UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. CVS PHARMACY, INC., Defendant.	COMPLAINT-IN-INTEREVENTION 18 Civ. 3047 (JGK) 19 Civ. 1550 (JGK) 19 Civ. 8454 (JGK) 19 Civ. 11244 (JGK) 20 Civ. 2173 (JGK)
UNITED STATES OF AMERICA *et al.* *ex rel*. RAHIMI, Plaintiffs, v. CVS PHARMACY, INC., Defendant.	18 Civ. 3047 (JGK)
UNITED STATES OF AMERICA *et al.* *ex rel.* ZIMNISKI, Plaintiffs, v. CVS HEALTH CORPORATION *et al.,* Defendants.	19 Civ. 1550 (JGK)

UNITED STATES OF AMERICA *et al.* *ex rel.* STRANGO, Plaintiffs, v. CVS HEALTH CORPORATION *et al*., Defendants.	19 Civ. 8454 (JGK)
UNITED STATES OF AMERICA *et al.* *ex rel*. WU, Plaintiffs, v. CVS HEALTH CORPORATION *et al.*, Defendants.	19 Civ. 11244 (JGK)
UNITED STATES OF AMERICA *et al.* *ex rel.* RJA, LLP, Plaintiffs, v. CVS PHARMACY, INC., Defendant.	20 Civ. 2173 (JGK)

The United States, by its attorney, Jay Clayton, the United States Attorney for the Southern District of New York, alleges for its complaint-in-intervention as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by plaintiff-intervenor the United States of America (the "Government") against defendant CVS Pharmacy, Inc. ("CVS"), to recover damages and civil penalties arising from CVS' violations of the False Claims Act (the "FCA"), 31 U.S.C. § 3729 *et seq*., in connection with dispensing insulin pens[1] to beneficiaries of federal healthcare programs, including Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program ("FEHBP," and collectively, "GHPs"). The Government also seeks to recover damages under the common law for payment by mistake of fact and unjust enrichment.

2. From January 1, 2010, through December 31, 2020, CVS violated the FCA by knowingly submitting, or causing to be submitted, false claims to GHPs for reimbursement for insulin pens where CVS: (i) dispensed more insulin to GHP beneficiaries than was specified by their prescriptions and refilled GHP beneficiary prescriptions substantially before GHP beneficiaries needed the refills; (ii) falsely under-reported the days-of-supply for the insulin refills (*i.e.*, the number of days that the dispensed quantity of insulin should last if used according to the prescriber's directions for use), which often prevented Pharmacy Benefit Managers ("PBMs") from detecting that the refills were premature; and (iii) failed to comply with applicable rules when refilling insulin prescriptions requiring pharmacies to calculate refill dates using the actual days-of-supply dispensed. As a result of these false claims, GHPs reimbursed CVS for more insulin than CVS was authorized to dispense and for more insulin than GHP beneficiaries needed pursuant

[1] A list of the types of insulin pens relevant to this action, by brand names and by national drug codes, is attached as Exhibit A hereto.

to their prescriptions.

3. When pharmacies like CVS seek reimbursement for medication dispensed to GHP beneficiaries, they are generally required to submit accurate data concerning, among other things, the days-of-supply for each prescription filled. In pharmacy practice, days-of-supply typically means the number of days that the amount of the drug being dispensed should last if the patient uses the drug according to her prescriber's directions for use. For insulin pens, a 30-day or 90-day supply is a common days-of-supply limit. GHPs and their agents, such as Medicare Part D sponsors and PBMs, typically rely on the days-of-supply data reported by pharmacies to determine whether a reimbursement claim for a refill is premature.

4. Insulin is frequently sold in cartons containing five insulin pens. When pharmacies like CVS dispense insulin pens to customers in full cartons, the amount dispensed can often exceed the applicable days-of-supply limit, resulting in claim rejections.

5. PBMs have developed rules to address reimbursement when dispensing medications like insulin in the smallest commercially-available container would exceed the days-of-supply limit. Some PBMs required pharmacies to seek an override of the limit and then to re-submit the claim reporting the accurate days-of-supply actually dispensed so the PBM could verify when the next refill would be needed. A limited number of PBMs permitted pharmacies to submit claims reporting the maximum days-of-supply allowed, even if that number was lower than the actual amount dispensed. Importantly, however, those PBMs still required pharmacies to track and use the actual days-of-supply dispensed to determine when patients would actually need a refill. All PBMs prohibited pharmacies from seeking reimbursment for premature refills, regardless of container size.

6. To fill insulin prescriptions as quickly as possible and to ensure that reimbursement

claims for insulin pens were not rejected, CVS instructed its pharmacy staff simply to report the maximum days-of-supply allowed under the beneficiary's plan when dispensing full insulin pen cartons, which was often lower than the actual days-of-supply dispensed. Moreover, many CVS pharmacies did not internally document and use the actual days-of-supply dispensed to determine when patients could next refill their prescription. To the contrary, CVS' dispensing software calculated refill dates automatically based on the frequently inaccurate days-of-supply data reported to the PBM and entered into the system. As a result, CVS pharmacy staff repeatedly refilled prescriptions prematurely, dispensing substantially more insulin to GHP beneficiaries than they actually needed and substantially sooner than they needed it according to their prescriptions.

7. CVS pharmacies took steps to prompt customers to come in and pick up the premature refills. For example, customers enrolled in CVS' auto-refill program received automatic prompts to come to the pharmacy and pick up their insulin refills. Pharmacy staff also called customers to ask them to pick up their premature refills.

8. CVS management was well aware that it was over-dispensing insulin via premature refills. PBMs conducted periodic audits of CVS pharmacies and repeatedly found violations of the dispensing rules, including reporting invalid days-of-supply data, refilling insulin pen prescriptions too soon, and dispensing insulin pens in excess of the quantities authorized by the prescription. PBMs issued chargebacks to CVS based on these violations. For several years, CVS management knew that insulin pens were among the drug products most frequently subject to chargebacks for premature refills. Yet, despite these audit findings, CVS failed to take necessary steps to address this long-standing problem during the relevant period.

9. CVS frequently dispensed more insulin to GHP beneficiaries than they actually needed and was permitted under their prescriptions and received millions of dollars for insulin pen

refills that were ineligible for reimbursement. In addition, as result of CVS' practice of repeatedly refilling insulin prescriptions too early, some GHP beneficiaries accumulated large quantities of unused insulin, which was both wasteful and potentially dangerous as insulin can expire.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over the Government's claims under the FCA pursuant to 28 U.S.C §§ 1331 and 1345.

11. This Court may exercise personal jurisdiction over CVS because CVS transacts business in this District and, in furtherance of the fraud alleged, submitted false claims in this District. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) as well as 28 U.S.C. §§ 1391(b) and 1391(c).

PARTIES

12. Plaintiff is the United States of America. Through its agencies, the Government administers GHPs. More specifically, the U.S. Department of Health and Human Services ("HHS") administers the Medicare and Medicaid programs; the U.S. Department of Defense ("DOD") administers the TRICARE program; and the U.S. Office of Personnel Management ("OPM") administers the FEHBP on behalf of federal employees.

13. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with a principal place of business in Rhode Island that operates a retail pharmacy chain throughout the United States, including in New York. CVS is one of the largest pharmacy chains in the United States, with more than 9,000 pharmacy locations nationwide.

The False Claims Act

14. The FCA was originally enacted in 1863 to address fraud on the Government in the midst of the Civil War, and it reflects Congress's objective to "enhance the Government's ability to recover losses sustained as a result of fraud against the Government." *See* S. Rep. No. 99-345, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266.

15. As relevant here, the FCA establishes treble damages liability to the Government where an individual or entity: (a) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or (b) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id*. § 3729(a)(1)(B).

16. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

17. "Knowing," within the meaning of the FCA, is defined to include a defendant acting in reckless disregard or deliberate indifference of the truth or falsity of information, as well as actual knowledge of such falsity. *See id*. § 3729(b(1).

BACKGROUND

I. Relevant Government Healthcare Programs

A. Medicare Part D

18. Medicare is a federal program that provides federally subsidized health insurance for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq*. As relevant here, Part D of Medicare, which was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, provides prescription drug benefits for Medicare beneficiaries. All persons enrolled in Medicare Parts A or B are eligible to enroll in a

prescription drug plan under Part D.

19. Under Medicare Part D, HHS, through its component the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. The Part D sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors, in turn, subcontract with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

20. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, the patient will have the prescription filled by a pharmacy, such as CVS. When the pharmacy dispenses drugs to that Part D beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (often through a PBM). The pharmacy receives reimbursement from the Part D sponsor (or the PBM) for the portion of the drug cost not paid by the beneficiary.

21. The Part D sponsor then is required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains data regarding the prescription reimbursement claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and whether the drug is covered under Medicare Part D. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

22. Under Medicare Part D, CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. *See* 42 C.F.R. §§ 423.315, 423.329. At the end of

the payment year, CMS then reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data submitted by the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled for Medicare beneficiaries under Part D. If CMS determines that it underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference; and if CMS determines that it overpaid the sponsor, it will recoup the overpayment from the Part D sponsor.[2]

23. The payments made by CMS to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. *See* 42 C.F.R. § 423.315(a).

24. In order to receive Part D funds from CMS, the Part D sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions. By statute, all contracts between a Part D sponsor and CMS must include a provision whereby the sponsor agrees 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. Further, CMS regulations expressly require Part D sponsors to certify, in their contracts with CMS, that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA. 42 C.F.R. § 423.505(h)(1).

25. Accordingly, contracts entered into between CMS and Part D sponsors since 2006

[2] After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. *See* 42 C.F.R. § 423.336.

have included a provision in which the sponsor "agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act (31 U.S.C. §§ 3729 *et seq.*)[.]" Further, CMS regulations also expressly require that all subcontracts between Part D sponsors and downstream entities – including pharmacies – contain language obligating the pharmacies to comply with all applicable federal laws, regulations, and CMS instructions. *See* 42 C.F.R. § 423.505(i)(4)(iv). At all relevant times, CVS entered into contracts with Part D sponsors containing such language.

B. Medicaid

26. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. *See* 42 U.S.C. § 1396d(b). Among the states, FMAP is at least 50 percent and as high as 83 percent.

27. The Medicaid programs in all 50 states and the District of Columbia reimburse for prescription drugs. The majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented

for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). *See* 42 C.F.R. § 430.30.

C. TRICARE and FEHBP

28. The Government, through DOD and OPM, administers TRICARE and the FEHBP, respectively. TRICARE provides healthcare benefits, including pharmacy benefits, for certain current and former members of the armed services and their dependents. *See* 10 U.S.C. § 1071 *et seq*. The FEHBP provides health care benefits, including pharmacy benefits, to eligible federal employees and their family members. *See 5* U.S.C. § 8901 *et seq*.

29. To qualify for TRICARE coverage, services, including pharmacy services, must be medically necessary. *See* 32 C.F.R. § 199.4(a). Similarly, the FEHBP provides coverage for pharmacy services for federal employees when they are medically necessary. *See* 5 U.S.C. §§ 8901 *et seq*.

30. When a TRICARE beneficiary's prescription is submitted to a TRICARE network pharmacy like CVS, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription medication is delivered to the patient (and not returned to the shelf by the pharmacy), the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the prescriber's identity, the date the

prescription was written, the number of refills authorized, the number of times the prescription has been filled, the amount claimed for reimbursement, and information on drug coverage under TRICARE. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

31. All pharmacies that provide services to TRICARE beneficiaries are required to comply with TRICARE's program requirements, including its anti-abuse provisions. TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. 32 C.F.R. § 199.9(b). More specifically, under TRICARE regulations, "[m]isrepresentations of dates, frequency, duration, or description of services rendered, or of the identity of the recipient of the services or the individual who rendered the services" are "presumed to be fraud." *Id.* § 199.9(c)(6)..

§ 199.2(c)(6).

II. Government Healthcare Programs Require Pharmacies Like CVS to Submit Accurate Days-of-supply Data and Prohibit Premature Refills

32. To seek reimbursement from GHPs, pharmacies like CVS are required to submit claims containing a standard set of data that have accepted definitions in the pharmacy billing context. Among the types of claims data that CVS must submit to GHPs or PBMs to obtain reimbursement are the "quantity dispensed" and the "days-of-supply" fields. In the pharmacy billing context, "quantity dispensed" means the total amount of insulin dispensed to a patient when she fills her prescription, and "days-of-supply" means the number of days that the quantity of insulin dispensed will last if the patient uses the insulin according to the directions for use provided by her insulin prescriber. Pharmacies typically follow a standard formula to calculate days-of-

supply. Specifically, a pharmacist divides the total quantity of medication being dispensed to a particular patient by that patient's "daily days-of-supply," *i.e.*, the specific quantity of medication that the prescription directs the patient to take each day.

33. GHP plans, and PBMs working on their behalf, typically set limits on the total days-of-supply that a pharmacy may dispense when filling prescriptions. For insulin pens, a 30-day or 90-day supply is a common limit. PBMs that adjudicate reimbursement claims on behalf of GHP plans typically reject claims submitted by pharmacies that exceed the applicable days-of-supply limits. In addition, PBMs typically deny reimbursement claims for prematurely refilled prescriptions—refills dispensed before the beneficiary would have consumed a substantial portion of the previously-dispensed quantity of medication if they had followed the prescriber's directions for use.

34. During the relevant times, the GHPs and PBMs working on their behalf generally required pharmacies like CVS to report all claims data, including days-of-supply data, accurately in the claims they submitted for reimbursement.

35. Under Medicare Part D, for example, CMS regulations have required Part D sponsors to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," has provided in relevant part:

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

> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.
> . . .

42 C.F.R. § 423.505(k). Compliance with the regulatory requirement that PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under Medicare Part D.

36. In accordance with this regulatory requirement, and since the Part D program began, CMS has required each Part D sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"), which states:

> Pursuant to the contract(s) between the [CMS] and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With

> regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

All approved Part D sponsors who received payment under Medicare Part D after 2006 have submitted these required Attestations in the same or similar format.

37. For pharmacies like CVS that participate in Medicare, CMS regulations further provide that: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3.

38. Congress has required Medicare Part D sponsors to ensure that claims paid for by Medicare Part D are screened to prevent over-utilization of medication. Congress directs Part D sponsors to implement "a cost-effective utilization management program." 42 U.S.C. § 1395w-104(c)(1)(A). CMS, in turn, requires that each Part D sponsor maintain "policies and systems to assist in preventing over-utilization . . . of prescribed medications" and to conduct concurrent drug utilization reviews to screen, *inter alia,* for "over-utilization." 42 C.F.R. § 423.153(b)(2) and (c)(2). Accordingly, CMS requires that a Part D sponsor agree in its contract with CMS to operate a drug utilization management program. 42 C.F.R. § 423.505(b)(6). CMS makes clear in its Medicare Prescription Drug Benefit Manual that drug "overutilization" includes "early refill[s]."

Medicare Prescription Drug Benefit Manual, Rev. 10, 02-19-10, Ch. 6, § 30.2.2.1. Part D sponsors have typically delegated the responsibility to conduct concurrent drug reviews for over-utilization to PBMs.

39. Similarly, pharmacies participating in Medicaid have typically been required to sign enrollment agreements with state Medicaid programs certifying compliance with the state and federal Medicaid requirements, including the requirement to submit accurate claims data. In New York, for example, pharmacies have been required to periodically sign a "Certification Statement for Provider Billing Medicaid," in which they certify that "ALL STATEMENTS, DATA AND INFORMATION TRANSMITTED ARE TRUE, ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE" and that "NO MATERIAL FACT HAS BEEN OMITTED[.]" (capitalization in original).

40. Like CMS in the Medicare context, State Medicaid programs have issued guidance to pharmacies explaining that Medicaid relies on the accuracy of the days-of-supply data submitted by pharmacies to decide whether to pay or deny refill claims, and that premature refills are not reimbursable. For example, in January 2015, New York Medicaid issued an update notifying pharmacies that an "early fill edit will be implemented that will tighten early fill parameters based on days supply on hand in an effort to further reduce overutilization, stockpiling and/or diversion of drugs. This new enhanced edit will deny a claim if more than a 10 day supply of medication is remaining of the cumulative amount that has been dispensed over the previous 90 days, and will augment current editing where claims are denied when less than 75% of the previously dispensed amount has been used (the more stringent rule will apply)."

41. Likewise, TRICARE and the FEHBP, and the PBMs acting on their behalf, require participating pharmacies to submit claims that accurately report days-of-supply and correctly

calculate refill dates.

42. PBMs have issued manuals and other guidance to pharmacies emphasizing the importance of the requirement to accurately report days-of-supply data in the claims they submit for reimbursement. For example, one national PBM instructed pharmacies that "[t]he days supply should accurately reflect the documented directions and quantity dispensed." A key reason that payors and PBMs require pharmacies to report accurate days-of-supply data is that they rely on the days-of-supply submitted by the participating pharmacies to determine whether to reimburse refill claims or to deny such claims as premature. Specifically, payors and PBMs typically calculate the date on which a prescription refill would be needed based on the date when a patient last filled a prescription and the days-of-supply reported by the pharmacy for that prior fill. Payors and PBMs also typically have automated drug utilization processes that deny as premature refill claims that are submitted too far in advance of the expected refill date.

43. PBMs have expressly prohibited pharmacies from prematurely refilling prescriptions. For example, the OptumRx Provider Manual for 2017 identified "refill too soon" as an "audit violation[]" that could result in "claims being recovered in total and no reimbursement will be forthcoming for what was actually dispensed," or" legal or other action… [a]gainst the network, pharmacy provider, including immediate termination of the agreement." Many PBM manuals have permitted pharmacies to refill most prescriptions only when a minimum percentage (*e.g.*, 75%) of the quantity previously dispensed has been consumed based on the number of days supplied.

44. Moreover, PBMs have developed specific rules to address the dispensation of medication contained in unbreakable packaging, which can apply to insulin pen cartons. Generally, payors will reject reimbursement claims for medications dispensed in amounts that

exceed the quantity and days-of-supply limits set forth in beneficiaries' Part D plans. However, with respect to instances where dispensing medications in the smallest commercially-available package would exceed the days-of-supply limit, some PBMs during the relevant time period required pharmacies to contact the payor to obtain an override of the days-of-supply limit and then to re-submit the claim reporting the actual days-of-supply dispensed. Obtaining the accurate days-of-supply dispensed allowed the PBM to verify when the next refill would be needed.

45. Certain other PBMs permitted pharmacies to submit claims listing the maximum days-of-supply allowed under the applicable plan even though the actual days-of-supply dispensed was higher. Importantly, however, because under-reporting the days-of-supply (*i.e.*, reporting that the dispensed quantity will last fewer days than it actually will) can lead to over-dispensing and premature refills, these PBMs required pharmacies to internally document and use the actual days-of-supply to determine refill dates and refill intervals.

46. Accordingly, pharmacies are prohibited from submitting reimbursement claims for premature refills of insulin pens and any other medication, even when dispensing the medication in the smallest commercially-available packaging (*e..g.*, a carton of five insulin pens) exceeds the applicable days-of-supply cap.

III. The Use of Insulin to Treat Diabetes

47. Insulin is a peptide hormone secreted by the pancreas that controls blood sugar levels. Patients with Type 1 and Type 2 diabetes often need insulin injections because they cannot generate enough insulin themselves.

48. To obtain the types of insulin pens at issue here from pharmacies like CVS, diabetic patients must obtain prescriptions from their physicians. When a physician prescribes insulin to a patient, the physician must provide directions specifying how frequently the patient should inject

insulin and how much insulin to inject each time.

49. The directions for use provided by physicians typically indicate the amount of insulin that patients need to inject in terms of a certain number of "units" of insulin. For example, an insulin prescription might direct a patient to inject 10 units subcutaneously every morning and 15 units every evening.

50. When they prescribe insulin, physicians emphasize to their patients the importance of following the prescribed directions for insulin usage. It is critical for patients to understand the importance of following their prescribed insulin regimen because, among other reasons, overusing insulin can exacerbate the risk of hypoglycemia (*i.e.*, excessively low blood sugar levels), which can lead to coma and other serious health consequences.

51. Manufacturers have offered insulin pens in cartons containing between two and five pens. Insulin pens frequently have been marketed in carton sizes containing five 300 unit/3 mL pens. In the five-pen boxes, each pen typically consists of a syringe, which contains 300 units (3 mL) of insulin solution, inside a hard plastic case. A box of five pens typically contains 1500 units (15 mL) of insulin solution.

FACTUAL ALLEGATIONS

52. From January 2010 through December 2020, CVS pharmacies engaged in a fraudulent practice of over-dispensing insulin pens to GHP beneficiaries by repeatedly prematurely refilling their insulin prescriptions before they needed additional medication. When billing GHP plans for these dispensings, CVS pharmacies frequently under-reported the days-of-supply of insulin dispensed, which prevented PBMs from detecting that the refills were too early and rejecting CVS' claims for payment. The pharmacies failed to calculate and apply the appropriate refill interval based on the actual amount of insulin dispensed, as required. CVS management was

well aware of this problem for years, but failed to take appropriate action to correct it resulting in millions of dollars of losses to the Government.

I. CVS' Improper Insulin Pen Dispensing Practices

55. As noted above, insulin pens are typically marketed in cartons containing five pens. Depending on the amount prescribed, dispensing a full carton of insulin pens may exceed a GHP plan's days-of-supply limit. During the relevant time period, CVS' general practice was to instruct pharmacies not to break open insulin pen cartons when filling insulin prescriptions and, when encountering claim rejections for exceeding plan days-of-supply limitations, to input whatever days-of-supply amount the plan allowed.

56. For example, in 2015, a Senior Finance Manager in CVS' Third-Party Audit group repeatedly advised CVS pharmacists to dispense the full box of five insulin pens and that when this resulted in insurance rejections for exceeding maximum days-of-supply limits, pharmacy staff should "back down the Day Supply to meet that maximum [plan limit]." CVS did not direct pharmacies to seek overrides of the days-of-supply limit when required by the PBM, or to document and use the actual days-of-supply dispensed to calculate refill dates to prevent premature refills.

57. In 2016, the Pharmacy Operations group made these instructions the standard response for internal FAQs from pharmacists with respect to insulin pens. By following these instructions, CVS pharmacy staff could process insulin pen prescriptions faster, as they would not have to take the time necessary to reach out to payors for overrides where required or to separately track the appropriate refill cadence using the actual days-of-supply dispensed.

58. As a result of this practice, CVS' dispensing software generated premature refill dates for insulin pen prescriptions. The software calculated the next refill date automatically based

on the days-of-supply data transmitted to PBMs as part of CVS' reimbursement claim and entered into CVS' computer system. Accordingly, when CVS pharmacy staff entered the inaccurate lower days-of-supply into the system (*e.g.*, reporting that a carton of five insulin pens was only a 30-day supply for the patient, when it was actually a 150-day supply), the system would generate refill dates that were frequently too early (*e.g.*, refilling when 75% of the 30-day period had elapsed, when a refill was not actually needed or reimbursable until 75% of the 150-day period had elapsed).

59. Many CVS customers were enrolled in CVS' auto-refill program and received automated communications by phone or text alerting them that their insulin pen refills were ready to be picked up on the premature refill dates generated by CVS' dispensing software. Insulin pen customers who were not enrolled in the auto-refill program also received communications prompting them to order refills well before they would have been close to exhausting their last fill. Indeed, an internal CVS presentation from June 2020 concerning prepackaged insulin products explained that, in addition to auto-refill, "[o]ther programs depend on accurate day supply field to appropriate[ly] prompt patient if they would like a refill" (emphasis in original). The slide identified the programs "Adherence Outreach," "Refill Reminder," and "ScriptSync" as having contributed to the "Refill too soon" issue.

60. Beyond these automated communications, some CVS pharmacy staff also called insulin pen customers requesting that they come to the pharmacy to pick up their premature refills at the pharmacy. For example, a pharmacist who worked at a CVS pharmacy in Indiana during 2006–2019 explained that CVS had "call cues" where pharmacy staff "acted like telemarketers," reaching out to patients to encourage them to pick up their refills, even if the patients did not need them yet. The former CVS pharmacist noted that patients would "stock up" because insurance

covered it.

61. CVS' practice of under-reporting days-of-supply also undermined the GHPs' ability to identify and deny reimbursement claims for premature refills. PBMs have used automated drug utilization screening programs to review pharmacy reimbursement requests and reject claims that exceed applicable days-of-supply limits or involve premature refills. When CVS pharmacies inaccurately under-reported the days-of-supply in their claim submissions, the PBM drug utilization programs could not detect and reject subsequent claims for payment for premature refills.

62. PBMs did, however, identify many instances of CVS over-dispensing and prematurely refilling insulin pen prescriptions during post-payment audits. During the relevant time period, PBMs conducted periodic post-payment audits of thousands of CVS pharmacies throughout the United States during which they reviewed prescriptions and other supporting documentation for samples of reimbursement claims, including claims for insulin pens dispensed to GHPs. These audits routinely identified violations for over-dispensing, invalid days-of-supply data, and premature refills involving insulin pens.

63. The relevant negative final audit findings were: EQB (Exceeds Quantity Limit/Overfill Quantity); OBQ (Overbilled Quantity); IDS (Incorrect/Invalid Days-of Supply); and RTS (Refill Too Soon). During 2010 through 2020, there were approximately 6,300 CVS pharmacies that underwent at least one audit yielding at least one of these final audit violations with respect to insulin pens. Furthermore, some of these pharmacies were audited multiple times during the relevant time period and were repeatedly cited with the same audit violations. When repeat audits of the same CVS pharmacies are included, the total number of instances when a pharmacy audit resulted in at least one of the above audit violations with respect to insulin pens is over 14,000.

II. CVS Management Knew About CVS' Improper Insulin Pen Dispensing Practices and That These Practices Resulted in the Submission of False Claims for Payment

64. CVS management knew for years that the instructions given to pharmacy staff for dispensing and billing insulin pens resulted in the over-dispensing and premature refilling of insulin pen prescriptions.

65. To begin, CVS managers knew about the widespread audit violations noted above. PBMs issued chargebacks to CVS demanding refunds for these improper fills. These negative audit findings and chargebacks were circulated widely within CVS.

66. In particular, year after year, CVS' Third-Party Audit group circulated analyses of the negative audit findings and chargebacks for insulin pens, including analyses noting that various insulin pen brands were among the top CVS drug products subject to chargebacks by dollar volume due to premature refills. Insulin pen brands consistently topped the rankings. For example, in 2014, the Lantus insulin pen ranked number two and the Humalog pen ranked number four with respect to refill-too-soon chargebacks. In 2015, the Lantus and Humalog pens ranked number one and two, respectively.

67. CVS management knew that the negative audit findings and chargebacks were caused by CVS pharmacy staff failing to seek days-of-supply overrides where required and not being able to input the actual days-of-supply dispensed into CVS' dispensing software.

68. For example, Third-Party Audit training materials from November 2019 noted that "half of third party write-offs" result from, among other things, "skip[ping] calling payers for overrides when rejections are received." As noted in an internal presentation made by the Third-Party Audit group in 2019 regarding all drugs, CVS management appreciated that some "payers expect[ed] pharmacies to call for override[s] when claims reject," but determined that this requirement was "not conducive to store workflow." Or as a CVS Industry Relations Director put

it in an April 2019 email, "calling for an override is outside the pharmacy workflow and historically the solution has been to just reduce the days supply to 30."

69. In March 2016, a CVS pharmacist warned a District Manager in an email concerning insulin customers enrolled in auto-refill that "[i]f we start dispensing full boxes of 5 pens the customer would end up with a stock pile due to the rx [system] populating for autofill before it is actually needed." An April 2019 Third-Party Audit group presentation to CVS Field Leadership further explained that "[i]nsurance issues will force teams to bill medications for 30 day supplies … when we fill it – we risk a Refill Too Soon chargeback." In a March 2020 email, a Senior Manager noted: "We definitely see audit activity resulting from stores not refilling using the proper refill cadence (due to plan limitations that prevent billing for the days supply the product should last)."

70. Well aware of these problems over multiple years, senior CVS personnel considered implementing an IT solution to mitigate the persistent premature refills. Specifically, starting as early as 2018, CVS personnel discussed the need to add a "therapeutic days supply" field in the dispensing system that would track the actual days-of-supply dispensed in each fill. Indeed, a large insurance plan advised CVS that other pharmacy chains had successfully implemented such a fix to reduce refill-too-soon chargebacks.

71. Nonetheless, CVS failed to implement this potential solution because, at least in part, it would take pharmacists extra time to calculate and enter the "therapeutic days supply" and could slow down the dispensing process. As Third-Party Audit personnel discussed in a 2020 internal email, "creating a new field to house a Therapeutic Days Supply … would yield the need for increased labor spend if requiring teams to pause to calculate and manually enter the Therapeutic days supply."

III. CVS' Under-Reporting of Days-of-supply Data and Improper Insulin Dispensing Practices Were Material to the Government Healthcare Programs' Payment Decisions

72. CVS' practice of inaccurately reporting days-of-supply data and over-dispensing and prematurely refilling insulin pen prescriptions was material to GHP payment decisions.

73. As explained above, GHPs require drug utilization screening to prevent overutilization, waste, and fraud, including premature refills. The responsibility for screening reimbursement requests has been typically delegated to PBMs, which employ drug utilization software to review claims submissions prior to payment. Accurate claims data, including data related to days-of-supply and the calculation of appropriate refill cadence, is critical to PBMs' ability to reject reimbursement requests when refills are too early.

74. Pharmacies are prohibited from dispensing more drugs than permitted under a patient's prescription and premature refills are ineligible for reimbursement. If GHPs and the PBMs acting on their behalf had known that CVS pharmacies were repeatedly prematurely refilling insulin prescriptions and as a result dispensing more insulin over time than authorized under prescriptions, they would not have paid for these dispensings.

75. As discussed above, PBMs' post-payment audits of thousands of CVS pharmacies routinely found audit violations for over-dispensing, prematurely refilling, and reporting invalid days-of-supply data in connection with the dispensing of insulin. Because these audit violations were material to payment decisions, the PBMs issued chargebacks to CVS demanding refunds. The fact that PBMs imposed chargebacks on CVS pharmacies for these violations demonstrates that these practices impacted payment decisions.

FIRST CLAIM

Violations of the False Claims Act: Presenting False Claims for Payment 31 U.S.C. § 3729(a)(1)(A)

76. The Government incorporates by reference each of the preceding paragraphs as

if fully set forth herein.

77. The Government asserts claims against CVS under 31 U.S.C. § 3729(a)(1)(A).

78. As a result of its improper dispensing practices in connection with the sale of insulin pens to GHP beneficiaries—including submitting requests for reimbursement that falsely under-reported days-of-supply data when CVS was prohibited from doing so, concealing that CVS had used inaccurate days-of-supply data to calculate refill dates in violation of applicable dispensing rules, and dispensing insulin pens to GHP beneficiaries prematurely and in quantities that exceeded the amounts authorized by their prescriptions—CVS knowingly, or acting with deliberate ignorance or reckless disregard of the truth, presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

79. The GHPs, Part D sponsors, PBMs and other payors working on behalf of the Government made payments because of the false or fraudulent claims.

80. By reason of these false or fraudulent claims, the Government has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements 31 U.S.C. § 3729(a)(1)(B)

85. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

86. The Government asserts claims against CVS under 31 U.S.C. § 3729(a)(1)(B).

87. As a result of its improper dispensing practices in connection with the sale of insulin pens to GHP beneficiaries—including submitting requests for reimbursement that falsely under-reported days-of-supply data when CVS was prohibited from doing so, concealing that CVS had used inaccurate days-of-supply data to calculate refill dates in violation of applicable dispensing

rules, and dispensing insulin pens to GHP beneficiaries prematurely and in quantities that exceeded the amounts authorized by their prescriptions—CVS knowingly, or acting with deliberate ignorance or reckless disregard of the truth, made, used, or caused to be made or used, false records and statements that were material to the payment of false or fraudulent claims for payment.

88. The GHPs, Part D sponsors, PBMs and other payors working on behalf of the Government made payments because of the false or fraudulent records or statements.

89. By reason of these false records or statements, the Government has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

THIRD CLAIM

Unjust Enrichment

90. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

91. Through the acts set forth above, CVS has received reimbursements from GHPs to which it was not entitled and therefore has been unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, CVS should not retain those payments, the amount of which are to be determined at trial.

FOURTH CLAIM

Payment by Mistake of Fact

92. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

93. The Government seeks relief against CVS to recover monies paid under mistake of fact. GHPs, Part D sponsors, PBMs and other payors working on behalf of the Government paid CVS for refills of insulin pen prescriptions dispensed to GHP beneficiaries based on the mistaken

and erroneous belief that CVS had submitted accurate days-of-supply data, that CVS had used accurate days-of-supply data to calculate refill dates, and that CVS was not dispensing insulin pens to GHP beneficiaries prematurely or in quantities exceeding the amounts authorized by their prescriptions. These erroneous beliefs, as well as the false records made or caused to be made by CVS, were material to the determination to pay these claims.

94. Because of these payments by mistake, CVS received monies to which it is not entitled.

95. By reason of the foregoing, the Government was damaged in a substantial amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the Government, requests that judgment be entered in its favor against CVS favor as follows:

1. On the First and Second Claims (violations of the FCA, 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B)), a sum equal to treble the Government's damages, in an amount to be determined at trial, plus a civil penalty in the maximum applicable amount for each violation of the FCA by CVS;

2. On the Third and Fourth Claims (Unjust Enrichment and Payment by Mistake of Fact), a sum equal to the damages to the maximum extent allowed by law; and

3. An award of costs incurred by the Government and such further relief as is proper.

Dated: November 26, 2025
New York, New York

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Ex. A

Exhibit A

NDC	Drug Name
00024592505	ADMELOG
00088250205	APIDRA
00002771559	BASAGLAR
00169320415	FIASP
00002751659	HUMALOG
00002771459	HUMALOG
00002771227	HUMALOG
00002879959	HUMALOG
00002879859	HUMALOG
00002879759	HUMALOG
00002880359	HUMULIN
00002880559	HUMULIN N
00002882427	HUMULIN R
66733082259	INSULIN LISPRO
00088221905	LANTUS
00169643910	LEVEMIR
00169643810	LEVEMIR
00169300715	NOVOLIN
00169633910	NOVOLOG
00169369619	NOVOLOG
00169330312	NOVOLOG
00024576105	SOLIQUA
00024587102	TOUJEO MAX
00024586903	TOUJEO
00169255013	TRESIBA
00169266015	TRESIBA
00169291115	XULTOPHY