.

6. CVS's insulin pen dispensing practice in-and-of-itself is not illegal because of the pharmacy option to seek a payer "days' supply limit override" and because many customers use their own resources rather than insurance to pay for their insulin. But rather than requesting a "days' supply limit" override from the insurer when selling to an insured customer, CVS lies to the payer about the days' supply to be in conformance with the payer's days' supply limit. The payer ordinarily cannot detect this lie because the provider's daily dosing instructions are not a required element on the claim form. CVS then enters this false (understated) days' supply into its internal computer system, misrepresents to the patient that it is dispensing this understated days' supply, and aggressively works to get the patient to refill his insulin pen prescription at the end of the false, understated "days' supply" period. The end result is that government payers, who have

agreed to pay for medication only when dispensed in conformance with a prescription, pay for far more medication than what has been prescribed and CVS profits far more than it should. In addition, CVS provides its customers with an opportunity to profit from the excessive amounts of insulin they have been dispensed by selling the insulin on the black market.

7. *Qui tam* Plaintiff Azam ("Adam") Rahimi, a CVS pharmacist, brings this civil action on behalf of and in the name of the United States of America ("United States") under the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, and on behalf of and in the name of the state plaintiffs under analogous *qui tam* provisions in state false claims laws.

## JURISDICTION AND VENUE

8. Count 1 of the Complaint is a civil action by Relator, acting on behalf of and in the name of the United States, against Defendant under the federal False Claims Act, 31 U.S.C. §§ 3729–33 ("FCA"). This Court has jurisdiction over Count 1 pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. § 3732(a).

9. Counts 2 through 30 of this Complaint are civil actions by Relator, acting on behalf of and in the name of the various states named as plaintiffs herein, under the false claims laws of such states. This Court has jurisdiction over Counts 2 through 30 under 28 U.S.C. § 1331, because the claims arise under federal law; under 31 U.S.C. § 3732(b), because these Counts arise from the same transactions or occurrences as the claims brought in Count 1; and/or under 28 U.S.C. § 1367, because these Counts form part of the same case or controversy as the claims brought in Count 1.

10. Defendant transacts business in this judicial district. In addition, Defendant has engaged in acts in this judicial district that are proscribed under § 3729 of the FCA. Accordingly, this Court has personal jurisdiction over the Defendant, and venue is appropriate in this district pursuant to both 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391.

11. Relator is unaware of any prior public disclosure of the allegations or transactions set forth in this Complaint, as those terms are used in 31 U.S.C. § 3730(e)(4)(A).

12. To the extent any allegation set forth in this Complaint may be similar to allegations or transactions that have been publicly disclosed within the meaning of 31 U.S.C. § 3730(e)(4)(A), Relator is permitted to proceed with this lawsuit because Relator is an "original source" as that term is defined in 31 U.S.C. § 3730(e)(4)(B).

13. Before filing this lawsuit, and before any public disclosure, Relator voluntarily brought the allegations herein to the attention of the Office of United States Attorney for the Southern District of New York and state government officials with responsibility for investigating health care fraud matters of this nature. Moreover, Relator's information set forth herein is independent from, and materially adds to, any public disclosures that may have occurred before Relator disclosed these matters to these officials.

## THE PARTIES

### Relator

14. Adam Rahimi is a pharmacist who resides in Fairfax, Virginia. He received his doctorate in Pharmacy in 2007 from St. John's University in Jamaica, NY. In 2012, he was hired to work as a retail pharmacist at a Target pharmacy in Woodbridge, Virginia. He subsequently has worked at other Target pharmacies, and he is currently a pharmacist at a Target pharmacy in Alexandria, Virginia. He has been employed by CVS ever since CVS Health acquired Target Corporation's pharmacy business in December 2016. As part of his responsibilities at CVS, Mr. Rahimi has been assigned to cover shifts at approximately thirty CVS pharmacies in the greater Washington, D.C. metropolitan area.

**Plaintiff United States of America**

15. Relator brings Count 1 of this action on behalf of the United States pursuant to the *qui tam* provisions of the federal FCA, 31 U.S.C. §§ 3729–33.

16. On behalf of the United States, Relator seeks recovery for damages to federally-funded health insurance programs from Defendant's insulin pen dispensing scheme, set forth above and below. In particular, Relator alleges damages to the Medicare Part D program, established under Title XVIII of the Social Security Act; the federal-state Medicaid program's drug benefit program, established under Title XIX of the Social Security Act; the Federal Employees Health Benefits Plan ("FEHBP"), established under 5 U.S.C §§ 8901–14; the U.S. Department of Defense TRICARE and CHAMPUS health care programs, established pursuant to 10 U.S.C. § 1071 *et seq.*; and the U.S. Department of Veteran's Affairs Health Benefits programs, established pursuant to 38 U.S.C. § 1701 *et seq.*

**State Plaintiffs**

17. Relator brings Counts 2 thorough 30 of this action on behalf of the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and the District of Columbia (the "state plaintiffs"). Specifically, he brings this action under the *qui tam* provisions of the following false claims laws of the state plaintiffs: the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*; the Colorado False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*; the Connecticut False Claims Act, Conn. Gen. Stat. § 4-274 *et seq.*; the Delaware False Claims and Reporting Act, 6 Del. Code § 1201 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. §68.081 *et seq.*; the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 46-171 *et seq.*;

the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. § 5-11-5.5-1 *et seq.*; the Iowa False Claims Act, Iowa Code § 685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.*; the Maryland False Health Claims Act, Md. Code Ann., Health-Gen. § 2-601 *et seq.*; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. §1-605 *et seq.*; the Oklahoma False Claims Act, Okla. Stat. Ann. tit. 63, § 5053 *et seq.*; the Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code § 36.001 *et seq.*; the Vermont False Claims Act, 32 VSA. 632**;** the Virginia Fraud Against Taxpayer Act, Va. Code Ann. § 8.01-216.1 *et seq.*; the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.010 *et seq.*; and the District of Columbia False Claims Act, D.C. Code § 2-381.01 *et seq.*

18. On behalf of the state plaintiffs, Relator seeks recovery for the damages to federal-state Medicaid programs, which are jointly funded by the United States and the state plaintiffs, and the other state health insurance programs, that arose from the Defendant's insulin pen overbilling scheme.

**The Defendant**

19. Defendant CVS is the largest pharmacy chain in the United States in terms of number of stores, number of prescriptions filled and prescription drug revenue. In 2016, CVS's

parent, CVS Health Corporation, reported that its retail and long-term care pharmacy division had dispensed more than 1 billion prescriptions, and earned net revenue and net profits of $81 billion and $23 billion, respectively. CVS stores are found in every state except Wyoming, as well as in the District of Columbia and Puerto Rico. CVS is headquartered in Woonsocket, RI, and incorporated in Delaware.

## TAXPAYER COVERAGE OF PRESCRIPTION DRUG SUBSIDIES

### Medicare Part D - Overview

20. Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, establishes the Health Insurance for the Aged and Disabled Program, popularly known as Medicare. A person generally is eligible for Medicare coverage if they are 65 years or older, if they have End Stage Renal Disease, or if they are disabled. Among other things, Medicare covers a portion of the costs of certain outpatient medications. Reimbursement for Medicare claims is made by the United States through the Center for Medicare & Medicaid Services ("CMS"), an agency within the Department of Health & Human Services.

21. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as "Medicare Part D." An individual is eligible to 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). With a few limited exceptions, Medicare did not cover outpatient prescription drugs before the MMA was passed. The new Part D benefits program became effective January 1, 2006. 42 U.S.C. § 1395w-101(a)(2).

22. Medicare Part D pays for certain outpatient prescription drugs, but only when they are dispensed pursuant to a prescription in accordance with applicable federal and state law.

Specifically, Medicare part D covers those drugs (other than drugs reimbursable under Medicare Part A or Part B) that may be dispensed only upon a prescription and that are described in the payment provision of the Medicaid statute. *See* 42 U.S.C. § 1395w-102(e) (defining "Covered Drug" by reference to 42 U.S.C. § 1396r-8(k)(2), which defines "Covered Outpatient Drug" for the purposes of Medicaid). As described more fully below, the Medicaid payment provisions restrict payment to reimbursement for drugs that, among other things, "may be dispensed only upon prescription," 42 U.S.C. § 1396r-8(k)(2), and define the term "prescribed drug" to include only those drugs that are "(1) [p]rescribed by a physician or other licensed practitioner of the healing arts within the scope of his professional practice as defined and limited by Federal and State law; (2) [d]ispensed by licensed pharmacists and licensed authorized practitioners in accordance with the state Medical Practice Act; and (3) [d]ispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records." 42 C.F.R. § 440.120(a) (interpreting and implementing 42 U.S.C. § 1396r-8(k)(2)).

23. Federal law and regulations require that any health care provider who furnishes health care services or items that may be reimbursed under Medicare must ensure that, to the extent of his or her authority, those services or items are provided "only when, and to the extent, medically necessary" and are "supported by evidence of medical necessity." *See* 42 U.S.C. § 1320c-5(a); 42 C.F.R. § 1004.10.

24. The Medicare Modernization, Improvement and Prescription Drug Act of 2003 requires Medicare Part D sponsors to implement concurrent drug utilization review systems, policies and procedures to review prescriptions before dispensing to prevent, *inter alia*, "over-utilization." 42 U.S.C. § 1395w-104(c)(1)(A); 42 C.F.R. § 423.505(b)(6); 42 C.F.R. §

423.153(b)(2) and (c)(2). As CMS has explained, the "minimum" requirements for a Part D plan's drug utilization management program include, *inter alia*: "policies and systems to assist in preventing over-utilization" of prescribed medications. Medicare Program; Medicare Prescription Drug Benefit, Final Rule, January 28, 2005, 70 Fed. Reg. 4194, 4277. Accordingly, CMS's Part D regulations provide that a Part D sponsor's drug utilization review "must include, but not be limited to . . . (iii) Over-utilization and under-utilization . . . ." 42 C.F.R. § 423.153(c)(2).

25. To administer the Part D program, CMS contracts with private entities known as Part D "plan sponsors" to provide Part D benefits to beneficiaries. As a condition of receiving Part D funds, the plan sponsors must agree to comply with the applicable requirements and standards of the Part D program, as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112. 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).

26. CMS also mandates that the Part D sponsors affirmatively require the pharmacies in their networks to agree by contract to perform services in a manner that is consistent with and complies with the Part D sponsor's contractual obligations; and to comply with all applicable federal laws, regulations, and CMS instructions, and with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(i)(4)(iii), (v). These applicable laws and regulations include, among other things, the provisions of the Social Security Act (cited above) that specify the meaning of the term "prescribed drug" when used in the context of claiming benefits from the Medicaid or Medicare program.

27. Further, CMS requires that the Part D plan sponsors require the pharmacies in their networks to "comply with minimum standards for pharmacy practice as established by the state."

42 C.F.R. § 423.153(c)(1); *see also* 42 C.F.R. § 423.505(b)(6) (requiring the contracts between CMS and Part D sponsors to mandate compliance with 42 C.F.R. § 423.153(c)(1)).

**Medicare Part D – Federal Reimbursement**

28. Payment for drugs under Medicare Part D involves a multistep electronic claims process. First, when a pharmacy such as a CVS retail pharmacy dispenses a drug to a Medicare Part D beneficiary, it submits an electronic claim to the beneficiary's Part D plan sponsor, often through a Pharmacy Benefits Manager on contract with the Part D plan. The pharmacy's claim expressly represents that the drug for which reimbursement is being requested was dispensed upon a prescription, that the pharmacy is billing the Medicare Part D program, and that the pharmacy understands that federal and state funds will be used to pay the claim. If and when it reimburses the claim, the Part D plan notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record. The PDE includes 37 fields of data about the billed-for drug, including information about the pharmacy where the prescription was filled, the prescriber, the quantity and days' supply, and whether the drug is "covered" under the Part D benefit.

29. The Part D plan's actual costs for the payment of prescription drug medication flow through directly to the U.S. Treasury, with the Government sharing in any increase or decrease in the sponsor's actual costs of drug coverage compared to its projected costs. In other words, the Part D program is not a capitated system in which the insurance company absorbs all risk of actual costs exceeding budgeted costs.

30. At the beginning of the plan year, CMS makes three types of prospective payments to the Part D plan sponsors based on the sponsors' approved bids: (1) a direct subsidy designed to cover the sponsor's cost of providing the benefits; (2) a low-income cost-sharing subsidy; and (3) a reinsurance subsidy. The direct subsidy (a monthly capitated payment) is paid to the Part D plan

sponsor in the form of advance monthly payments equal to the Part D plan's standardized bid, risk-adjusted for health status as provided in 42 C.F.R. § 423.329(b), minus a monthly beneficiary premium as determined in 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D plan sponsor for each Part D beneficiary enrolled in the plan based on the anticipated costs of treating the patient—costs that were identified in the plan's bid. CMS also makes payments to the Part D plan sponsor to subsidize cost-sharing, such as premiums, by certain low-income, subsidy-eligible individuals as provided in 42 C.F.R. §§ 423.780 and 423.782. Finally, during the plan year, CMS pays a reinsurance subsidy to the Part D plan sponsor to cover the government's share of the drug costs above an enrollee's "catastrophic threshold," a specified dollar amount at which the patient is deemed to have particularly high prescription drug costs.

31. After the close of the plan year, CMS uses the PDE data to determine the Part D sponsor's actual allowable costs, and then performs a reconciliation that compares the prospective payments made to the Part D sponsor (based on anticipated costs) to the Part D sponsor's actual allowable costs. Based on this reconciliation, CMS calculates final payments and risk-sharing amounts. CMS ultimately shares in the difference between the plan's budgeted costs and actual costs, paying out more taxpayer funds if actual costs exceeded budgeted costs, and vice-versa.

32. Payments to a Part D plan sponsor are conditioned on providing the information to CMS that is necessary for CMS to administer the Part D program and make payments to Part D plan sponsors for qualified prescription drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that the data elements of a PDE constitute "information . . . necessary to carry out this subpart" and that CMS relies on the information in all 37 data elements of a PDE record to process payments and validate claims. *See* CMS, Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)

(April 27, 2006), *available at* https://www.cms.gov/Medicare/Prescription-Drug-Coverage/Drug CoverageClaimsData/downloads/PDEGuidance.pdf.

33. Part D sponsors who fail to submit required claims-level information contained in the PDE to CMS risk having to return monthly payments to CMS during reconciliation. *See* 42 C.F.R. § 423.343(b), (c)(2), (d)(2). In addition, Part D sponsors are responsible for correcting submitted PDE data that they determine to be erroneous. *See* Updated Instructions, *supra*, at 4.

34. Federal regulations require that the Part D plan sponsor, as a condition of receiving monthly advance payments from CMS, certify to the accuracy, completeness, and truthfulness of the PDE data, and all other data submitted in support of CMS's decisions on payment. 42 C.F.R. § 423.505(k)(1). Likewise, the network pharmacies that submit claims data to Part D plans must certify to the accuracy, completeness, and truthfulness of that data and acknowledge that it will be used for the purpose of seeking federal funds. 42 C.F.R. § 423.505(k)(3).

**TRICARE/CHAMPUS**

35. The United States provides medical care, including pharmacy benefits, to certain current and former members of the armed services and their dependents through the TRICARE and CHAMPUS programs. *See* 10 U.S.C. §§ 1071, 1074g; 32 C.F.R. § 199.21. Under these programs, TRICARE and CHAMPUS beneficiaries have access to a uniform formulary of prescription drugs, which are defined as drugs that by law require a physician's or dentist's prescription. *See* 10 U.S.C. § 1074g; 32 C.F.R. §§ 199.2, 199.21. TRICARE and CHAMPUS coverage extends only to medically necessary services. 32 C.F.R. § 199.4(a)(1)(i). Pharmacies must certify the accuracy of the information stated on their claims to TRICARE and CHAMPUS, including the accuracy of the days' supply dispensed.

**VA Health Benefits Programs**

36. Through the VA, the United States offers medical benefits to qualified veterans. *See* 38 U.S.C. § 1701; 38 C.F.R. § 17.38(a). These medical benefits include the prescription drugs available under the VA's national formulary system. 38 C.F.R. § 17.38(a)(1)(iii). VA Health Benefits cover medical services only if "it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice." *Id.* § 17.38(b). Electronic claims submitted by non-VA pharmacies for medication reimbursement must include the days' supply of medication dispensed.

**The Federal Employee Health Benefits Program**

37. To provide health insurance benefits to federal employees, the United States Office of Personnel Management contracts with qualified carriers to offer federal employees a range of health insurance plans. All FEHBP plans provide prescription drug coverage. Providers submitting claims to FEHBP must submit an accurate days' supply on the claim form.

**Medicaid - Federal Coverage Requirements**

38. Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, establishes the joint federal-state Medicaid program created to enable the states to implement medical assistance programs, primarily for the poor and disabled. The United States funds and oversees the Medicaid program through CMS. The state plaintiffs participate in the Medicaid program, under which they pay for pharmaceutical drugs (including insulin) in certain circumstances for Medicaid beneficiaries. Reimbursement for covered drugs is made by each state's Medicaid program agency, which, in turn, seeks reimbursement for a portion of its expenditures from the federal government.

39. The federal government covers the costs of medications under the Medicaid program only if the drugs are "prescribed drugs," *i.e.*, medications which may be "dispensed only

upon prescription." *See* 42 U.S.C. § 1396r-8(k)(2). The term "prescribed drug" is defined by regulation to include drugs that are: "(1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law; (2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and (3) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records." 42 C.F.R. § 440.120(a). Thus, the federal government pays for prescription medications only when they are dispensed in accordance with prescriptions that comply with state law.

40. Federal law and regulations require that any health care provider who bills Medicaid for health care services must ensure that, to the extent of his or her authority, those services are provided "only when, and to the extent, medically necessary" and are "supported by evidence of medical necessity." *See* 42 U.S.C. § 1320c-5(a); 42 C.F.R. § 1004.10.

41. The Omnibus Budget and Reconciliation Act of 1990 ("OBRA 1990") requires states to establish a drug utilization review (DUR) program for Medicaid-covered outpatient drugs "in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results." 42 U.S.C. § 1396r-8(g) (1) (A). The states implement this federal requirement by requiring pharmacies to review prescriptions for overutilization and errors before dispensing medication; many states impose this obligation regardless of whether the prescription will be paid for by Medicaid. *See*, *e.g.*, Florida Rule 64B16-27-810; Indiana Code § 12-15-35-40; 247 Code of Mass. Regs.§ 9.07(2); NJ Stat. § 45:14-66; NY CCS Soc. Serv. § 369-cc(3).

**Medicaid - State Coverage Requirements**

42. Most state Medicaid programs limit coverage to services that are medically necessary. *See, e.g.*, Cal. Code Regs. tit. 22, § 51303(a) (limiting coverage to "reasonable and necessary" services); Fla. Admin. Code Ann. r. 59G-1.035 (covering only medically necessary services); 130 Mass. Code Regs. § 450.204 ("The MassHealth agency will not pay a provider for services that are not medically necessary . . . ."); 18 N.Y. Comp. Codes R. & Regs. § 500.1(b) (limiting coverage to "medically necessary and appropriate services"). In addition, the state Medicaid programs comply with the federal statute limiting Medicaid reimbursement to medication dispensed "on a prescription," *i.e.*, in conformity with the instructions of a health care practitioner regarding not only the drug name and strength, but also the quantity of medication to be consumed over a set period of time. *See, e.g.*, Florida Medicaid, Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook, ch. 2, at 3 (July 2014) (stating that "Medical and pharmacy boards agree that a prescription's authorization is for the total quantity and duration on the prescription unless specific restriction on the quantity per dispensing are indicated on the prescription");[1] Georgia Dep't of Cmty. Health, Policies and Procedures for Pharmacy Services § 602.4 (Apr. 1, 2015) ("Both the exact quantity and the day supply must be billed to Georgia Medicaid based on the metric decimal quantity prescribed and the prescriber's exact written directions . . . . Quantities Dispensed: Always submit the quantity prescribed, and submit the exact calculation of day supply per the Prescriber's dosing instructions.");[2] Illinois Medicaid, Handbook for Pharmacy Services, ch. P-204.4 (July 2013) ("Drugs shall, in no event,

---

[1] *Available at* http://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/Prescribed_Drug_Services_Handbook_July_2014.pdf.
[2] *Available at* https://www.mmis.georgia.gov/portal/Portals/0/StaticContent/Public/ALL/HANDBOOKS/Pharmacy%20services%20%2013-04-2015%20144137.pdf.

be dispensed more frequently or in larger amounts than the prescriber ordered without direct prescriber authorization by way of a new prescription order.");[3] Md. Code Regs. 10.03.03.05 ("Prescriptions shall be dispensed at the lower of the quantity prescribed or the maximum days' supply allowed . . . ."); Michigan Dep't of Cmty. Health, Medicaid Provider Manual – Pharmacy § 11.1 (Apr. 1, 2015) ("Prescription quantities are limited to the quantity specified by the prescriber.");[4] Minnesota Department of Human Services, Pharmacy Services Provider Manual (May 6, 2014) ("A prescribed drug must be dispensed in the quantity specified on the prescription unless the pharmacy is using unit dose dispensing or the specified quantity is not available in the pharmacy when the prescription is dispensed.");[5] Nevada Medicaid and Nevada Check Up Pharmacy Manual, § 3.1 (Mar. 20, 2015) ("Prescriptions must be dispensed pursuant to the orders of a physician or legally authorized prescriber.");[6] N.Y. State Medicaid Program, Pharmacy Manual Policy Guidelines, at 4 (Version 2013-1, September 2013) ("Quantities for prescription drugs shall be dispensed in the amount prescribed.");[7] Rhode Island Medicaid Provider Manual – Pharmacy, Pharmacy Coverage Policy (stating that "[a]ll medication is dispensed on the basis of a written prescription from the prescribing provider" and for "maintenance" medications such as insulin "[t]he original prescription may be dispensed in the quantity that the prescribing provider indicates on the prescription.");[8] Texas Vendor Drug Program, Pharmacy Provider Procedure Manual § 5.3.2 (Feb. 1, 2015) ("Providers must dispense the quantity prescribed or ordered by the

---

[3] *Available at* http://www2.illinois.gov/hfs/SiteCollectionDocuments/p200.pdf.
[4] *Available at* http://www.mdch.state.mi.us/dch-medicaid/manuals/MedicaidProviderManual.pdf.
[5] *Available at* http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_008992.
[6] *Available at* https://www.medicaid.nv.gov/Downloads/provider/NV_Pharmacy_Manual.pdf.
[7] *Available at* https://www.emedny.org/ProviderManuals/Pharmacy/PDFS/Pharmacy_Policy_Guidelines.pdf.
[8] *Available at* http://www.eohhs.ri.gov/ProvidersPartners/ProviderManualsGuidelines/MedicaidProviderManual/Pharmacy/PharmacyCoveragePolicy.aspx#15.1.

prescriber . . . .");[9] Virginia Medicaid Pharmacy Manual, ch. 4, at 1 (rev. Jan. 27, 2014) (stating that Virginia's Medicaid program "will pay for a maximum of a 34-day supply of medication per member in accordance with the prescriber's orders and subject to the Board of Pharmacy regulations.");[10] Washington Apple Health, Prescription Drug Program Provider Guide, at 20 (Apr. 1, 2015) ("The following practices constitute an abuse of the program and a misuse of taxpayer dollars: . . . Excessive filling – Excessive filling consists of billing for an amount of a drug or supply greater than the prescribed quantity.");[11] Wis. Admin. Code DHS § 107.10(3)(d) ("[L]egend drugs shall be dispensed in the full amounts prescribed . . . .").

43. The state Medicaid programs also require pharmacies wishing to bill and obtain payment from Medicaid to abide by all applicable federal and state laws. *See, e.g.*, Medi-Cal, Drug Medi-Cal Provider Agreement, at 2, 8 (rev. 9/14) (requiring providers billing Medi-Cal, the state Medicaid program, to certify that they will comply with all "federal laws and regulations governing and regulating Medicaid providers.");[12] Fla. Stat. § 409.907(1) (stating that Florida's Medicaid program covers only those goods and services provided in compliance with requirements relating to licensure and applicable federal and state law); Ill. Adm. Code tit. 89, § 140.12(d) (stating that Medicaid pays for goods and services only if providers comply with applicable federal and state laws.); Mass. Gen. Laws. ch. 118E, § 36(4) (stating that providers participating in MassHealth, the state Medicaid program, must comply with "all laws, rules and regulations governing the operation

[9] *Available at* http://www.txvendordrug.com/downloads/procedure-manual.pdf.
[10] *Available at* https://www.ecm.virginiamedicaid.dmas.virginia.gov/WorkplaceXT/getContent?vsId={85176287-60C5-4F6A-81CE-A1DCC3E93144}&impersonate=true&objectType=document&id={929E01B3-0D22-463F-9D8B-CC3427FEFB2C}&objectStoreName=VAPRODOS1.
[11] *Available at* http://www.hca.wa.gov/medicaid/billing/Documents/guides/prescription_drug_program_bi.pdf.
[12] *Available at* https://files.medi-cal.ca.gov/pubsdoco/Publications/masters-other/provappsenroll/24enrollment_DHCS6009.pdf.

of the program"); eMedNY, New York State Medicaid Enrollment Form, at 8 (rev. 05/15) (stating that "[a]s a Medicaid Provider you agree to abide by all applicable Federal and State laws.").[13]

44. In turn, state laws governing the practice of pharmacy require that medication may be dispensed only upon a prescription that states the physician's "directions for use," including the quantity to be taken by the patient on a daily basis. *See, e.g.*, Cal. Bus. & Prof. Code § 4040(a)(1)(B) (prescription must include "[t]he name and quantity of the drug or device prescribed and the directions for use"); Fla. Stat. § 456.42(1) (requiring that a "written prescription for a medicinal drug issued by a health care practitioner" must contain "the quantity of the drug prescribed" and "the directions for use of the drug"); 105 Mass. Code Regs. § 721.020 (stating that every prescription "shall contain . . . the quantity of dosage units" prescribed and "directions for use, including any cautionary statements required."); 225 Ill. Comp. Stat. 85/3(e) (stating that a valid prescription must specify both quantity and directions for use); N.Y. Comp. Codes R. & Regs. tit. 8, § 29.7(a)(1) (pharmacists may not in the course of professional conduct "[d]ispens[e] a written prescription which does not bear . . . the . . . quantity of the drug prescribed" or the "directions for use").

45. State Medicaid rules generally limit the number of "days' supply" that Medicaid will pay for at a time. *See, e.g.*, Md. Code Regs. 10.03.03.05 ("Prescriptions shall be dispensed at the lower of the quantity prescribed or the maximum days' supply allowed . . . . ").

**State Medicaid Programs - Claims Submission Requirements**

46. Pharmacies enrolled as providers in state Medicaid programs must submit claims in accordance with the state Medicaid programs' policies and procedures.

[13] *Available at* https://www.emedny.org/info/ProviderEnrollment/ProviderMaintForms/436701_BUSNS _FORM_BusinessEnrlForm.pdf.

47. Almost all pharmacy claims are now submitted electronically. For claims submitted electronically, the Health Insurance Portability and Accountability Act ("HIPAA") requires that pharmacies and state Medicaid programs use the HIPAA-compliant National Council for Prescription Drugs Program ("NCPDP") Telecommunication Standard for electronic claim submission. *See* 42 U.S.C. §§ 1320d-1(a)(3), 1320d-2(a)(2). The Telecommunication Standard consists of an array of defined data fields about the drug claim, including a field called "days' supply," in which the pharmacy is supposed to state the "estimated number of days that the prescription will last." *See* NCPDP Reference Manual, Chapter 3: Flat File Format, at 38 (Oct. 2005).[14] In the states at issue in this case, the NCPDP field for "days' supply" is always required. *See, e.g.*, California Medicaid Management Information System, NCPDP Standard Payer Sheet, at 4 (May 2013);[15] Magellan Medicaid Administration, Florida D.0 Payer Specification, at 6 (May 13, 2011);[16] State of Illinois Department of Healthcare and Family Services, Provider Payor Sheets for NCPDP Version D.0 ECP Input Transactions, at 4 (rev. Dec. 7, 2011);[17] MassHealth, Pharmacy Online Processing System (POPS) Billing Guide, at 8 (Aug. 2013);[18] eMedNY, Standard Companion Guide Transaction Information, at 19 (May 22, 2014).[19]

48. Under federal law, a state Medicaid agency accepting federal Medicaid funds must require a provider billing Medicaid either: (i) to certify the truthfulness, accuracy and completeness of the information on their claim using wording set forth in the federal regulation or alternative wording approved by the federal government; or, ii) to acknowledge in endorsing or depositing

---

[14] *Available at* http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/downloads/NCPDPflatfile.pdf.
[15] *Available at* http://files.medi-cal.ca.gov/pubsdoco/Publications/masters-other/5010/NCPDP%20Payer%20Sheet_V5.1.pdf.
[16] *Available at* http://www.fdhc.state.fl.us/medicaid/Prescribed_Drug/pdf/Florida_D0_Payer_Spec_Final.pdf.
[17] *Available at* http://www2.illinois.gov/hfs/SiteCollectionDocuments/ncpdp_it.pdf.
[18] *Available at* http://www.mass.gov/eohhs/docs/masshealth/pharmacy/pops-billing-guide.pdf.
[19] *Available at* https://www.emedny.org/hipaa/5010/transactions/NCPDP_D.0_Companion_Guide.pdf.

Medicaid payment that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws. 42 CFR §455.18 and §455.19. The states implement this federal rule by requiring providers billing Medicaid to certify the truthfulness, accuracy and completeness of the information on their claims, which includes the "days' supply" being dispensed. *See, e.g.*, Florida Medicaid Management Information Systems, Electronic Data Interchange Agreement, at 3 (Nov. 2013);[20] Illinois Department of Healthcare and Family Services, Agreement for Participation in the Illinois Medical Assistance Program, at 2 (April 2014);[21] MassHealth, Trading Partner Agreement, at 1 (Feb. 2011);[22] eMedNY/Medicaid Management Information System, Certification Statement for Provider Billing Medicaid, at 1 (Dec. 2010).[23]

49. Further, by enrolling as providers in state Medicaid programs, pharmacies also agree to follow all applicable program rules and regulations.

## THE FRAUDULENT SCHEME

### Insulin Pens

50. The scheme in this case involves insulin pen products that are packaged in 5-pen boxes, such as, but not limited to the Lantus Solostar, Basaglar Kwikpen, Apidra Solostar, Levemir Flexpen, Novolog Flexpen, and Humalog Kwikpen.

51. Insulin pens are designed to provide diabetic patients with an accurate and convenient way to administer the precise doses of insulin directed by their physician.[24] Each pen

---

[20] *Available at* https://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/Public%20Misc%20Files/electronic%20data%20interchange%20agreement_20131121.pdf.
[21] *Available at* https://www.illinois.gov/hfs/SiteCollectionDocuments/hfs1413.pdf.
[22] *Available at* http://www.mass.gov/eohhs/docs/masshealth/privacy/hipaa-trading-partner.pdf.
[23] *Available at*: https://www.emedny.org/info/providerenrollment/ProviderMaintForms/490501_ETIN_CERT_Certification_Statement_Cert_Instructions_for_Existing_ETINs.pdf.
[24] Strictly speaking, the products at issue in this case are insulin analogs, which are modified versions of human insulin designed to act more quickly or more slowly than genuine human insulin.

comes pre-loaded with a vial containing three milliliters ("ml") of insulin at a concentration of 100 units per ml. Thus, each pen contains 300 units of insulin. The pen can be easily calibrated to deliver the dose appropriate for the patient, and each pen can deliver multiple doses over a period of time. Doses are administered with disposable needles that are discarded after each use. Unlike traditional insulin, an opened insulin pen does not need to be refrigerated between doses—it can be stored at room temperature for up to 28 days after the first use. Unused pens can be kept in a refrigerator for up to a year.

52. The manufacturers of insulin pens, such as Sanofi-Aventis (the maker of Lantus and Apidra Solostar), Novo Nordisk (the maker of Levemir and Novolog Flexpen), and Eli Lilly (the maker of Humalog Kwikpen), sell them to pharmacies either as individual pens or in boxes of five pens. Each box contains 15 ml of insulin, or 1,500 units. Each pen in the box is individually sealed and labeled with the drug's name, NDC number, manufacturer, lot number and expiration date. In addition, each pen is labelled with a bar code for use by the pharmacy when the pharmacy removes the pen from the box and dispenses it individually. The insulin in the pen is protected from degradation and contamination until the pen device is pierced with a needle by the patient upon initial use. The insulin in an unopened pen does not expire for a full year; once the pen has been pierced with a needle, however, the insulin degrades within approximately 30 days.

53. It is lawful and safe for a pharmacy to open insulin pen cartons and dispense individual insulin pens. There is no statement on the insulin pen carton or label that the product must be dispensed inside the original carton in which it is shipped. In contrast to medications that do have such a restriction reflected on the carton or label, the FDA does not require insulin pen manufacturers to inform pharmacies that the pens must be dispensed inside the cartons. Accordingly, the preeminent organizations that publish guidance and news for pharmacists

exclude insulin pens from their lists of medications that must be dispensed in the manufacturer-provided packaging. Information on the insulin pen product package insert provided to pharmacies confirms that the unopened pen devices protect the integrity and stability of the enclosed insulin until the product's expiration date. Moreover, manufacturer customer assistance desks inform pharmacies that the cartons may be opened prior to dispensing.

54. Insulin pen cartons are not considered a "unit-of-use container" that should be dispensed by the pharmacy without repackaging. U.S. Pharmacopeia, the compendium of medication information that is relied upon by the FDA as an authoritative source on a number of topics, defines a "unit-of-use container" to be a container that, *inter alia*, is "labelled as such." Insulin pen cartons are not labelled as "unit-of-use containers."

55. Insulin pens make up a large and growing portion of the insulin market - and, consequently, federal healthcare program payments for insulin pens are substantial. For instance, in 2015, Medicare Part D paid more than $6.9 billion for insulin pens. And in 2015, Medicaid paid more than $5.9 billion in the aggregate for Lantus, Levemir, and Novolog insulin pens. Insulin pens are relatively expensive items. In New York, for example, Medicaid reimbursements rates for individual pens range from $73.83 to $205.16 per 3 ml pen, and from $369.15 to $1,025.79 per 15 ml box. *See* N.Y State Dep't of Health, List of Medicaid Reimbursable Drugs, at 35, 229-230, 267, 271, and 356-357, https://www.emedny.org/info/fullform.pdf.

**Reimbursement for Insulin Pens**

56. Federal and state health care programs pay for insulin pens based on the number of milliliters of insulin dispensed, not based on the number of boxes dispensed. *See, e.g.*, Pennsylvania Dep't of Human Servs., *Drug Fee Schedule* (June 17, 2015) (setting a "Payment

Rate Per Unit" of "$22.91842 per Milliliter" for Levemir Flexpen);[25] N.Y State Dep't of Health, *List of Medicaid Reimbursable Drugs*, at 33, 196, 231, 234, 311 (June 17, 2015) (stating that the basis of reimbursement for the insulin pen products at issue in this case is "ml");[26] Texas Medicaid/CHIP Vendor Drug Program, *Formulary Drug Search* (June 17, 2015) (stating that Texas Medicaid reimburses for Lantus Solostar based on a package size of 3 ml);[27] Washington State Healthcare Authority, *Current NCPDP Billing Standards*, at 2 (June 17, 2015) (stating that "Injectables that are liquid-filled vials, ampoules, and syringes must be billed as the total number of milliliters (ml) dispensed").[28]

**Determining Quantity to Dispense**

57. The amount of insulin a practitioner will prescribe for a patient varies widely, depending on factors such as the patient's weight and activity level, what type of diabetes the patient has, whether the patient is a child or an adult, and how long the patient has been on insulin therapy. Further, the total daily dose is generally divided between two or more injections, which may not be equal in size. Because of the wide range of possible doses and dosing regimens, the practitioner must provide clear instructions for the patient, and the patient's dose may be adjusted frequently over the course of the disease.

58. When a pharmacist receives a practitioner's order for insulin, he or she must determine how much to dispense to comply with the practitioner's directions. To do so, the pharmacist must first multiply the patient's total daily dose by the days' supply to be dispensed. The days' supply to be dispensed will depend on any instructions on this issue found in the

---

[25] *Available at* http://www.dhs.state.pa.us/publications/forproviders/schedules/drugfeeschedule/index.htm?Result=true&NDC=00169643910.
[26] *Available at* https://www.emedny.org/info/fullform.pdf.
[27] *Available at* www.txvendordrug.com/formulary/FormularyResults.asp?sort=Descr&NDC=&Descr=lantus&MKID=&submit=Search.
[28] *Available at* http://www.hca.wa.gov/medicaid/pharmacy/documents/current_ncpdp_billing_standards.pdf.

practitioner's order, any limits on days' supply in the patient's health insurance plan, and, in the case of CVS and many other retail pharmacies, a policy that encourages pharmacists to bill Medicare Part D for 90-day supplies of insulin and other medications taken for chronic conditions. If a patient required 20 units per day, a 30-day supply, properly determined, would be 600 units, or 6 ml. For the same patient, a 90-day supply, properly determined, would be 1,800 units, or 18 ml; and a 100-day supply, properly determined, would be 2,000 units, or 20 ml.

59. Next, the pharmacist must determine the number of pens needed to provide a sufficient quantity to cover the total days' supply. Each pen contains 300 units of insulin, or 3 ml. So, to dispense the 6 ml required for a 30-day supply for the patient above, the pharmacist should dispense exactly two pens. A 90-day supply for the same patient should require exactly six pens—that is, one five-pen box plus one individual pen. When dispensing individual pens, pharmacists outside of CVS commonly dispense them in a sealed, ziplock bag, with a copy of the product's package insert and information about the prescription stapled to the pharmacy paper bag.

**CVS's Dispensing of 15 ml Cartons**

60. Relator consistently has been informed upon inquiring of CVS pharmacy staff throughout the country that CVS stores dispense insulin pens only in the shipping cartons and do not open the cartons in order to dispense individual pens. Some CVS pharmacists have told Relator that their store's practice is not to open pens, other CVS pharmacists have said that boxes are not opened in their CVS district as a matter of district policy or general practice, while others have characterized the practice of not opening boxes as "CVS policy." None of these pharmacists have maintained to Relator that this practice stems from safety concerns; rather, they have cited CVS's financial interests in moving inventory. In particular, a CVS pharmacist in Maryland, a CVS pharmacist in Virginia, two CVS pharmacists in New York, and a CVS pharmacist in Florida have informed Relator that the CVS policy in their districts is to dispense insulin pens only in cartons.

The CVS pharmacist in Florida informed Relator that this dispensing practice is, in fact, official "CVS policy." A CVS pharmacist in Fresno, California informed Relator that his store dispenses pens only in cartons. In addition, in the last two years, Relator has witnessed first-hand the insulin pen dispensing practices of multiple CVS stores in Maryland and Virginia, because he has worked substitute shifts in approximately thirty different CVS pharmacies in the area and has transferred insulin pen prescriptions between local CVS stores. He has seen that the consistent practice in CVS stores is to dispense insulin pens only in cartons.

**CVS's Falsifying "Days' Supply" on Claim Form**

61. CVS's general practice of dispensing pens in 5 pen cartons is not, standing alone, necessarily an illegal practice that leads to the submission false claims. For example, assume a prescriber has directed that a patient take 20 units of insulin per day, a dose that will total 600 units of insulin every 30 days, which is the equivalent of 2 pens of insulin since each pen contains 300 units. And assume that the government health plan has a 30-day supply limit, and the pharmacy is intent on dispensing pens only in 5-pen cartons. In this example, the 5-pen carton would be a 75-day supply for the patient because each carton contains 15 ml, or 1,500 units of insulin, and 1,500 units divided by 20 units equals 75. Dispensing a full carton to this particular patient would run afoul of the payer's 30-day supply limit. However, almost all payers have procedures pursuant to which a pharmacy may request a waiver, termed an "override," of the days' supply limit. Accordingly, the pharmacy could dispense a full carton of pens to this patient and stay in compliance with payer rules if it were to request and receive a payer override of the days' supply limit that permitted it to dispense a 75-day supply. In addition, pharmacies with sufficient leverage in the market, such as CVS, have a realistic possibility of negotiating contracts with payers that permit larger days' supply for particular products.

62. Through his employment at CVS, however, Relator has learned that CVS pharmacists are not trained or expected to seek waivers of days' supply limits when dispensing insulin pens in quantities that exceed days' supply limits. He has learned through his employment that when one or more boxes of insulin pens exceeds the maximum days' supply covered by insurance or ordered by the physician, CVS pharmacists regularly falsify the "days' supply" being dispensed, falsely inform their customers of the understated days' supply on a CVS print-out attached to the bag with the dispensed medication, and then actively encourage their customers to prematurely refill the prescription upon expiration of the understated days' supply. He has witnessed this first-hand when working substitute shifts in approximately 30 different CVS stores in Virginia and Maryland, and when transferring insulin pen prescriptions between stores.

63. In general, there are three types of situations that lead CVS pharmacists to falsify the days' supply on claims for insulin pens. The first situation is one in which the government health plan pays for no more than 30 days of insulin at a time, yet the 15 ml box of insulin pens being dispensed will last the patient significantly more than 30 days if the insulin is taken in the daily doses prescribed by the physician.

64. The second situation is one in which the insurance plan covers up to a 90 days' supply, and the CVS pharmacist bills for the full 90-day supply, rather than a lesser quantity, because of a CVS policy, called "CVS 90," that financially incentivizes pharmacists to bill for a full 90-day supply whenever possible. There is nothing illegal per se about the CVS 90 policy, but, when combined with the CVS policy to dispense pens only in boxes and to avoid seeking days' supply limit overrides, the policy leads to false claims. Pursuant to the CVS 90 policy, CVS evaluates pharmacists based on: i) the number of times they ask a patient whether they would like their prescriptions to be dispensed in 90-day supplies when insurance permits; and, ii) the

percentage of patients who accept the pharmacists' offer to convert their fills to 90- day supplies. CVS's 2018 goal is for 55% of CVS customers to accept the offer to receive their prescriptions in 90-day fills. CVS corporate headquarters issues weekly reports showing how each pharmacy is performing against this metric.

65. The CVS 90 policy leads to false claims for insulin pens because, if a CVS pharmacist dispenses a 90-day supply of insulin pens, in most cases, this will mean that extra insulin will be dispensed. This is because a 90-day supply of insulin, computed according to the doctor's directions for use, will rarely correspond to an exact multiple of a 15 ml carton, and the pharmacist will have to "round up" in order to dispense nothing but full cartons. In this situation, CVS would have had the option of billing for a days' supply less than 90 that accurately reflected the period of time that the dispensed medication would last the patient. For example, if a patient is prescribed 40 units of insulin per day, and her insurance plan covers up to 90 days of insulin at a time, and the pharmacist follows the "CVS 90" policy, the pharmacist will end up charging the government for 3 cartons of insulin, equal to 45 ml, even though this is 9 ml more than what is needed by the patient. (90 x 40 units = 3,600 units, or 36 ml, and rounding up to a multiple of 15 ml one arrives at 45 ml, the amount of insulin in 3 cartons.) However, the pharmacist could have instead complied with the law if he or she dispensed two cartons and accurately billed the government for a 70-day supply. A 70-day supply of 40 units per day equals 2,800 units, or 28 ml, requiring the dispensing of 10 pens, the amount in two cartons. (Two cartons have 30 ml of insulin, and the tenth pen cannot be opened prior to dispensing due to the seal that protects the integrity of the insulin in the pen, so two cartons is the appropriate amount to dispense when the prescription calls for 28 ml.)

66. In the third situation in which false claims occur, CVS pharmacists falsify the actual days' supply on the claim form in order to dispense a full carton while still ostensibly complying with a days' supply requested by the physician. For example, if a physician prescribes 10 units of insulin a day and asks the pharmacy to dispense a "trial" 14-day supply, a 15 ml carton will dispense 13.6 ml of insulin beyond what the patient requires; the patient only needs 140 units of insulin to cover the 10-day period (10 units x 14), and 140 units is equivalent to 1.4 ml.

67. Misrepresenting the days' supply on the claim form in order to dispense more than what the doctor ordered not only violates CVS's certifications of the accuracy of its claims data and the rules of government health programs, it also contravenes CVS's understanding of the proper way to bill insurance. Thus, CVS informed pharmacies in a "CVS Audit Tips and Best Practices" document, updated in November 2013, that "[t]he days supply should accurately reflect the documented directions and quantity dispensed. The days supply adjudicated on the claim needs to be an accurate reflection of the calculation made from the prescribed does [sic] and quantity."

**CVS's Dispensing and Billing for Premature Refills**

68. CVS's widespread practice of falsifying the days' supply on insulin pen claims also leads the pharmacy chain to routinely dispense refills to patients significantly prior to the time when additional medication would be needed if taken according to the prescriber's daily dosing directions. When refills are dispensed significantly prior to when additional medication is needed, government payers consider these to be "early" or "premature" refills and do not pay for them when detected. CVS's premature refilling of insulin pen prescriptions result from the fact that, when CVS determines the appropriate time to dispense a refill, it relies on the same false days' supply data that it had included on the claim to insurance. So, for example, if CVS dispenses a 15 ml carton of insulin pens to a patient who needs just 3 ml (1 pen) every 30 days, and falsely informs

insurance that the 15 ml is a 30-day supply, CVS will use that same false information to determine when it may dispense a refill.

69. CVS encourages its patients to refill their prescriptions within three or four days of when the purported "days' supply" will be used up, using several techniques. First, CVS has programmed its computer billing and dispensing software to take the "days' supply" data that is found in its prescription database - the same false "days' supply" that CVS used to bill insurance - and place this "days' supply" figure on a pamphlet that it provides the customer who picks up a prescription. What this means is that CVS would falsely inform the patient described above - the one who needs just 3 ml of insulin (1 pen) every 30 days - that the 15 ml carton is a 30 days' supply, increasing the odds that the patient would come in for a premature refill about 4 months early.

70. The second technique utilized by CVS's corporate headquarters to encourage customers to refill their prescriptions before the end of the "days' supply" period stated in CVS's computer system is to aggressively push a CVS automatic refill program called "ReadyFill." CVS's corporate headquarters incentivizes pharmacy staff to place as many of the pharmacy's customers as possible on ReadyFill by: i) requiring pharmacy staff to make a set number of weekly calls asking customers if they wish to enroll in the program; ii) setting a corporate-wide goal for the percentage of customers that should be enrolling in the program when contacted (currently this goal is 60%); iii) issuing weekly reports on individual employee and pharmacy success in meeting this goal; and, iv) taking each pharmacy's and each employee's success in meeting this metric into account in evaluating employee performance and determining compensation and bonuses. CVS's weekly reports rank pharmacies compared to other pharmacies in the same district, and remind

pharmacy staff to "ensure you are having conversations weekly with colleagues who are not performing."

71. In the event that a customer signs up for CVS's "ReadyFill" automatic refill program, their prescriptions will be automatically refilled by CVS within three to four days of the expiration of the "days' supply" in CVS's prescription database, which is the same days' supply used to bill insurance, and they will receive repeated, automated reminder calls to pick up the refill, followed by an in-person call if they do not pick up the refill in response to the automated messages. If the patient described above - the one who needs just 3 ml of insulin (1 pen) every 30 days - were to enroll in ReadyFill, within 30 days of having dispensed a full 15 ml carton of pens to the patient, CVS would notify the patient that it was time to pick up a refill of <u>another</u> 15 ml carton.

72. The third technique used by CVS headquarters to motivate customers to pick up refills prior to the expiration of the "days' supply" in CVS's computer system is the deployment of a refill reminder program for all customers, regardless of whether they have signed up for auto refills, called "Adherence Outreach." This program involves multiple automatic and in-person phone calls, and, in some cases, text communications to remind patients to order refills before the expiration of the days' supply period found in CVS's computer system. Individual pharmacists are evaluated, compensated and considered for bonuses based on their success, or lack of success, in persuading customers to order and pick-up refills within 14 days of the refill reminder call. The chain wide target outcome is that 29% of customers will order and pick up refills within 14 days of the call. For the patient described above, this would mean that CVS would repeatedly urge the patient to order a refill of another 15 ml carton before the expiration of the false 30-day supply period found in CVS's computer system. If CVS's automatic reminders did not get the customer

to order the refill, then he or she would receive a personal call from a pharmacy staff member who would be financially incentivized to get the refill ordered and picked up expeditiously.

73. CVS provides its pharmacists with a "script guide" for calls made to remind patients to pick up fills and refills. This script guide is plainly designed to mollify any clinical concerns the patient might have about ordering more medication so that CVS can dispense another fill of the drug. Here is an example of a script that CVS provides pharmacists making "script pick up calls":

"SCRIPT PICK UP CALL – Conversation Guide

Be Genuine, provide your name and role at CVS. **Confirm patient's full name and date of birth**. *Hi Mrs. Smith, I'm Ryan, your pharmacist/technician at CVS on Main St.*
*In reviewing your profile, I noticed your* ***prescription(s) is ready for pickup****. Will we be seeing you today or tomorrow to pick them up?*
If patient does not plan to pick up, understand why. Common barriers to adherence a pharmacist may discuss with the patient include:

-High Cost: Offer cost-saving generics and/or different formulations if available
-Side effects: Offer tips to mitigate unwanted side effects or switch to another therapy
-Unsure of need: Discuss the chronic condition, inform that symptoms may not be obvious
Taking medications regularly can be challenging. Empathize by answering questions to help patient manage medications and ensure patient gets the medication they need."

On a weekly basis, CVS evaluates its pharmacies and staff on their success in getting customers to pick up fills and refills, and these evaluations factor into compensation and bonuses.

**CVS Management's Knowledge of Pervasive False Claims for Insulin Pens**

74. CVS's corporate management has been aware that many of its pharmacists understate the days' supply and charge for premature refills when billing insurance for insulin pens, and that this practice has led to the pervasive submission of false claims to health insurance plans - and, of course, a windfall of illicit profits for the company. Pharmacy benefit managers working for health insurance companies regularly audit claims submitted by pharmacies, looking for, among other things, whether the days' supply is correctly stated and whether refills have been dispensed prematurely. As a result of these payer audits - including, in particular, audits by CVS's

affiliate, the Caremark pharmacy benefits manager - CVS's corporate management has learned about the widespread nature of its pharmacies' false claims for insulin pens. For example, in July 2015, Caremark notified CVS pharmacies that four of the top ten prescription drug products that its auditors identified as involving "early refills" were insulin pen products, namely the Humalog Kwikpen, the Levemir Flexpen, the Novolog Flexpen and the Novolog Mix 70-30 Flexpen, and two of the top ten prescription drug products with the wrong quantity or days' supply were insulin pen products, namely, the Lantus Solostar and the Novolog Flexpen.

75. CVS has also been aware that government payers do not pay for quantities of insulin pens that exceed what is necessary for a patient to take the prescribed daily doses, and do not pay for premature refills of insulin pens. CVS knows that government payers consider the "days' supply" stated on the claim form to be material to their payment determination. For example, while government payers rarely are provided with a copy of the prescriber's dosing instructions, so their ability to detect inaccurate days' supply and premature refills is limited, they do have software edits in place to catch and reject electronic pharmacy refill claims that were submitted more than a certain number of days before the expiration of the prior day's supply that was reported to the payer. In addition, when a government payer conducts an on-site audit of pharmacy claims, they often compare the actual prescriptions in the pharmacy's files to the claims submitted to the payer, looking for, among other things, claims with an incorrect days' supply and/or premature refills, as assessed based on the payer's computation of the correct days' supply from the prescriber's daily dose instructions.

76. For example, through 2013 and 2014 audits of small samples of CVS claims and their corresponding prescriptions, D.C. Medicaid, NJ Medicaid and Virginia Medicaid adjusted several CVS insulin claims for insulin pens that they determined had an incorrect "days' supply,"

charging back the amounts Medicaid had paid for the excessive quantities of insulin. In addition, on or about December 21, 2012, CVS notified its Florida pharmacies in a "Payer Relations Weekly Update" that Florida Medicaid pays for only 34 days of insulin at a time, and "therefore, insulin products, including pen devices, must be dispensed as the amount needed for a maximum of a 34-day supply. If necessary, manufacturer packages, that can be broken, must be broken to meet the Medicaid requirement. Florida Medicaid will monitor claims for compliance of this policy."

77. Notwithstanding their knowledge of the pervasive pattern of false claims involving insulin pens, CVS managers have failed to take meaningful steps sufficient to remedy the underlying problem. CVS pharmacy staff throughout the country, including in Florida, continue to act under the understanding that CVS's policy is that pharmacies should dispense insulin pens only in boxes and that it is acceptable to CVS if they misrepresent days' supply in order to obtain reimbursement.

**Examples of False Claims**

78. CVS pharmacies have submitted many thousands of false claims to federal and state health insurance programs for insulin pens, and many thousands of false statements to get these false claims paid. The claims are false not only because of the false representation of "days' supply," but also because, in each instance, CVS has falsely certified on the provider agreement or claim form that it is complying with government program rules that: i) restrict payment to medication dispensed on a prescription; ii) restrict payment to medically necessary medication; and iii) limit the days' supply that may be dispensed and billed for at one time. For example[29]:

[29] To protect the privacy of patients, Relator has not disclosed certain information, such as the identity of specific patients or their doctors, for the example prescriptions set forth herein; the CVS Rx # should provide sufficient, particularized information for CVS to be able to identify the referenced false claims.

• In filling a prescription identified as Rx Number 1107837, a CVS pharmacy in Stafford, Virginia, charged Magellan Complete Care MCO, a Medicaid managed care plan, for a full carton of Basaglar Kwikpens dispensed to patient J on January 9, 2018, falsely informing the government payer that the carton was a 30-day supply. The prescriber had ordered a daily dose of 25 units, which means that the carton containing 15 ml (equal to 1,500 units) of insulin actually represented a 60-day supply (1,500 units/25 units=60). The CVS pharmacy proceeded to dispense premature refills of a full carton, again stating that the carton was just a 30-day supply, on February 2, 2018 and March 12, 2018.

* In filling a prescription identified as Rx Number 1388905, a CVS pharmacy in Woodbridge, Virginia, charged Anthem HealthKeepers MCO, a Medicaid managed care plan, for a full carton of Lantus Solostar pens dispensed to the same patient J on February 4, 2017, falsely informing the government payer that the carton was a 30-day supply. The prescriber had ordered a daily dose of 25 units, which means that the carton containing 15 ml (equal to 1,500 units) of insulin actually represented a 60-day supply (1,500 units/25 units=60). The CVS pharmacy proceeded to dispense a premature refill of a full carton, again stating that the carton was just a 30-day supply, on March 2, 2017.

* In filling a prescription identified as Rx Number 8876813, a CVS pharmacy in Silver Spring, Maryland, charged an insurance plan identified as PDPBNO15581/PN03200000, a Medicare Part D plan, for a full carton of Lantus Solostar pens dispensed to patient G on June 8, 2017, falsely informing the government payer that the carton was a 30-day supply. The prescriber had ordered a daily dose of 30 units, which means that the carton containing 15 ml (equal to 1,500 units) of insulin actually represented a 50-day supply (1,500 units/30 units=50). The CVS pharmacy proceeded to dispense premature refills of a full carton, again stating that the carton was

just a 30-day supply on July 11, 2017, August 4, 2017, October 10, 2017, December 19, 2017, January 18, 2018, February 13, 2018 and March 14, 2018.

* In filling a prescription identified as Rx Number 8861442, the CVS pharmacy in Silver Spring, Maryland, charged an insurance plan identified as Priority PTNR MCO-MD PRO-DUR, a Medicaid managed care plan, for a full carton of Basaglar pens dispensed to patient R on July 20, 2017, falsely informing the government payer that the carton was a 30-day supply. The prescriber had ordered a daily dose of 36 units, which means that the carton containing 15 ml (equal to 1,500 units) of insulin actually represented a 41-day supply (1,500 units/36 units= just over 41). The CVS pharmacy proceeded to dispense premature refills of a full carton, again stating that the carton was just a 30-day supply, on August 15, 2017, September 17, 2017, October 15, 2017, November 14, 2017, December 12, 2017, January 17, 2017, February 12, 2018 and March 11, 2018.

* In filling sequential prescriptions identified as Rx Numbers 8829195, 8837114 and 8847689, the CVS pharmacy in Silver Spring, Maryland, charged an insurance plan identified as Priority PTNR MCO-MD PRO-DUR, a Medicaid managed care plan, for a full carton of Levemir Flextouch pens dispensed to patient H on December 19, 2016, falsely informing the government payer that the carton was a 30-day supply, and then dispensed refills of the 15 ml carton on January 15, 2017, March 25, 2017, April 29, 2017, May 31, 2017 and June 27, 2017. On each prescription, the prescriber had ordered a daily dose of 15 units, which means that the carton containing 15 ml (equal to 1,500 units) of insulin actually represented a 100-day supply (1,500 units/15 units= 100). In total, the initial fill and 5 refills, which CVS dispensed to cover a 180 day period, constituted a 600 day supply.

* In filling a prescription identified as Rx Number 0414479**,** a CVS pharmacy in Haddonfield, N.J., charged an insurance plan identified as PDP BN610097FN9999/WRP BN610515 PNPAAD, a Medicare Part D plan, for a full carton of Lantus Solostar pens dispensed to patient B on April 24, 2016, falsely informing the government payer that the carton was a 30-day supply. The prescriber had ordered a daily dose of 30 units, which means that the carton containing 15 ml (equal to 1,500 units) of insulin actually represented a 50-day supply (1,500 units/30 units= 50). The CVS pharmacy proceeded to dispense premature refills of a full carton, again stating that the carton was just a 30-day supply, on May 24, 2016 and June 30, 2016.

## DAMAGES

79. Through the foregoing conduct, CVS has knowingly submitted false claims that have caused the federal-state Medicaid program, in each state in which CVS does business, as well as Medicare Part D, FEHBP, TRICARE/CHAMPUS and the VA, to pay for the excessive amounts of insulin dispensed by CVS's pharmacies. The United States and the state Plaintiffs have been damaged by the amount paid to CVS for insulin pens that should not have been dispensed, because CVS failed to abide by the patients' actual prescriptions, billed for medically unnecessary quantities of medication, and failed to comply with the government payers' "days' supply" limitations.

80. Through the foregoing conduct, the Defendant has also knowingly avoided an obligation to repay funds owed the United States and the state Plaintiffs by improperly failing to disclose and return overpayments. The United States and the state Plaintiffs overpaid CVS for the pens that were dispensed in excess of the number of pens that should have been dispensed. CVS has knowingly retained this difference and failed to disclose or return it. *See* 42 U.S.C. § 1320a-7k(d) (imposing an affirmative duty on health care providers who bill Medicare or Medicaid to

disclose any Medicare or Medicaid overpayments they identify to the government health care program within 60 days of discovery).

**COUNT ONE**

(Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*)

81. This is a civil action by Plaintiff Adam Rahimi, acting on behalf of and in the name of the United States, against the Defendant under the False Claims Act.

82. Relator re-alleges paragraphs 1 through 80 as though fully set forth herein.

83. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1)(A).

84. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

85. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the United States, in violation of 31 U.S.C. § 3729(a)(1)(G).

86. Based on the foregoing allegations, the United States has suffered actual damages, with the exact amount to be determined at trial.

**COUNT TWO**

(California False Claims Act, Cal. Gov't Code § 12650 *et seq.*)

87. Relator re-alleges Paragraphs 1 through 80 inclusive.

88. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

89. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).

90. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of California, in violation of Cal. Gov't Code § 12651(a)(7).

91. Based on the foregoing allegations, the state of California has suffered actual damages, with the exact amount to be determined at trial.

**COUNT THREE**

(Colorado False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*)

92. Relator re-alleges Paragraphs 1 through 80 inclusive.

93. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(1)(a).

94. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(1)(b).

95. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Colorado, in violation of Colo. Rev. Stat. § 25.5-4-305(1)(f).

96. Based on the foregoing allegations, the state of Colorado has suffered actual damages, with the exact amount to be determined at trial.

**COUNT FOUR**

(Connecticut False Claims Act, Conn. Gen. Stat. § 4-274 *et seq.*)

97. Relator re-alleges Paragraphs 1 through 80 inclusive.

98. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation Conn. Gen. Stat. § 4-275(a)(1).

99. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Conn. Gen. Stat. § 4-275(a)(2).

100. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Connecticut, in violation of Conn. Gen. Stat. § 4-275(a)(8).

101. Based on the foregoing allegations, the state of Connecticut has suffered actual damages, with the exact amount to be determined at trial.

**COUNT FIVE**

(Delaware False Claims and Reporting Act, 6 Del. Code § 1201 *et seq.*)

102. Relator re-alleges Paragraphs 1 through 80 inclusive.

103. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of 6 Del. Code § 1201(a)(1).

104. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of 6 Del. Code § 1201(a)(2).

105. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Delaware, in violation 6 Del. Code § 1201(a)(7).

106. Based on the foregoing allegations, the state of Delaware has suffered actual damages, with the exact amount to be determined at trial.

**COUNT SIX**

(Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*)

107. Relator re-alleges Paragraphs 1 through 80 inclusive.

108. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

109. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Fla. Stat. § 68.082(2)(b).

110. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Florida, in violation of Fla. Stat. § 68.082(2)(g).

111. Based on the foregoing allegations, the state of Florida has suffered actual damages, with the exact amount to be determined at trial.

**COUNT SEVEN**

(Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*)

112. Relator re-alleges Paragraphs 1 through 80 inclusive.

113. Defendant CVS has knowingly presented or caused to be presented false or fraudulent claims to the state of California, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).

114. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).

115. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Georgia, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).

116. Based on the foregoing allegations, the state of Georgia has suffered actual damages, with the exact amount to be determined at trial.

**COUNT EIGHT**

(Hawaii False Medicaid Claims Act, Haw. Rev. Stat. § 46-171 *et seq.*)

117. Relator re-alleges Paragraphs 1 through 80 inclusive.

118. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Haw. Rev. Stat. § 46-171(a)(1).

119. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Haw. Rev. Stat. § 46-171(a)(2).

120. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Hawaii, in violation of Haw. Rev. Stat. § 46-171(a)(6).

121. Based on the foregoing allegations, the state of Hawaii has suffered actual damages, with the exact amount to be determined at trial.

**COUNT NINE**

(Illinois False Medicaid Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq.*)

122. Relator re-alleges Paragraphs 1 through 80 inclusive.

123. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(1)(A).

124. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of 740 Ill. Comp. Stat. 175/3(1)(B).

125. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Illinois, in violation of 740 Ill. Comp. Stat. 175/3(1)(G).

126. Based on the foregoing allegations, the state of Illinois has suffered actual damages, with the exact amount to be determined at trial.

## **COUNT TEN**

(Indiana False Claims and Whistleblower Protection Act,
Ind. Code Ann. § 5-11-5.5-1 *et seq.*)

127. Relator re-alleges Paragraphs 1 through 80 inclusive.

128. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Ind. Code Ann. § 5-11-5.5-2(b)(1) and (b)(8).

129. Defendant CVS has made or used, or caused to be made or used, false records or statements to obtain payment or approval of false claims , in violation of Ind. Code Ann. § 5-11-5.5-2(b)(2) and (b)(8).

130. Defendant CVS has made or used, or caused to be made or used, false records or statements to avoid an obligation to pay or transmit property, in violation of Ind. Code Ann. § 5-11-5.5-2(b)(6) and (b)(8).

131. Based on the foregoing allegations, the state of Indiana has suffered actual damages, with the exact amount to be determined at trial.

## **COUNT ELEVEN**

(Iowa False Claims Act, Iowa Code § 685.1 *et seq.*)

132. Relator re-alleges Paragraphs 1 through 80 inclusive.

133. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Iowa Code § 685.2(1)(a).

134. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Iowa Code § 685.2(1)(b).

135. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Iowa, in violation of Iowa Code § 685.2(1)(g).

136. Based on the foregoing allegations, the state of Iowa has suffered actual damages, with the exact amount to be determined at trial.

## COUNT TWELVE

(Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. Ann. § 46:437.1 *et seq.*)

137. Relator re-alleges Paragraphs 1 through 80 inclusive.

138. Defendant CVS has knowingly presented or caused to be presented false or fraudulent claims, in violation of La. Rev. Stat. Ann. § 46:438.3(A).

139. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of La. Rev. Stat. Ann. § 46:438.3(B).

140. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Louisiana, in violation of La. Rev. Stat. Ann. § 46:438.3(C).

141. Based on the foregoing allegations, the state of Louisiana has suffered actual damages, with the exact amount to be determined at trial.

**COUNT THIRTEEN**

(Maryland False Health Claims Act, Md. Code Ann., Health-Gen. § 2-601 *et seq.*)

142. Relator re-alleges Paragraphs 1 through 80 inclusive.

143. Defendant CVS Defendant has knowingly presented or caused to be presented false claims for payment or approval, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).

144. Defendant CVS knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).

145. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Maryland, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(8).

146. Based on the foregoing allegations, the state of Maryland has suffered actual damages, with the exact amount to be determined at trial.

**COUNT FOURTEEN**

(Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A *et seq.*)

147. Relator re-alleges Paragraphs 1 through 80 inclusive.

148. Defendant CVS Defendant has knowingly presented or caused to be presented false claims for payment or approval, in violation of Mass. Gen. Laws ch. 12, § 5B(a)(1).

149. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Mass. Gen. Laws ch. 12, § 5B(a)(2).

150. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the commonwealth of Massachusetts, in violation of Mass. Gen. Laws ch. 12, § 5B(a)(9).

151. Based on the foregoing allegations, the commonwealth of Massachusetts has suffered actual damages, with the exact amount to be determined at trial.

**COUNT FIFTEEN**

(Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*)

152. Relator re-alleges Paragraphs 1 through 80 inclusive.

153. Defendant CVS has knowingly made, or caused to be made, false representations of material fact for use in determining rights to benefits or payments, in violation of Mich. Comp. Laws § 400.603(2).

154. Defendant CVS, with knowledge of the occurrence of an event affecting its initial or continued right to any benefit or payment, has knowingly concealed or failed to disclose that event with an intent fraudulently to secure the benefit or payment in a greater amount or quantity than is due, in violation of Mich. Comp. Laws § 400.603(3).

155. Based on the foregoing allegations, the state of Michigan has suffered actual damages, with the exact amount to be determined at trial.

**COUNT SIXTEEN**

(Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*)

156. Relator re-alleges Paragraphs 1 through 80 inclusive.

157. Defendant has knowingly presented or caused to be presented false claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

158. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Minn. Stat. § 15C.02(a)(2).

159. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Minnesota, in violation of Minn. Stat. § 15C.02(a)(7).

160. Based on the foregoing allegations, the state of Minnesota has suffered actual damages, with the exact amount to be determined at trial.

**COUNT SEVENTEEN**

(Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*)

161. Relator re-alleges Paragraphs 1 through 80 inclusive.

162. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).

163. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Mont. Code Ann. § 17-8-403(1)(b).

164. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Montana, in violation of Mont. Code Ann. § 17-8-403(1)(g).

165. Based on the foregoing allegations, the state of Montana has suffered actual damages, with the exact amount to be determined at trial.

**COUNT EIGHTEEN**

(Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*)

166. Relator re-alleges Paragraphs 1 through 80 inclusive.

167. Defendant has knowingly presented or caused to be presented false claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

168. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

169. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Nevada, in violation of Nev. Rev. Stat. § 357.040(1)(g).

170. Based on the foregoing allegations, the state of Nevada has suffered actual damages, with the exact amount to be determined at trial.

**COUNT NINETEEN**

(New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*)

171. Relator re-alleges Paragraphs 1 through 80 inclusive.

172. Defendant CVS knowingly presented or caused to be presented false claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).

173. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the state of New Jersey, in violation of N.J. Stat. Ann. § 2A:32C-3(b).

174. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property the state of New Jersey, in violation of N.J. Stat. Ann. § 2A:32C-3(g).

175. Based on the foregoing allegations, the state of New Jersey has suffered actual damages, with the exact amount to be determined at trial.

**COUNT TWENTY**

(New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*)

176. Relator re-alleges Paragraphs 1 through 80 inclusive.

177. Defendant CVS has knowingly presented or caused to be presented false claims for payment, in violation of N.M. Stat. Ann. § 27-14-4(A).

178. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state of New Mexico, in violation of N.M. Stat. Ann. § 27-14-4(C).

179. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money or property to the state of New Mexico, in violation of N.M. Stat. Ann. § 27-14-4(E).

180. Based on the foregoing allegations, the state of New Mexico has suffered actual damages, with the exact amount to be determined at trial.

## COUNT TWENTY-ONE

(New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*)

181. Relator re-alleges Paragraphs 1 through 80 inclusive.

182. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

183. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of N.Y. State Fin. Law § 189(1)(b).

184. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of New York, in violation of N.Y. State Fin. Law § 189(1)(h).

185. Based on the foregoing allegations, the state of New York has suffered actual damages, with the exact amount to be determined at trial.

**COUNT TWENTY-TWO**

(North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*)

186. Relator re-alleges Paragraphs 1 through 80 inclusive.

187. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

188. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

189. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of North Carolina, in violation of N.C. Gen. Stat. § 1-607(a)(7).

190. Based on the foregoing allegations, the state of North Carolina has suffered actual damages, with the exact amount to be determined at trial.

**COUNT TWENTY-THREE**

(Oklahoma False Claims Act, Okla. Stat. Ann. tit. 63, § 5053 *et seq.*)

191. Relator re-alleges Paragraphs 1 through 80 inclusive.

192. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Okla. Stat. Ann. tit. 63, § 5053.1(B)(1).

193. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved, in violation of Okla. Stat. Ann. tit. 63, § 5053.1(B)(2).

194. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state of Oklahoma, in violation of Okla. Stat. Ann. tit. 63, § 5053.1(B)(7).

195. Based on the foregoing allegations, the state of Oklahoma has suffered actual damages, with the exact amount to be determined at trial.

## COUNT TWENTY-FOUR

(Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*)

196. Relator re-alleges Paragraphs 1 through 80 inclusive.

197. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

198. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

199. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Rhode Island, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

200. Based on the foregoing allegations, the state of Rhode Island has suffered actual damages, with the exact amount to be determined at trial.

## COUNT TWENTY-FIVE

(Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*)

201. Relator re-alleges Paragraphs 1 through 80 inclusive.

202. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

203. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

204. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Tennessee, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

205. Based on the foregoing allegations, the state of Tennessee has suffered actual damages, with the exact amount to be determined at trial.

**COUNT TWENTY-SIX**

(Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code § 36.001 *et seq.*)

206. Relator re-alleges Paragraphs 1 through 80 inclusive.

207. Defendant CVS has knowingly made or caused to be made false statements of material fact to permit a person to receive a benefit or payment that is not authorized or that is greater than the benefit or payment that is authorized, in violation of Tex. Hum. Res. Code § 36.002(1).

208. Defendant CVS has knowingly concealed or failed to disclose information permitting a person to receive a benefit or payment that is not authorized or that is greater than the benefit or payment that is authorized, in violation of Tex. Hum. Res. Code § 36.002(2).

**COUNT TWENTY-SEVEN**

(Vermont False Claims Act, 1.32 V.S.A., Ch. 7, Subchapter 8, § 630 *et seq.*)

209. Relator re-alleges Paragraphs 1 through 80 inclusive.

210. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of 1.32 V.S.A., Ch. 7, Subchapter 8, § 631(1).

211. Defendant CVS has knowingly made or used, or caused to be made or used, a false statement or record material to a false claim, in violation of 1.32 V.S.A., Ch. 7, Subchapter 8, § 631(2).

212. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Vermont, in violation of 1.32 V.S.A., Ch. 7, Subchapter 8, § 631 (10).

213. Based on the foregoing allegations, the state of Vermont has suffered actual damages, with the exact amount to be determined at trial.

## COUNT TWENTY-EIGHT

(Virginia Fraud Against Taxpayer Act, Va. Code Ann. § 8.01-216.1 *et seq.*)

214. Relator re-alleges Paragraphs 1 through 80 inclusive.

215. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

216. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

217. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the commonwealth of Virginia, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

218. Based on the foregoing allegations, the commonwealth of Virginia has suffered actual damages, with the exact amount to be determined at trial.

## COUNT TWENTY-NINE

(Washington Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.010 *et seq.*)

219. Relator re-alleges Paragraphs 1 through 80 inclusive.

220. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of Wash. Rev. Code § 74.66.020(1)(a).

221. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Wash. Rev. Code § 74.66.020(1)(b).

222. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the state of Washington, in violation of Wash. Rev. Code § 74.66.020(1)(g).

223. Based on the foregoing allegations, the state of Washington has suffered actual damages, with the exact amount to be determined at trial.

**COUNT THIRTY**

(District of Columbia False Claims Act, D.C. Code § 2-381.01 *et seq.*)

224. Relator re-alleges Paragraphs 1 through 80 inclusive.

225. Defendant CVS has knowingly presented or caused to be presented false claims for payment or approval, in violation of D.C. Code § 2-381.02(a)(1).

226. Defendant CVS has knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of D.C. Code § 2-381.02(a)(2).

227. Defendant CVS has knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money to the District of Columbia, in violation of D.C. Code § 2-381.02(a)(6).

228. Based on the foregoing allegations, the District of Columbia has suffered actual damages, with the exact amount to be determined at trial.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff Adam Rahimi prays for the following relief:

1. On Counts One through Thirty, judgment for the United States or the State, as applicable, against the Defendant in an amount equal to three times the damages the federal or state plaintiff government, respectively, has sustained because of the Defendant's actions, plus the maximum civil penalty for each violation that is authorized by the federal or state law under which suit is brought by the Relator on behalf of the federal or state plaintiff, respectively;

2. On Counts One through Thirty, an award to the Relator for the maximum allowed under the federal or state law under which suit is brought by the Relator on behalf of the federal or state plaintiff, respectively;

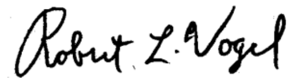
3. Against the Defendant, attorney's fees, expenses, and costs of suit; and

4. Such other and further relief as the Court deems just and proper.

## DEMAND FOR JURY TRIAL

Plaintiff hereby demands that this matter be tried before a jury.

Respectfully submitted,



________________________________________

Robert L. Vogel (S.D.N.Y. Bar No. RV1527)
VOGEL, SLADE & GOLDSTEIN, LLP
1300 Connecticut Avenue N.W., Ste. 701
Washington, D.C. 20036
Tel.: 202-537-5900
rvogel@vsg-law.com

Of Counsel:
Shelley R. Slade
Janet L. Goldstein
VOGEL, SLADE & GOLDSTEIN, LLP
1300 Connecticut Avenue N.W., Ste. 701
Washington, D.C. 20036
Tel.: 202-537-5900
sslade@vsg-law.com
jgoldstein@vsg-law.com

Attorneys for Adam Rahimi

Dated: April 6, 2018