UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA,
ex rel. HILLARY ESTRIGHT,

Plaintiff and Relator,

v.

CVS PHARMACY, INC.,
CVS RX SERVICES, INC.,
ALABAMA CVS PHARMACY, L.L.C.,
ALASKA CVS PHARMACY, L.L.C.,
AMERICAN DRUG STORES DE, L.L.C,
ARIZONA CVS STORES, L.L.C.,
ARKANSAS CVS PHARMACY, L.L.C.,
BUSSE CVS, L.L.C.,
CONNECTICUT CVS PHARMACY, L.L.C.,
CVS 2948 HENDERSON, L.L.C,
CVS ALBANY, L.L.C.,
CVS INDIANA, L.L.C.,
CVS MANCHESTER NH, L.L.C.,
CVS BELLMORE AVENUE, L.L.C.,
CVS STATE CAPITAL, L.L.C.,
CVS MICHIGAN, L.L.C.,
IDAHO CVS PHARMACY, L.L.C.,
DELAWARE CVS PHARMACY, L.L.C.,
DISTRICT OF COLUMBIA CVS PHARMACY, L.L.C.,
GARFIELD BEACH CVS, L.L.C.,
GEORGIA CVS PHARMACY, L.L.C.,
GERMAN DOBSON CVS, L.L.C.,
GOODYEAR CVS, L.L.C.,
GRAND ST. PAUL CVS, L.L.C.,
HIGHLAND PARK CVS, L.L.C.,
HOLIDAY CVS, L.L.C.,
HOOK- SUPERX, L.L.C.,
IOWA CVS PHARMACY, L.L.C.,
KANSAS CVS PHARMACY, L.L.C.,
KENTUCKY CVS PHARMACY, L.L.C.,
LONGS DRUG STORES CALIFORNIA, L.L.C.,
LOUISIANA CVS PHARMACY, L.L.C.,
MARYLAND CVS PHARMACY, L.L.C.,
MISSISSIPPI CVS PHARMACY, L.L.C.,

Jury Trial Demanded

C.A. No. 22-cv-222-WES-PAS

CONSOLIDATED COMPLAINT IN INTERVENTION

MISSOURI CVS PHARMACY, L.L.C.,
MONTANA CVS PHARMACY, L.L.C.,
NAVARRO DISCOUNT PHARMACIES, INC.
NEBRASKA CVS PHARMACY, L.L.C.,
NEVADA CVS PHARMACY, L.L.C.,
NEW JERSEY CVS PHARMACY, L.L.C.,
NORTH CAROLINA CVS PHARMACY, L.L.C.,
OHIO CVS STORES, L.L.C.,
OKLAHOMA CVS PHARMACY, L.L.C.,
OREGON CVS PHARMACY, L.L.C.,
PENNSYLVANIA CVS PHARMACY, L.L.C.,
RHODE ISLAND CVS PHARMACY, L.L.C.,
SHEFFIELD AVENUE CVS, L.L.C.,
SOUTH CAROLINA CVS PHARMACY, L.L.C.,
SOUTH WABASH CVS, L.L.C.,
TENNESSEE CVS PHARMACY, L.L.C.,
THOMAS PHOENIX CVS, L.L.C.,
UTAH CVS PHARMACY, L.L.C.,
VERMONT CVS PHARMACY, L.L.C.,
VIRGINIA CVS PHARMACY, L.L.C.,
WARM SPRINGS ROAD CVS, L.L.C.,
WASHINGTON CVS PHARMACY, L.L.C.,
WASHINGTON LAMB CVS, L.L.C.,
WEST VIRGINIA CVS PHARMACY, L.L.C.,
WISCONSIN CVS PHARMACY, L.L.C., and
WOODWARD DETROIT CVS, L.L.C.,

Defendants.

Table of Contents

INTRODUCTION

Plaintiff, the United States of America, by its undersigned counsel, for its complaint against CVS Pharmacy, Inc. and its subsidiaries named herein ("CVS"), alleges as follows:

1. The United States brings this action to hold CVS accountable for unlawfully dispensing massive quantities of opioids and other controlled substances to fuel its own profits at the expense of public health and safety.

2. CVS is the largest pharmacy chain in the United States. It is wholly-owned by the sixth largest corporation in the United States, which reported over $116 billion in Pharmacy & Consumer Wellness revenue for 2023. CVS operates more than 9,000 pharmacies and fills more than a billion prescriptions each year.

3. CVS is among the top dispensers of opioids in the United States. Between 2015 and 2020, CVS sold over twelve billion doses of opioids in the United States, many of which were paid for by federal healthcare programs.

4. From at least October 17, 2013, to the present, CVS routinely dispensed controlled substances pursuant to prescriptions that were not valid, were not for a medically accepted indication, were not medically necessary, and/or were not issued in the usual course of professional practice. These included illegitimate prescriptions for extremely high doses and excessive quantities of potent opioids that fed dependence and addiction, as well as illegitimate prescriptions for dangerous combinations of opioids and other drugs.

5. CVS's actions contributed to the opioid crisis, a national public health emergency with devastating effects in the United States. Over the past decade, hundreds of thousands of Americans have died as the result of overdoses from opioids and other controlled substances, including from the illegitimate use of prescription opioids and other prescription drugs.

6. Pharmacists serve as critical gatekeepers against the unlawful dispensing of opioids and other controlled substances. The Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq*., and CVS's own policies and procedures require pharmacists to assess the legitimacy of controlled substance prescriptions before dispensing them. Pharmacists who are confronted with prescriptions bearing the hallmarks of abuse and diversion—"red flags," in pharmacy terminology—*may not* fill these prescriptions without taking steps to investigate and resolve these signs of a prescription's invalidity.

7. CVS and its pharmacists knew that they were required by law *not* to dispense drugs pursuant to prescriptions that bore unresolved red flags of invalidity, medical inappropriateness, and/or dangerousness. As CVS recognized in its own training materials, pharmacies and pharmacists are supposed to be the "last line of defense" to prevent dangerous opioids and other controlled substances from being used for illicit, and sometimes deadly, purposes.

8. Instead of ensuring compliance with its and its pharmacists' responsibility to dispense opioids safely and legally, CVS implemented performance metrics and incentive compensation policies that it knew pressured and incentivized pharmacists to fill prescriptions as quickly as possible, without assessing their legitimacy.

9. To reduce its labor costs, CVS set staffing levels so low that it was impossible for pharmacists to comply with their legal obligations and meet CVS's demanding metrics. CVS repeatedly ignored the increasingly impassioned complaints from pharmacists that their pharmacies were dangerously understaffed.

10. These unsafe performance metrics and staffing levels drove one CVS pharmacy employee to warn CVS in writing that "[s]afety issues arise when one is dealing with medication

and also being rushed to fulfill an order like mcdonalds . . . . CVS has concocted an assembly-line style of medication preparation and only cares about profits." CVS ignored the warning.

11. CVS pharmacists described working at CVS as "soul crushing" because it was impossible to meet the company's expectations while performing their jobs properly and safely. As one pharmacist explained:

> We are talking about taking less than a minute to decide the accuracy, safety, interaction with other meds, etc. . . . What do you think the chances are that I made no mistakes on any of the prescriptions I did today? Slim to none. . .
>
> If I was filling a prescription for your child, your spouse, your parent, how would you feel? Honestly, we have NEVER worked with these few hours, aka support, and it is simply unsafe. CVS is putting payroll before the safety of its patients. . . . Patient safety and employee wellness aren't even on the radar to those making decisions about resources. . . . I am terrified for my patients I have grown to love, and heartbroken for my staff that have become my family.

12. CVS's pharmacists at multiple stores have walked out to protest these unsafe working conditions. The Ohio Board of Pharmacy also fined CVS and placed eight stores on probation due to inadequate and unsafe staffing levels.

13. Due to these corporate-driven conditions, CVS's pharmacists regularly filled prescriptions they knew had unresolved red flags and should not be filled.

14. Moreover, CVS knew from its own pharmacists, information collected at the corporate level, and public sources that it was filling prescriptions written by prescribers who were *not* acting in the usual course of professional practice, including:

a. A prescriber who was flagged by a CVS pharmacist as having written powerful opioid prescriptions for a patient who had died;

b. A prescriber whom CVS pharmacists identified as a "PILL MILL" and for whom pharmacists advised colleagues "DO NOT FILL" his prescriptions;

c. A prescriber who routinely picked up controlled substances for his patients and paid for them out of his own wallet, and whom CVS learned was not delivering these prescriptions to his patients; and

d. A prescriber who flagrantly lied to CVS compliance investigators about the basis of his medical board suspension, when CVS had the actual suspension order.

15. CVS failed to instruct pharmacies not to fill any prescriptions from these prescribers, and others, whom it knew to be practicing outside the usual course of professional practice. CVS even prohibited individual pharmacies from refusing to fill all prescriptions from these prescribers. As a result, its pharmacists continued to fill at least thousands of illegitimate prescriptions written by these pill mill prescribers.

16. CVS also refused to implement compliance measures that its own compliance professionals recommended, which were intended to reduce the number of invalid prescriptions bearing red flags of diversion and abuse that CVS dispensed. CVS refused to implement these safety measures primarily due to fear that they would slow the speed of prescription filling and increase labor costs. For example, CVS decided not to require its pharmacists to fill out a due diligence checklist before dispensing certain high-risk opioids after determining that the checklist would cost $11 million dollars—a tiny fraction of CVS's annual revenues—in increased labor costs to implement.

17. CVS's unlawful dispensing of at least thousands of controlled substance prescriptions caused massive public harm. To take just one example, in 2018 CVS dispensed excessive doses of extraordinarily potent opioids bearing egregious red flags of diversion to a Virginia patient. The patient died from a mixed drug overdose, including opioid toxicity, just four days after the patient's final fill of an opioid prescription at CVS. The doctor who wrote these prescriptions pled guilty to illegally prescribing opioid prescriptions soon after this patient overdosed and admitted that the opioid prescriptions she wrote for this patient lacked any

legitimate medical purpose. CVS pharmacists filled prescriptions for this patient—which included high dose prescriptions for oxycodone and morphine overlapping with alprazolam—notwithstanding that (1) the company had been repeatedly alerted to the doctor's inappropriate prescribing, and (2) the prescriptions themselves exhibited red flags, reflecting, for example, doctor shopping and repeated submission of opioid prescriptions to be filled early. CVS filled both high dose opioid prescriptions and overlapping benzodiazepine prescriptions for this patient, a combination sometimes referred to within CVS as the "double threat," without resolving the red flags.

18. As a result of the knowing failures of CVS and its executives, managers, pharmacists, and other employees to prevent the dispensing of illegal prescriptions for opioids and other drugs, from at least January 7, 2015, to the present, CVS violated the CSA. *See* 21 U.S.C. §§ 829, 842; 21 C.F.R. § 1306.04. For each violation, CVS is liable for a civil penalty. 21 U.S.C. § 842(c)(1). The United States also seeks injunctive relief to address and restrain further violations, including appropriate changes to corporate compliance programs and policies. 21 U.S.C. § 843(f)(1); 21 U.S.C. § 882.

19. CVS also violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, from at least October 17, 2013, to the present, by knowingly submitting, or causing to be submitted, false or fraudulent claims for controlled substance prescriptions to federally-funded healthcare programs, including Medicare, Medicaid, and TRICARE (the "Federal Healthcare Programs"). For each false claim, CVS is liable for treble damages and penalties under the FCA.

I. PARTIES

20. Plaintiff, the United States of America, brings this civil enforcement action for violations of the CSA and FCA.

21. 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 Rhode Island. CVS Pharmacy, Inc. maintains Drug Enforcement Administration ("DEA") registrations and directly operates stores in six states. As detailed below, CVS Pharmacy, Inc. also operates thousands of additional stores across the United States through various subsidiaries maintaining their own DEA registrations.

22. Defendant CVS Rx Services, Inc., a direct subsidiary of CVS Pharmacy, Inc. that is directly funded by CVS Pharmacy, Inc., is a New York corporation with a principal place of business in Rhode Island. CVS Rx Services, Inc.'s sole function is to employ the pharmacists who work at CVS retail pharmacy locations in the United States.

23. CVS Pharmacy, Inc. directly or indirectly owns numerous subsidiaries that maintain DEA registrations and operate stores that dispense controlled substances to patients. These subsidiaries include Defendants Alabama CVS Pharmacy, L.L.C. (Alabama), Alaska CVS Pharmacy, L.L.C. (Alaska), American Drug Stores Delaware, L.L.C. (Delaware), Arizona CVS Stores, L.L.C. (Arizona), Arkansas CVS Pharmacy, L.L.C. (Arkansas), Connecticut CVS Pharmacy, L.L.C. (Connecticut), CVS 2948 Henderson, L.L.C. (Nevada), CVS Albany, L.L.C. (New York), CVS Indiana, L.L.C. (Indiana), CVS Manchester NH, L.L.C. (New Hampshire), CVS Bellmore Avenue, L.L.C. (New York), CVS State Capital, L.L.C. (Maine), CVS Michigan, L.L.C. (Michigan), Idaho CVS Pharmacy, L.L.C. (Idaho), Delaware CVS Pharmacy, L.L.C. (Delaware), District of Columbia CVS Pharmacy, L.L.C. (District of Columbia), Garfield Beach CVS, L.L.C.

(California), Georgia CVS Pharmacy, L.L.C. (Georgia), German Dobson CVS, L.L.C. (Arizona), Grand St. Paul CVS, L.L.C. (Minnesota), Highland Park CVS, L.L.C. (Illinois), Holiday CVS, L.L.C. (Florida), Hook-SupeRx, L.L.C. (Delaware), Iowa CVS Pharmacy, L.L.C. (Iowa), Kansas CVS Pharmacy, L.L.C. (Kansas), Kentucky CVS Pharmacy, L.L.C. (Kentucky), Longs Drug Stores California, L.L.C. (California), Louisiana CVS Pharmacy, L.L.C. (Louisiana), Maryland CVS Pharmacy, L.L.C. (Maryland), Mississippi CVS Pharmacy, L.L.C. (Mississippi), Missouri CVS Pharmacy, L.L.C. (Missouri), Montana CVS Pharmacy, L.L.C. (Montana), Navarro Discount Pharmacies, Inc. (Florida), Nebraska CVS Pharmacy, L.L.C. (Nebraska), Nevada CVS Pharmacy, L.L.C., New Jersey CVS Pharmacy, L.L.C. (New Jersey), North Carolina CVS Pharmacy, L.L.C. (North Carolina), Ohio CVS Stores, L.L.C. (Ohio), Oklahoma CVS Pharmacy, L.L.C. (Oklahoma), Oregon CVS Pharmacy, L.L.C. (Oregon), Pennsylvania CVS Pharmacy, L.L.C. (Pennsylvania), Rhode Island CVS Pharmacy, L.L.C. (Rhode Island), South Carolina CVS Pharmacy, L.L.C. (South Carolina), Tennessee CVS Pharmacy, L.L.C. (Tennessee), Utah CVS Pharmacy, L.L.C. (Utah), Vermont CVS Pharmacy, L.L.C. (Vermont), Virginia CVS Pharmacy, L.L.C. (Virginia), Warm Springs Road CVS, L.L.C. (Nevada), Washington CVS Pharmacy, L.L.C. (Washington), West Virginia CVS Pharmacy, L.L.C. (West Virginia), Wisconsin CVS Pharmacy, L.L.C. (Wisconsin), Woodward Detroit CVS, L.L.C. (Michigan), Busse CVS, L.L.C. (Illinois), Goodyear CVS, L.L.C. (Arizona), Sheffield Avenue CVS, L.L.C. (Illinois), South Wabash CVS, L.L.C. (Illinois), Thomas Phoenix CVS, L.L.C. (Arizona), and Washington Lamb CVS, L.L.C. (Nevada) (collectively, the "Pharmacy Subsidiaries").

24. At all times material hereto, CVS Pharmacy, Inc., CVS Rx Services, Inc., and the Pharmacy Subsidiaries operated as a single integrated entity. All financial gains and losses by the Pharmacy Subsidiaries inure directly to the benefit or detriment of CVS Pharmacy, Inc. (and its

corporate parent). CVS Pharmacy, Inc. is the general agent for CVS Rx Services, Inc., and the Pharmacy Subsidiaries. CVS Pharmacy, Inc. and its corporate headquarters employees serve as managing members, officers, and board directors for CVS Rx Services, Inc., and the Pharmacy Subsidiaries. The Pharmacy Subsidiaries and CVS Rx Services, Inc. have no independent decision-making abilities; CVS Pharmacy, Inc. dominates, controls, and directs all facets of their operations. CVS Pharmacy, Inc. promulgates general policies and procedures company-wide (for example, for pharmacist compensation and training), including at stores the Pharmacy Subsidiaries operate.

25. CVS Pharmacy, Inc. makes decisions regarding anti-diversion programs; signs settlement agreements on behalf of the Pharmacy Subsidiaries and CVS Rx Services, Inc.; and maintains RxConnect, CVS's prescription management software. CVS Pharmacy, Inc. also supplies legal, merchandising, cash management, property administration, tax preparation, and business advisory services to the Pharmacy Subsidiaries and CVS Rx Services, Inc.

26. CVS Pharmacy, Inc., CVS Rx Services, Inc., and the Pharmacy Subsidiaries are a joint enterprise that has sold opioids and other controlled substances in Rhode Island and throughout the United States. These entities have an agency and fiduciary relationship whereby they each joined the fraudulent and illegal acts of the others in the dispensing of opioids and each act of the Pharmacy Subsidiaries or CVS Rx Services, Inc. is attributable to CVS Pharmacy, Inc.

27. CVS Pharmacy, Inc., CVS Rx Services, Inc., and the Pharmacy Subsidiaries are collectively referred to herein as "CVS" or the "CVS Defendants."

II. JURISDICTION AND VENUE

28. This Court has subject matter jurisdiction over the CSA claims for civil penalties and injunctive relief pursuant to 21 U.S.C. §§ 842(c)(1)(A), 843(f), and 882, and 28 U.S.C. §§ 1331, 1345, and 1355.

29. This Court has subject matter jurisdiction over the FCA claims for civil damages and penalties pursuant to 31 U.S.C. § 3732 and 28 U.S.C. §§ 1331, 1345, and 1355, and over the common law claims pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).

30. This Court has personal jurisdiction over all CVS Defendants. CVS Pharmacy, Inc., CVS Rx Services, Inc., and Rhode Island CVS Pharmacy, L.L.C. are found in, maintain their principal place of business in, transact business in, are licensed in, and engaged in the illegal conduct alleged below in this District, among others, resulting in harm to the public and the United States in this District. CVS Pharmacy, Inc., and Rhode Island CVS Pharmacy, L.L.C. are also incorporated in this District.

31. The Court has personal jurisdiction over the remaining Pharmacy Subsidiaries for Counts Two to Six pursuant to 31 U.S.C. § 3732(a) because CVS Pharmacy, Inc., CVS Rx Services Inc., and Rhode Island CVS Pharmacy, L.L.C. can be found in, transact business in, and committed proscribed acts in this District. The Court also has pendent personal jurisdiction over all claims because all claims arise from a common nucleus of operative fact. *See* 28 U.S.C. § 1367.

32. The remaining Pharmacy Subsidiaries are also subject to personal jurisdiction in this District because CVS Pharmacy, Inc. exercised control and dominated the operations of the Pharmacy Subsidiaries such that the presumption of corporate separateness between CVS Pharmacy, Inc. and the Pharmacy Subsidiaries must be disregarded.

33. Venue is proper in the District of Rhode Island because a substantial part of the events or omissions giving rise to the claims occurred in this District, 28 U.S.C. § 1391(b); the claims accrued in this District, and CVS is found in this District, 28 U.S.C. § 1395(a). CVS also is located, resides, did business, and engaged in the illegal conduct in this District, 21 U.S.C. § 843(f); 31 U.S.C. § 3732(a).

III. THE CONTROLLED SUBSTANCES ACT

A. The Controlled Substances Act Governs Controlled Substance Dispensing

34. The CSA and its implementing regulations set forth a comprehensive regulatory regime for the manufacture, distribution, and dispensing of controlled substances. Congress enacted the CSA to facilitate the availability of controlled substances for authorized medical use, while also preventing controlled substances from being diverted for illegal purposes. The CSA establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. § 841(a)(1). The CSA and its implementing regulations govern every step in the handling of certain drugs, including manufacturing, distributing, prescribing, and dispensing.

35. The CSA creates a category of drugs, known as "controlled substances," that are subject to strict federal monitoring and regulation based on their potential for abuse. Controlled substances are categorized into five schedules based on several factors, including whether they have a currently accepted medical use to treat patients, their abuse potential, and the likelihood they will cause dependence if abused. A drug becomes a "controlled substance" when it is added to one of these schedules.

36. Schedule I drugs are those found to have no accepted medical use. Schedules II through V contain drugs found to have legitimate medical purposes but also to have the potential for abuse.

37. Under the CSA, pharmacies may dispense controlled substances only when registered to do so with the DEA. *See* 21 U.S.C. § 823(g); 28 C.F.R. § 0.100; 21 C.F.R. § 1300.01. A pharmacy's DEA registration is contingent upon the registrant's compliance with federal laws relating to controlled substances. 21 U.S.C. §§ 823(g), 824(a).

B. Controlled Substances May Be Dispensed Only for a Legitimate Medical Purpose Pursuant to Prescriptions Issued in the Usual Course of Professional Practice

38. Pharmacies registered with the DEA can dispense controlled substances listed in Schedules II through IV based only on a prescription issued by a practitioner. 21 U.S.C. § 829(a), (b).

39. Implementing regulations establish that controlled substances in Schedules II through IV may be dispensed only pursuant to prescriptions that are "effective," meaning valid. 21 C.F.R. § 1306.04(a). The CSA likewise forbids dispensing Schedule V controlled substances "other than for a medical purpose." 21 U.S.C. § 829(c).

40. To be "effective," controlled substance prescriptions must be issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a).

41. Section 1306.04(a) imposes a "corresponding responsibility" on the pharmacist who fills a prescription to independently determine that the prescription was issued for a legitimate medical purpose in the usual course of professional practice.

42. Section 1306.04(a) also provides:

> An order purporting to be a prescription issued not in the usual course of professional treatment …. is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription …. shall be subject to the penalties provided for violations of law relating to controlled substances.

43. A person, including a pharmacy, acts knowingly under the CSA by acting with actual knowledge, willful blindness, or deliberate ignorance of the fact that a prescription lacked a legitimate medical need or was written outside of the usual course of professional treatment. *See, e.g., Pharmacy Doctors Enters.*, 83 Fed. Reg. 10876-01, 10896 (DEA Mar. 13, 2018), *aff'd Pharmacy Doctors Enters., Inc. v. D.E.A.*, 789 F. App'x 724, 730–32 (11th Cir. 2019).

C. Pharmacists Must Adhere to Professional Pharmacist Practice Standards

44. The CSA and its regulations also require pharmacists who fill controlled substance prescriptions to follow the usual course of professional practice. *See* 21 C.F.R. § 1306.06.

45. To exercise their corresponding responsibility and dispense in the usual course of professional practice, a pharmacist must undertake the following three key duties before filling a controlled substance prescription:

(1) Identify red flags of illegitimacy;
(2) Resolve any red flags of illegitimacy; and
(3) Document the basis for filling the prescription.

46. These three obligations are recognized responsibilities of pharmacists in the professional practice of pharmacy.

47. CVS's own trainings recognized these professional obligations. CVS instructed pharmacists that they must identify and resolve red flags, and document red flag resolution, before dispensing controlled substances. It also instructed pharmacists to refuse to fill controlled substance prescriptions unless any red flags were resolved. Furthermore, CVS required pharmacists to document the basis for the resolution of red flags in sufficient detail to demonstrate the steps that the pharmacist took.

48. A pharmacist who fails to fulfill these three obligations when dispensing controlled substances does not adhere to the usual course of his or her professional pharmacy practice, as required by 21 C.F.R. § 1306.06. Failure to document the process of addressing red flags is thus evidence of a pharmacist's failure to fulfill professional obligations and exercise corresponding responsibility.

D. CVS Has Acknowledged That CVS Entities Are Responsible for the Invalid Prescriptions Its Pharmacies Filled

49. As a corporate DEA registrant, CVS is responsible for its pharmacies' and pharmacists' compliance with the CSA. 21 U.S.C. §§ 822(b), 823(g).

50. CVS is a "person" liable under the CSA when its pharmacies dispense controlled substances in violation of the CSA.

51. CVS has acknowledged that it is obligated under the CSA to exercise corresponding responsibility as an entity and that it has violated these obligations in the past, including in the following circumstances:

a. In May 2015, CVS agreed to pay the United States a $22 million civil penalty for alleged CSA violations at two CVS stores in Sanford, Florida. The DEA had revoked these pharmacies' registrations, finding that the stores "dispensed numerous prescriptions when their pharmacists either knew or had reason to know that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice," in violation of 21 C.F.R. § 1306.04. In that settlement, CVS acknowledged that:

> [I]t has a corresponding responsibility to dispense only those prescriptions that have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and that knowingly filling a prescription not in the usual course of professional treatment . . . subjects CVS to penalties under the CSA . . . .
>
> [C]ertain CVS/pharmacy retail stores did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA and its implementing regulations.

b. Similarly, in 2016, to resolve a separate federal investigation, CVS admitted:

> [C]ertain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA and its implementing regulations by not conducting "corresponding responsibility" when dispensing certain controlled substances in some instances between 2008 and 2012.

52. More generally, the CSA also requires "[a]ll applicants and registrants," including pharmacies, to "provide effective controls and procedures to guard against . . . diversion of controlled substances." 21 C.F.R. § 1301.71(a). This obligation encompasses all forms of diversion, including the unlawful dispensing of illegitimate prescriptions.

E. The CSA Imposes Restrictions on Refills of Schedule III and IV Controlled Substances

53. Unlike Schedule II prescriptions, for which refills are never permitted, *see* 21 C.F.R. § 1306.12(a), the CSA authorizes refills of Schedule III and IV prescriptions in certain circumstances. However, no Schedule III or IV prescription "shall be filled or refilled more than six months after the date [of the prescription] or be refilled more than five times after the date of the prescription unless renewed by the practitioner." 21 U.S.C. § 829(b); 21 C.F.R. § 1306.22.

54. In addition, the CSA prohibits Schedule III and IV prescriptions from being "dispensed without a written or oral prescription in conformity with section 503(b) of the [Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 353(b)]." *See* 21 U.S.C. § 829(b). If the prescription is oral, the pharmacist must promptly reduce it to writing. *See* 21 C.F.R. § 1306.21(a). Under the FDCA, refills are permitted only where "authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist." 21 U.S.C. § 353(b). Where a patient has exceeded the number of authorized refills, the patient necessarily lacks a written or oral prescription for the drug that conforms to the requirements of the FDCA. Dispensing a refill without authorization therefore also violates the CSA. *See* 21 U.S.C. § 829(b).

IV. THE FALSE CLAIMS ACT AND FEDERAL HEALTHCARE PROGRAMS

A. The False Claims Act

55. The FCA provides, in part, that any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States Government for damages and penalties. 31 U.S.C. § 3729(a)(1)(A)-(B).

56. To show that a person acted "knowingly" under the FCA, the United States must prove that the person, with respect to information: (1) had actual knowledge of the information; (2) acted in deliberate ignorance of the truth or falsity of the information; or (3) acted in reckless disregard of the truth or falsity of the information. The United States does not have to prove that the person had the specific intent to defraud. *Id.* § 3729(b)(1).

57. The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4).

58. The FCA provides that a person is liable to the United States for three times the amount of damages which the Government sustains, plus a civil penalty per violation. For a violation that occurred on or before November 2, 2015, the False Claims Act imposes a penalty, adjusted for inflation, of not less than $5,500 and not more than $11,000 per violation. *See* 31 U.S.C. § 3729(a); Federal Civil Penalties Adjustment Act of 1990, 28 U.S.C. § 2461 note; Pub. Law No. 104-410. For a violation that occurred after November 2, 2015, the inflation-adjusted penalty is not less than $13,946 and not more than $27,894. *See* 28 C.F.R. § 85.5.

B. Federal Healthcare Programs

1. Medicare Part D

59. Congress established the Medicare Program in 1965 to provide health insurance coverage for people aged 65 or older and for people with certain disabilities or afflictions. *See* 42

U.S.C. §§ 426, 426a. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, 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 the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a). CVS presented, or caused to be presented, reimbursement claims under Medicare Part D.

60. Unlike the traditional fee-for-service Medicare program, Part D is based on a private market model. Medicare contracts with private entities known as Part D Plan "Sponsors" to administer prescription drug plans. A Part D Plan Sponsor is either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan, a Program of All-Inclusive Care for the Elderly ("PACE") organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

61. Part D Plan Sponsors are regulated and subsidized by the Centers for Medicare & Medicaid Services ("CMS") pursuant to one-year, annually renewable contracts. Part D Plan Sponsors, in turn, enter into subcontracts with pharmacies or other downstream entities to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

62. When a pharmacy dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the Part D Plan Sponsor for the costs not paid by the beneficiary. The Part D Plan Sponsor then notifies CMS that a drug has been purchased and dispensed through a Prescription Drug Event ("PDE") record,

which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy.

63. More specifically, when a customer brings a prescription to a CVS pharmacy, a CVS employee, either a pharmacy technician or a pharmacist, enters the prescription data into CVS's dispensing system, called RxConnect. CVS also collects the customer's insurance card or, for existing customers, uses existing insurance information on file. CVS submits prescription and insurance information to the third-party payer (either commercial insurance or a Federal Healthcare Program).

64. Each PDE that is submitted to CMS by a Part D Plan Sponsor is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and is used to reconcile payments to a Part D Plan Sponsor. The data contained in PDEs are data related to payment of claims.

65. Submitting PDE claims data to CMS, which is necessary for CMS to administer the Part D program and make payments to Part D Plan Sponsors for qualified drug coverage, is a material condition of payment for CMS's provision of Medicare funds to Part D Plan Sponsors. *See* 42 C.F.R. § 423.322.

66. Throughout the year, CMS makes prospective payments to Part D Plan Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy designed to cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy; and (3) the reinsurance subsidy.

67. 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 by application of 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.

68. CMS also makes payments to the Part D Plan Sponsor for premium and cost-sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R. § 423.780 and 42 C.F.R. § 423.782. Cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost-Sharing Subsidies" and are documented and reconciled using PDE data submitted to CMS.

69. The reinsurance subsidy is paid to the Part D Plan Sponsor to cover the Government's share of drug costs above an enrollee's catastrophic threshold.

70. Part D Plan Sponsors who fail to submit required claims-level information contained in the PDE to CMS risk having to return the monthly payments to CMS during reconciliation. *See* 42 C.F.R. § 423.343(b), (c)(2), (d)(2). In addition, Part D Plan Sponsors are responsible for correcting submitted PDE data that they determine are erroneous. *See* CMS, UPDATED INSTRUCTIONS: REQUIREMENTS FOR SUBMITTING PRESCRIPTION DRUG EVENT DATA (PDE) at 22 (Apr. 27, 2006).

71. After the close of the plan year, CMS is responsible for reconciling the Part D Plan Sponsor's prospective payments to its actual allowable costs by relying upon data elements submitted by Sponsors in their PDE records. *See generally id*. After CMS reconciles a plan's prospective payments and actual allowable costs, CMS 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. Determining risk-sharing amounts involves 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. 42 C.F.R. § 423.336.

72. To receive Part D funds from CMS, Part D Plan Sponsors and their authorized agents, employees, and contractors are required to comply with all applicable federal laws and regulations, as well as CMS instructions.

73. By statute, all contracts between a Part D Plan Sponsor and the Department of Health and Human Services ("HHS") 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.

74. Medicare Part D Plan Sponsors also must 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).

75. Regulations further require that all subcontracts between Part D Plan Sponsors and downstream entities (including pharmacy benefit managers ("PBMs") and pharmacies like CVS) must contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. *Id.* § 423.505(i)(4)(iv). Defendant CVS executed such agreements on behalf of itself and its pharmacies.

76. A Part D Plan Sponsor is required by federal regulation to certify to the accuracy, completeness, and truthfulness of all data related to the payment. This provision, entitled "Certification of data that determine payments," provides in relevant part, as follows:

> (1) General rule. ***As a condition for receiving a monthly payment . . . 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 . . . ***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.…
>
> (2) [Part D Sponsor] Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, . . . must certify (based on best knowledge, information, and belief) that the claims data

> it submits . . . are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

Id. § 423.505(k)(1), (k)(3) (emphasis added).

77. All approved Part D Plan Sponsors that received payment under Medicare Part D in benefit years relevant to this Complaint submitted the required attestations for data submitted that related to payment. *Id.* § 423.505(k).

78. The "Certification of data that determine payments" provision of the applicable regulation further provides: "[i]f 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." *Id.* § 423.505(k)(3).

79. Compliance with the requirement that PDE data submitted by the Part D Plan Sponsor is "accurate, complete, and truthful" based on best knowledge, information, and belief, is a condition of payment to the Sponsor under the Medicare Part D Program. *Id.* § 423.505(k)(2).

80. Medicare covers only drugs that are used for a medically accepted indication, which means a use that is approved under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, or a use which is supported by one or more citations included or approved for inclusion in one of the specified compendia. 42 U.S.C. §1395w-102(e)(1), (e)(4); *Id.* § 1396r- 8(g)(1)(B)(i), (k)(6); 42 C.F.R. § 423.100.

81. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, for example where they are issued for recreational use, are not for "medically accepted indications" and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 1395w-102(e)(1), (e)(4).

82. In addition, Medicare only covers drugs that are dispensed upon a valid prescription. *Id*. § 1395w-102(e); 42 C.F.R. § 423.100. "A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription." 42 C.F.R. § 423.104(h). A valid prescription must comply "with all applicable State law requirements constituting a valid prescription." *Id*. § 423.100.

83. State laws generally require that prescriptions be issued for a legitimate medical purpose by practitioners acting in the usual course of professional practice. *See, e.g.*, R.I. Gen. Laws § 21-28-3.18 (a) (requiring pharmacies only fill "valid" prescriptions in "good faith"; Fla. Admin Code. r. 64B16-27.831(1)(a) (defining a "valid prescription"); Cal. Health & Safety Code § 11150 (requiring prescriptions be issued by practitioners acting within the "scope of project"); N.J. Stat. § 24:21-15 (requiring prescriptions be issued by practitioners within their usual course of professional practice); 720 Ill. Comp. Stat. § 570/312(h) (providing that any prescription issued "not in the regular course of treatment" is not a valid prescription); Va. Code Ann § 54.1-303(A) (defining a "valid prescription").

84. PDEs submitted to Medicare for controlled substances that are not for medically accepted indications and/or are not based on valid prescriptions do not contain accurate, complete, and truthful information about all data related to payment.

2. Medicaid

85. Medicaid is a joint federal-state program created in 1965 that provides healthcare benefits for certain groups, primarily for low-income and disabled patients. Each state administers a state Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specific minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

86. As with Medicare, Medicaid coverage extends only to "prescribed drugs," and does not include drugs dispensed pursuant to invalid prescriptions. *See id*. § 1396d(a)(12).

87. 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. *Id.* § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended . . . as medical assistance under the State plan." *Id.* § 1396b(a)(1).

88. The vast 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 any adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

89. Providers, like CVS, who participate in the Medicaid program must sign enrollment agreements with the states that certify compliance with the state and federal Medicaid requirements. Although there are variations among the states, the agreement typically requires the

prospective Medicaid provider to agree that the provider will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

90. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations. In Rhode Island, for example, providers, including pharmacies like CVS, certify in provider agreements that they will "comply with all requirements for participation as set forth in applicable Federal and State statutes and regulations, and Program policies, within the authorities of such statutes and regulations, of the Rhode Island State Medicaid Agency as published in Provider manuals and bulletins." Providers "agree[] to comply with all the State and Federal laws and regulations that apply to the specific jurisdiction in which services and professional activities are delivered," and further certify "that the goods or services listed were medically necessary, authorized (if the goods or services claimed required preauthorization under existing statutes or regulations), and actually rendered to the RI Medicaid beneficiary."

3. TRICARE

91. TRICARE (formerly known as CHAMPUS) is part of the United States military's healthcare system, designed to maintain the health of active-duty service personnel, provide healthcare during military operations, and offer healthcare to non-active-duty beneficiaries, including dependents of active-duty personnel, and military retirees and their dependents. The military health system, which is administered by the U.S. Department of Defense, is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE contracts with PBMs to administer its retail and mail order pharmacy programs.

92. TRICARE will pay only "for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care. However, TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means." 32 C.F.R. § 199.4(e)(11).

93. CVS was a TRICARE network pharmacy during the relevant time period until December 1, 2016. CVS rejoined the TRICARE network on December 15, 2021.

94. When a TRICARE beneficiary's drug 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 ten-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.

95. TRICARE authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim, and the PBM sends the payment to the pharmacy. As a

fiscal intermediary for the Government, the PBM is authorized to disburse government funds for healthcare benefits and receives reimbursement for such funds from the Federal Reserve Bank.

96. All pharmacies that provide services to TRICARE beneficiaries are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Billing for non-covered services is included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(2).

C. Materiality

97. Compliance with federal and state requirements relating to pharmacies' dispensing of controlled substances was, and still is, material to the United States' decision to reimburse claims for controlled substances. Compliance with such requirements is central to the Federal Healthcare Programs' benefits and is a condition of these medications being covered by these Federal Healthcare Programs. As such, had the United States known that the claims submitted were for invalid prescriptions and/or improperly dispensed controlled substances in violation of such requirements, the United States would not have reimbursed these claims.

98. Prior to at least 2013 and up through the present, Federal Healthcare Programs have publicly set forth the importance of these requirements as it relates to the prescribing of and payment for controlled substances, and opioids in particular.

99. For instance, CMS notified Part D Plan Sponsors in 2011 that they should take immediate steps to stop prescription drug misuse and fraud, noting the cost to Medicare for opioids like OxyContin and instructing Sponsors to investigate suspect claims and withhold payment for fraudulent claims. *See* https://www.cms.gov/newsroom/fact-sheets/obama-administration-and-expanded-efforts-fight-fraud.

100. In 2015, CMS issued public guidance to pharmacy providers that discussed Medicaid prescription drug expenditures, prescribing practices that could trigger audits, proper billing practices by pharmacy providers, and fraud, waste, and abuse. CMS stated that "[a]buse may include improper payment for services, payment for services that fail to meet professionally recognized standards of care, or payment for services that are medically unnecessary," with further reference to the FCA as an important tool for combating fraud, waste, and abuse. *See* https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/pharmacy-selfaudit-booklet4-billing-practice.pdf.

101. In January 2017, in addressing combatting opioid misuse, CMS again encouraged Part D Plan Sponsors to combat opioid misuse by investigating, auditing, and terminating from their network improper prescribers and pharmacies who dispense drugs improperly. https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/cms-opioid-misuse-strategy-2016.pdf.

102. Moreover, in April 2017, the Secretary of the United States Department of Health and Human Services declared that the opioid epidemic is a national public health emergency under federal law. This declaration highlighted the government's concern over the writing and filling of improper prescriptions and the importance that the federal government places on curtailing such improper prescriptions.

103. The government has also denied payment for controlled substance medications, and sought to recoup payments already made, when such prescriptions are not valid, are not for a medically accepted indication, and/or are not medically necessary.

104. The United States Department of Justice has litigated and settled numerous actions where it was alleged that providers and/or pharmacies submitted claims for controlled substances

to Federal Healthcare Programs that lacked a valid prescription, were not for a medically accepted indication, and/or were not medically necessary.

V. CVS ROUTINELY FILLED INVALID PRESCRIPTIONS

105. Numerous red flags are recognized in professional pharmacy practice as likely signs of prescription invalidity, diversion, or abuse. To fulfill their corresponding responsibility under the CSA, pharmacists must identify, address, and resolve these red flags. Red flag identification and resolution is also an important component of the "usual course of professional [pharmacy] practice," with which the CSA's implementing regulations require pharmacists to conform when they fill prescriptions. *See* 21 C.F.R. § 1306.06.

106. Red flags requiring resolution before dispensing include, for example:

(1) *Excessive Quantities of Opioids*. Prescriptions resulting in high daily morphine milligram equivalents ("MME")—a standardized measure used to compare the relative potency of different opioid medications. The 2016 Opioid Prescribing Guidelines issued by the Centers for Disease Control recommend that clinicians "carefully reassess evidence of individual benefits and risk when considering increasing dosage to ≥50 [MME]/day, and . . . avoid increasing dosage to ≥90 MME/day or carefully justify a decision" to prescribe that amount. The 2022 Guidelines similarly recommend that "before increasing total opioid dosage to ≥50 MME/day, clinicians should pause and carefully reassess evidence of individual benefits and risks."

(2) *Doctor Shopping*. Obtaining controlled substance prescriptions from multiple prescribers, which may reflect that the patient is seeing multiple prescribers in an attempt to obtain larger quantities of a controlled substance than a single prescriber would be willing to prescribe, or to obtain combinations of controlled substances that a single prescriber would be unwilling to prescribe.

(3) *Pharmacy Shopping*. Obtaining controlled substance prescriptions from multiple pharmacies, which may reflect that the patient is visiting multiple pharmacies in an attempt to fill prescriptions for multiple or duplicative controlled substances that a single pharmacist would be unwilling to fill at the same time.

(4) *"Trinities."* Combinations of an opioid and one or more non-opioid "potentiator" drugs that can increase the euphoric effect of opioids and the risk of abuse and overdose. Trinities include a combination of an opioid, a benzodiazepine (for example, Xanax or Valium), and a muscle relaxer, such as carisoprodol (brand name Soma).

(5) *Other Dangerous Drug Combinations*. Other dangerous drug combinations that may be indicative of diversion including multiple immediate-release opioids prescribed together or close in time, or immediate-release opioids and methadone, another powerful opioid, prescribed at the same time.

(6) *Early Fills and Refills*. A request to fill a controlled substance prescription early, which suggests that the individual was either taking a higher quantity than prescribed or diverting at least some of the pills to other individuals.

(7) *Cash Payments*. Cash payments, particularly where a recipient has some type of insurance available and used it to pay for other prescriptions, which may be a sign of diversion because cash may be used to avoid scrutiny of a prescription by the insurer.

(8) *Other Signs of Diversion Recognized by CVS and Others*. These include, but are not limited to, long distances between the patient, prescriber, and pharmacy; prescribers who only take cash or who frequently write prescriptions for the same drug, quantity, and dosage (pattern prescribing); prescribers writing prescriptions for narcotics outside of their practice specialties; lack of documentation of allergy or pregnancy when relevant; failure to comply with state rules and regulations; simultaneous prescribing of contra-indicated prescriptions (e.g., a stimulant and a depressant); and medications that are inappropriate or unusual for the patient's age.

107. CVS's own policies and pharmacist trainings recognized these signs of illegitimate use, abuse, and diversion, and show its corporate understanding that its pharmacists are required to identify and resolve these red flags prior to dispensing controlled substances. For example, CVS's October 2015 Guidelines for Controlled Substances specifically identified early fills, doctor shopping, trinity cocktails, and cash payments for prescriptions by patients holding insurance (among others) as red flags of diversion.

108. CVS's August 2015 biannual pharmacist training similarly identified numerous red flags, including early fills, doctor shopping, trinity cocktails, and cash payments for prescriptions by patients holding insurance.

109. The August 2015 biannual training also stated that "[a]ll identified red flags must be resolved . . . in RxConnect prior to filling the prescription. If any red flags are unable to be resolved, a Pharmacist must refuse to fill the prescription."

110. In order to resolve such red flags, the pharmacist had to take one or more steps, identified in CVS's policies and trainings. These steps included, for example:

(a) reviewing the pharmacy's dispensing history for the patient;
(b) reviewing the patient's diagnosis to confirm that the drug is an appropriate therapeutic for the patient's condition;
(c) reviewing any drug utilization review ("DUR") alerts (system alerts generated by pharmacy dispensing software to direct pharmacists' attention to potential issues with prescriptions);
(d) contacting the prescriber to resolve issues relating to the prescription; and
(e) checking the state prescription drug monitoring program ("PDMP") database for all prescriptions obtained by the patient, whether or not those prescriptions were filled at CVS.

111. Checking the state PDMP database would inform the pharmacist whether, among other things, the patient appeared to be engaged in doctor- or pharmacy-shopping, as well as information concerning the patient's other medications, which would reveal whether the patient was receiving dangerous combinations of drugs from multiple prescribers or pharmacies. The PDMP database would also reveal whether the patient was traveling long distances to acquire a prescription. Where PDMP was available, checking PDMP in appropriate circumstances has been part of the usual course of professional pharmacy practice.

112. Carrying out the steps to resolve red flags of diversion takes time and may require responses from doctors' offices that frequently cannot be obtained at night or on weekends. Nonetheless, as CVS recognized, completing these steps, and resolving red flags is a necessary component of corresponding responsibility. For example, a 2018 CVS pharmacist training on corresponding responsibility instructed pharmacists filling opioid prescriptions with MME levels over 50 to document why they did so.

113. The "usual course of professional practice" also requires a pharmacist to document red flag resolution before filling a prescription. CVS's own trainings recognized this professional

obligation: CVS instructed pharmacists that they must document red flag resolution in sufficient detail to demonstrate the steps the pharmacist took.

114. Such documentation serves as the best evidence that the pharmacist did, in fact, resolve red flags prior to dispensing. Conversely, the absence of such documentation—particularly when CVS's own policies explicitly required it—is compelling evidence that the pharmacist did not resolve red flags prior to dispensing, and, consequently, that the dispensing pharmacist did not comply with their corresponding responsibility obligations.

115. CVS routinely filled opioid and other controlled substance prescriptions bearing egregious red flags of diversion without resolving those red flags, and without documenting any such resolution, in violation of CVS's policies, the CSA, and the CSA's implementing regulations. CVS also violated the CSA by dispensing at least hundreds of Schedule III and Schedule IV controlled substance prescriptions in violation of the CSA's limitations on refills of such prescriptions.

116. CVS also filled at least thousands of controlled substance prescriptions written by prescribers who were known "pill mills"—that is, prescribers who issue large numbers of controlled substance prescriptions without medical purpose.

117. For thousands of these invalid prescriptions, CVS submitted claims for payment to Federal Healthcare Programs in violation of the FCA.

VI. CVS KNOWINGLY FILLED INVALID PRESCRIPTIONS

A. CVS Deliberately Set Staffing Levels and Created Working Conditions in Its Pharmacies that Put Profit Over Safety and Caused Its Pharmacies to Dispense Controlled Substances Pursuant to Invalid Prescriptions

118. From at least October 17, 2013, CVS prioritized profits over safety in dispensing controlled substances. CVS knew that its pharmacists lacked the time to comply with their

professional practice obligations, including their exercise of corresponding responsibility. CVS also knew that its staffing policies and compensation and performance metrics emphasized speed over safety. As a result of these policies and practices, CVS caused its pharmacists to knowingly dispense controlled substances pursuant to invalid and dangerous prescriptions. These problems persist.

1. CVS's Inadequate Staffing Caused Pharmacists to Dispense Drugs at Unsafe Speeds

119. CVS did not provide stores with sufficient pharmacist and technician hours to comply with their legal obligations while also meeting corporate expectations.

120. CVS developed pharmacist and technician staffing and hours budgets at the corporate level. CVS's headquarters group responsible for addressing staffing management ("GSM") played a critical role in setting these budgets.

121. A "key objective[]" for GSM was to "control/reduce labor spend." GSM sought to achieve this result by reducing pharmacist and technician hours without reducing the number of prescriptions dispensed. At times, incentive compensation for GSM employees was based on their success in reducing labor costs.

122. To achieve the goal of reducing labor costs, CVS developed "labor standards"—essentially, calculations to define the time it should take pharmacy staff to fill prescriptions and perform the other tasks CVS expected (such as providing vaccinations, making medication reminder calls, and counseling patients about medications). CVS then applied these labor standards to the anticipated number of prescriptions each pharmacy was expected to fill to set its budgets for pharmacist and technician labor hours at retail pharmacies.

123. GSM set standards for tasks requiring the exercise of pharmacists' professional expertise simply by measuring how long it took a select set of pharmacists to perform these tasks.

CVS did not assess whether these pharmacists actually performed the tasks consistent with their legal and professional obligations, nor did they seek field pharmacist input in setting labor standards. The labor model simply used the performance of pharmacists who succeeded in meeting performance metrics (discussed in greater detail below) as a benchmark.

124. Because the labor budgets were set by reference to pharmacists who did not necessarily comply with their CSA obligations, these budgets did not provide the hours necessary for all pharmacists to meet their CSA obligations.

125. Nor did GSM build sufficient variability into these labor standards to account for the relative complexity or risk involved in a pharmacist's handling of a given prescription based on the presence of red flags.

126. CVS's labor standards also created working conditions that resulted in unsafe dispensing decisions by failing to provide sufficient time for pharmacists to take breaks to drink water or use the bathroom. Although CVS's standards ostensibly included a "personal allowance" to cover such breaks, that allowance was set at five percent of total work time—a fixed number—not based on the needs of pharmacy staff. Inadequate allotted time for addressing basic human needs exacerbated the extreme strain placed on CVS pharmacists by CVS's unrealistic labor standards, further jeopardizing patient safety. For example, one pharmacist developed a urinary tract infection from being unable to go to the bathroom during their 13-hour shift. Another had to pull off to the side of the road to vomit on the commute home because they had no time to eat all day.

127. Nor did CVS give its pharmacies or pharmacists discretion to adjust staffing as needed to perform their jobs legally and safely.

128. CVS also made ad hoc changes to labor budgets to ensure that they would appear to indicate that staffing was sufficient. The labor model did not determine the expected annual chainwide spending on pharmacists and technician labor. Instead, CVS corporate executives prepared "top-down" expectations for what spending would be. If the top-down expectations did not provide enough funding for the labor spend called for by the model, CVS would increase the number of prescriptions pharmacists and technicians were expected to fill per hour. Thus, when management's targeted labor spending did not provide enough funding to staff the pharmacies, CVS just adjusted the labor budget to call on staff to work faster.

129. Because of CVS's unrealistic expectations, pharmacies often failed to fill the number of prescriptions that CVS expected.

130. When pharmacies failed to meet CVS's expectations for prescriptions filled, GSM reduced the pharmacist or technician labor hours for that store. This created a vicious cycle in which overworked pharmacists received less help if they failed to hit targets.

131. Where pharmacist and technician hours were reduced, the remaining pharmacists and technicians were even busier, making it even harder for them to exercise corresponding responsibility properly.

132. CVS's practices and policies regarding pharmacist and technician labor budgets caused chronic and severe understaffing at its retail pharmacies.

133. CVS's approach to budgeting labor hours led directly to CVS pharmacists being unable to exercise appropriate due diligence on prescriptions and therefore to filling illegitimate prescriptions in violation of the CSA.

134. These problems continue. For example, in March 2024, a store in Florida dispensed oxycodone tablets in the bottle of a different medication provided to an 11-year-old child. To an

11-year-old taking oxycodone for the first time, the side effects could be serious and might require hospitalization. The dispensing pharmacist acknowledged they were extremely busy throughout the day, that they routinely needed to perform multiple tasks simultaneously, and that the chaotic nature of the pharmacy contributed to their putting the oxycodone tablets in the child's pill bottle.

2. CVS's Performance Metrics Exacerbated Understaffing and Improper Dispensing

135. CVS implemented performance metrics that disincentivized the proper exercise of corresponding responsibility.

136. CVS incentive compensation policies and performance metrics rewarded pharmacists for the volume of prescriptions filled, and for filling prescriptions quickly, and punished them for failing to meet such metrics. They did not, however, reward pharmacists for carefully scrutinizing controlled substance prescriptions for red flags and documenting the outcome of that work.

Incentives Based on Volume and Profit Goals

137. CVS's performance metrics set goals for the volume of prescriptions that should be filled in a given timeframe.

138. CVS measured its pharmacists' and pharmacy managers' performance, and based their incentive compensation, in significant part, on "script count to budget"—comparing the number of prescriptions the pharmacist filled to the number of prescriptions CVS corporate expected the pharmacist to fill. Pharmacists who filled more prescriptions than expected received more favorable performance reviews and higher bonuses.

139. While controlled substance prescriptions were nominally excluded from this metric after 2012, pharmacists still needed time to fill these prescriptions, leaving less time available for pharmacists to fill the non-controlled substance prescriptions on which they were measured. As a

result, pharmacists were expected to, and were financially motivated to, fill controlled substance prescriptions quickly and without thorough checks. Moreover, CVS's benchmarks for the number of prescriptions it expected its pharmacies to fill steadily increased.

140. Incentive compensation and performance reviews for field managers who directly or indirectly supervised retail pharmacists and technicians were also based, in part, on this script count to budget metric.

141. Incentive compensation and performance reviews for field managers were also based on "management-controlled profit to budget," a metric designed to reward regional managers for delivering profits above what the company expected from their region. This metric was heavily influenced by the labor hours each store used. Stores with fewer hours per volume of prescriptions had lower labor costs and generated a higher management-controlled profit. These metrics incentivized managers to understaff their stores and pressure pharmacists to fill prescriptions too quickly, without regard to their legal obligations.

Incentives Based on Speed of Filling

142. CVS also measured store and pharmacist performance by assessing the speed with which pharmacists filled prescriptions.

143. For example, CVS's computer system displayed a "triage queue"—a list of the tasks for the pharmacy employees to complete.

144. CVS graded store and pharmacist performance on the percentage of items in the triage queue, including filling controlled substance prescriptions, that the pharmacy completed in the allotted time. Pharmacists could receive lower performance reviews or be disciplined if they did not clear the entire queue before leaving each evening, thus further pressuring them to fill controlled substance prescriptions too quickly despite their legal obligations.

145. If a customer requested a prescription within fifteen minutes, the pharmacist was supposed to make sure it was ready in fifteen minutes—without regard to what else was in the queue or the staffing. For those prescriptions, as the time elapsed got close to fifteen minutes, the prescription would show up on the computer screen as yellow. If the time went past fifteen minutes, the prescription would show up at the top of the screen in red.

146. Pharmacists and staff were evaluated, among other things, on the degree to which they avoided or reduced such red-light alarms.

Incentives Based on Customer Satisfaction Surveys

147. CVS's pharmacists' and field managers' performance reviews and incentive compensation were also based in part on customer satisfaction surveys. Those surveys asked customers, among other things, if they were satisfied with the time it took to fill their prescriptions.

148. This metric motivated CVS's pharmacists and managers to fill controlled substance prescriptions quickly, at the expense of the proper exercise of their corresponding responsibility, because properly resolving red flags takes time and can delay the filling of the prescription, leading to customer complaints.

149. Likewise, refusing to fill prescriptions frequently led to customer complaints, as well as store manager dissatisfaction with the pharmacist.

150. CVS's performance metrics, along with its staffing policies, resulted in even higher expectations for the number of prescriptions that pharmacists were expected to fill, making it even more difficult for them to exercise corresponding responsibility. As a result, these overworked pharmacists disregarded their CSA obligations in a rush to meet the performance metrics imposed by CVS.

B. CVS Knew and Willfully Ignored that Its Pharmacists Were Dispensing Drugs So Fast that It Imperiled Public Health and Safety

151. Through various sources, CVS knew that its pharmacists were filling prescriptions at unsafe speeds at the expense of public health and legal compliance, but continued to enforce the staffing levels and employment policies that drove that improper dispensing.

1. Pharmacy Board Actions

152. Numerous state pharmacy board actions warned CVS that its working conditions raised significant patient safety concerns in its pharmacies, yet CVS still failed to address these issues.

153. Numerous state pharmacy boards have found that understaffed CVS locations committed dispensing errors.

154. For example, in July 2020, the Oklahoma Board of Pharmacy fined CVS for conditions at four pharmacies, including inadequate staffing and dispensing errors. At one store, investigators found an error rate of nearly 22 percent, or 66 errors out of the 305 prescriptions reviewed. Some of the errors at the four impacted pharmacies significantly impacted patient safety. For example, CVS failed to properly dispense anticonvulsant medication to a teenager, leading to nonstop, violent, uncontrollable seizures. The region's district leader reportedly stated that "district leaders were repeatedly voicing their concerns about the budgets" for staffing to corporate management and that they were worried about patient safety.

155. Between August 2021 and March 2023, the Virginia Board of Pharmacy issued numerous citations to CVS related to pharmacists failing to verify the accuracy of dispensed prescriptions. Understaffing contributed to the errors resulting in these citations.

156. For example, in February 2022, inspectors found a CVS pharmacy so busy that employees were "barely . . . able to take a bathroom break on a 12-hour shift," if they took a break

at all. The pharmacy staff reported "unsafe" and "stressful" work conditions due to lack of adequate staffing and a corporate focus on numerous burdensome metrics, including prescription turnaround time. The staff reported that these metrics contributed to errors and affected "the ability to dispense prescriptions safely."

157. Since June 2021, the Ohio Board of Pharmacy has issued numerous citations to CVS locations, alleging that, among other things:

a. CVS pharmacies lost medications (including controlled substances);

b. CVS pharmacies were extremely disorganized and permitted unqualified employees to perform pharmacist duties;

c. CVS pharmacists repeatedly stated that understaffing contributed substantially to these problems, but that their complaints fell on deaf ears; and

d. One district leader stated that it was "the worst [they] had seen the staff shortage," but they were nonetheless "unsuccessful" in getting help from other districts.

158. On or about February 6, 2024, the Ohio Board of Pharmacy indefinitely placed CVS #2063 on probation due to inadequate staffing and ordered it, among other things, to:

> ensure that sufficient personnel are scheduled at all times in order to minimize fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with the requisite judgment, skill, competence, and safety to the public. Staffing levels shall not be solely based on prescription volume but, in determining the need for staff, CVS #2063 shall consider any other requirements of the practice of pharmacy by pharmacy personnel during working hours.

159. Later in 2024, CVS paid a $1.25 million fine to resolve the Ohio Board's claims of critical understaffing at 22 stores. As part of that resolution, eight stores were placed on probation, with CVS committing an additional $250,000 to pay for enhanced monitoring of those eight stores.

2. Manager Notifications

160. CVS corporate management was also repeatedly informed by their own employees and managers that pharmacists lacked sufficient time to fill prescriptions safely. Pharmacists and technicians regularly raised alarms about insufficient staffing, but their complaints were ignored.

161. CVS's managers across the country were also aware that pharmacies were understaffed, and pharmacy employees overworked. Field managers, including district leaders and pharmacy supervisors, acknowledged that they knew that pharmacists were wildly overworked and lacked the time to properly assess controlled substance prescriptions for red flags, call prescribers, and, where appropriate, reject prescriptions. One district leader admitted that CVS pharmacists would check off in the dispensing software that they had called a prescriber about a prescription, even though they had not actually done so and did not have the time to do so.

162. Multiple district leaders and pharmacist supervisors also admitted that they knew that pharmacists did not have sufficient time to check PDMP before filling prescriptions.

163. One pharmacy supervisor explained the pharmacists were "in a bind to not check PDMP due to the timeliness requirements" under which they operated.

164. Another acknowledged that the "majority of pharmacists were not checking PDMP."

165. A third supervisor acknowledged that they "turned a blind eye" to the fact that pharmacists under their direction were not checking PDMP because they lacked time to both do so and meet CVS's demanding expectations.

3. Internal Complaints and Escalations

166. CVS's "ethics line"—which the company used to record, track, and monitor reports of unethical conduct of store employees, among others—received hundreds of complaints relating to understaffing.

167. Several of these ethics line complaints highlighted the insufficient staffing for pharmacists and technicians. For example, one pharmacy employee wrote that CVS's staffing was so insufficient that the pharmacists were not able "to have basic human rights, such as going to the bathroom," because if they did, there would not be anyone to watch the pharmacy. Another wrote that "stores . . . are forced to operate on skeleton crews resulting in mentally and physically overworked employees."

168. Moreover, in dozens of ethics line submissions, pharmacists and technicians complained that pharmacies were so severely understaffed that patient health and safety were at risk.

169. One pharmacy employee stated that severe understaffing led to a "major public safety risk."

170. Another pharmacist complained that CVS created "a dangerous work environment" in which "staff cannot safely and adequately serve [their] patients in need."

171. A pharmacist complained patients were at "an increased risk for medication errors." Another pharmacy employee complained that "errors [were] more likely to go undetected and reach the patient."

172. One pharmacist admitted that they "often bl[e]w through [computer alerts identifying dangerous prescription combinations] because it [was] all [they could] do to barely stay afloat in the massive amount of prescriptions coming [their] way to verify."

173. Multiple pharmacy employees raised the alarm that dangerous understaffing could even cause deaths due to dispensing errors, including reporting that:

a. understaffing was "going to lead to . . . a fatal error with a patient."

b. "potential for errors . . . could be harmful or even fatal to . . . patients."

c. "endless tasks demanded of [pharmacists] at CVS make it nearly impossible to assist patients the way they deserve and increases the possibility of catastrophic errors."

d. "[i]f there is just one [prescription] that gets overlooked and rushed, it could be fatal for someone. Why is that not a concern for this company?"

e. "stores and pharmacies are grossly understaffed . . . The working conditions are getting worse every day . . . . [D]istrict leaders do not help improve the situation and are unwilling to assist." The complaining pharmacist added that "with the increased workload that COVID-19 placed on the stores there should be more people to handle the tasks. This year there were fewer schedule hours on average than any other year. . . . With the extra stress[] placed on the pharmacy there is an increased risk of an accident. . . . Unless something changes it is only a matter of time until somebody gets injured."

174. In such reports, CVS pharmacists acknowledged that CVS's staffing policies reflected a decision by management to place profit above patient safety, noting, for example that "the systems currently in place act opposite of the oath that pharmacists take to maintain patient safety. The system jeopardizes the patients as well as the licenses of the pharmacists tasked to care for them."

175. Corporate management regularly ignored these ethics line complaints. Upon review of every one of the complaints quoted above, CVS corporate management concluded that the stores had labor budget hours consistent with the other stores and did not need additional budget hours.

4. Public Media Reports and Pharmacist Surveys

176. CVS management also was aware that its pharmacies were dangerously understaffed because public media reports and pharmacist surveys highlighted these problems.

177. In December 2016, the Chicago Tribune conducted a study to assess "how often stores would dispense dangerous drug pairs without warning patients." The study found that CVS "had the highest failure rate of any chain . . . dispensing the medications with no warning 63 percent of the time." The Chicago Tribune's study, which was widely shared within CVS, noted that pharmacies "emphasize[d] fast service over patient safety." It also reported that pharmacists

"described assembly-line conditions in which staff hurried to fill hundreds of prescriptions a day"; criticized CVS's practice of measuring prompt service because it "pressures [pharmacists] to focus more on corporate criteria than on drug interactions and other safety checks;" and observed that these metrics created "unreal pressure."

178. In February 2020, the New York Times also reported that CVS pharmacists were "struggling with understaffed and chaotic workplaces" where "it had become difficult to perform their jobs safely, putting the public at risk of medication errors." The Times reported that one CVS pharmacist wrote to the Texas State Board of Pharmacy that they were "a danger to the public working for CVS." This article was also widely circulated within CVS.

179. In March 2021, NBC News similarly reported that "overworked, understaffed" pharmacists at chain pharmacies, including CVS, put "patient safety at risk."

180. Various pharmacist job satisfaction surveys have found that pharmacists working at CVS lack sufficient time to perform their duties safely. For example, a 2021 survey by the Ohio Board of Pharmacy contained alarming anonymous statements from CVS pharmacists about their workloads, including:

a. CVS "acts in such a criminally negligent way that I don't feel I have enough time to check prescriptions safely";

b. CVS lacks "enough staff to run a true, safe healthcare facility";

c. pharmacists "feel like [they] are drowning, and no one is going to help [them]"; and

d. when "[I] expressed concerns . . . about patient safety and regulatory compliance," I was told that "giving me a bigger labor budget would be a detriment to 'shareholder value.'"

C. CVS Knowingly Refused to Implement Recommended Corrective Actions to Reduce the Filling of Invalid Prescriptions in Violation of the CSA and FCA

181. CVS repeatedly refused to implement available procedures to prevent or diminish illegal dispensing because it did not want to reduce sales or increase labor costs.

182. CVS executives decided not to implement those procedures after recognizing the volume of alarms and issues they would raise, which could decrease profitability.

183. Thus, CVS executives knew that they had the ability to slow, stop—or, by contrast, encourage—the stream of invalid prescriptions by their policies. Year after year, CVS executives made decisions to choose profits over legal compliance and prioritized volume and speed over care and safety, ignoring desperate pleas from their own pharmacists for help.

1. CVS Intentionally Did Not Provide Pharmacists the Necessary Information to Exercise Corresponding Responsibility Adequately

184. CVS used prescription management software called RxConnect to, among other tasks, provide pharmacists with information regarding returning patients (called "patient profiles"), but chose not to share with its pharmacists all of the information CVS possessed relevant to a pharmacist's corresponding responsibility.

185. RxConnect did not alert pharmacists to the majority of red flags of diversion identified in CVS's policies and trainings, despite the availability of that information. The lack of automated alerts to pharmacists is particularly significant in light of the intense time pressure under which CVS placed pharmacists.

186. Moreover, if a CVS pharmacist properly exercised their corresponding responsibility and refused to fill a prescription, CVS had no mechanism to alert pharmacists at other locations. As a result, a patient whose prescription was appropriately rejected at one CVS could simply take the prescription to another CVS to get the drug filled. For example, at a 2017

focus group, one Indiana CVS pharmacist described to a corporate group at CVS headquarters, which is responsible for supporting CVS pharmacists in complying with their corresponding responsibility, how, on two occasions, a patient's son had picked up his mother's morphine prescriptions for her, immediately gone to the store bathroom, and left behind a pink residue indicating that he had crushed and used his mother's tablets in the store bathroom. The pharmacist reported that they refused to fill the prescriptions going forward and called the prescriber, but the patient "just start[ed] filling at a different CVS."

187. CVS elected not to systematically track instances in which pharmacists refused to fill prescriptions pursuant to the exercise of corresponding responsibility, even though such a system would have permitted CVS to ensure that its pharmacists were not filling prescriptions that had been previously identified as illegitimate. (Such a system would have also allowed CVS to assess the performance of its pharmacists). Even so, the very limited refusal-to-fill data that CVS did collect shows that CVS pharmacists filled controlled substance prescriptions that other CVS pharmacists had previously rejected.

188. Furthermore, CVS did not provide pharmacists, through RxConnect or any other mechanism, with information about prescribers' prescribing habits that CVS routinely collected and reviewed at the corporate level. Nor was there a notes field to allow pharmacists to record observations about particular prescribers that would be visible to all other CVS pharmacists. CVS intentionally did not create such a prescriber notes fields to avoid pharmacists using the information "to justify automatically refusing a prescription"—even when presented with a controlled substance prescription written by a known pill mill prescriber.

189. Thus, even after a CVS pharmacist determined that a prescriber was writing invalid prescriptions and practicing outside the ordinary course of medicine, there was no system for the

pharmacist to flag that prescriber to warn other CVS pharmacists of the pattern of invalid prescriptions or to instruct other CVS pharmacists on carefully scrutinizing or refusing to fill that prescribers' prescriptions in the future.

190. To the contrary, CVS directed individual pharmacies not to create their own lists of blocked prescribers for whom they would not fill prescriptions.

191. CVS even undid prescriber blocks that were implemented at Target pharmacies during the period before they were acquired by CVS. Before the acquisition, Target pharmacies had blocked pharmacists from filling controlled substance prescriptions from certain prescribers. When CVS acquired Target's pharmacies, CVS did not retain those blocks. As a result, former Target pharmacies were free to resume filling prescriptions for prescribers like Howard Diamond (discussed below) who had been blocked before CVS assumed control of the pharmacy.

2. CVS Refused to Implement Available Programs to Deter Filling Invalid Prescriptions

192. The corporate group at CVS headquarters responsible for supporting CVS pharmacists in complying with their corresponding responsibility ("GCR") had responsibilities that ostensibly included designing, implementing, and executing compliance programs that would address CVS's CSA compliance.

193. On multiple occasions, however, GCR piloted programs that could have improved compliance with the CSA and FCA, but CVS corporate leaders refused to implement the programs even though they were proven to be effective.

194. For example, in 2015 and 2016, GCR piloted a program to test the impact of requiring pharmacists to document whenever they refused to fill a prescription due to the exercise of their corresponding responsibility. Although the vast majority of participating pharmacists

reported that they saw value in the program, and the information would have permitted CVS to rapidly detect and block or limit prescriptions to high-risk prescribers, CVS cancelled the program.

195. Thus, rather than implement a system that would allow pharmacists not only to refuse to fill themselves, but also to identify suspicious or known pill mill prescribers to other pharmacists, CVS chose to turn a blind eye to this problem by ending the program and depriving pharmacists of valuable information.

196. Further, in or about 2016, CVS generated an algorithm to identify pharmacists of concern based upon their controlled substance dispensing patterns. However, it abandoned the project in 2017.

197. Similarly, in 2018, CVS piloted a program requiring participating pharmacists to fill out a due diligence checklist before dispensing certain high-risk opioids. The checklist required pharmacists to identify the prescription's dosage, the patient's diagnosis, and whether the pharmacist reviewed PDMP. They further required pharmacists to record all red flags, whether the prescriber was contacted, red flag resolution, and whether the prescription was filled. Use of such a checklist helped to ensure that pharmacists were complying with their legal and professional obligations to identify, resolve, and document red flags and refuse to fill prescriptions where appropriate.

198. Many CVS pharmacists in the pilot program reported that they saw the benefit of such checklists, but CVS cancelled the program and refused to implement it chainwide even though an estimate showed that implementation would cost $11 million in increased labor costs—a tiny fraction of CVS's annual revenues.

199. CVS also did not implement limitations for cash-paying patients who had insurance and thus routinely filled prescriptions for such patients without inquiry or documentation.

3. CVS's Own Compliance Programs Revealed Unlawful Dispensing, which CVS Chose Not to Rectify

200. Several of CVS's potential compliance initiatives also revealed significant unlawful dispensing at CVS pharmacies. When presented with this information, CVS, instead of rectifying the unlawful dispensing, refused to supply the resources to address it.

201. For example, in 2019, CVS added to RxConnect a module that would automatically identify high MME prescriptions and trinities. This module, called the opioid risk module, initially required a "mandatory intervention"—*i.e.*, a call from the pharmacy to the prescriber—to fill trinity cocktails or extremely high MME prescriptions. However, when the module was put into effect, the "sheer number of alerts [from the module were] overwhelming," demonstrating that enormous numbers of trinity and high MME prescriptions were presented to CVS to be filled.

202. After recognizing the number of required mandatory interventions the module was identifying, CVS, rather than requiring its pharmacists to make the calls to prescribers for trinity and high MME prescriptions, instead paused and then watered down the alert to remove the "mandatory intervention" requirement.

203. CVS put the watered-down module back online in November 2019. Once pharmacists were no longer required to contact prescribers for trinity and high MME prescriptions, an internal analysis found that they chose not to do so over 80% of the time.

204. Similarly, CVS created a program for GCR to regularly review profiles of patients with outlier opioid dispensing. However, CVS provided the program with resources to review only a small number of patients. For example, as of July 2015, the program was able to review only patients receiving 900 or greater units of an opioid on a supply of 40 days or less, meaning patients for whom CVS was dispensing more than 22 units of opioids per day. Even as of April 2018, the

program had resources to review only patients receiving prescriptions generating at least 3,000 cumulative daily MME.

205. Thus, CVS was aware of patients receiving highly dangerous amounts of opioids but, rather than refusing to fill those prescriptions, or at least supplying the resources necessary to conduct the required due diligence on those prescriptions, CVS allowed pharmacists to continue to fill these prescriptions without resolving red flags.

D. CVS Knowingly Filled Invalid Prescriptions from Known "Pill Mills"

206. CVS filled prescriptions that its pharmacists and others at CVS knew were invalid because, among other reasons, the prescribers were "pill mills" known to be routinely prescribing outside the ordinary practice of medicine.

207. Specific pharmacists at CVS knew of illegitimate prescribing by particular prescribers because they repeatedly received illegitimate prescriptions from those prescribers.

208. CVS also obtained knowledge regarding illegitimate prescribing through the operation of its Prescriber Review Program, which has existed since 2012. Through this program, GCR received information about prescribers with suspicious controlled substance prescribing from pharmacists, as well as other business units, government data, internal audits, corporate prescription data, and algorithmic analysis of that data.

209. Through the Prescriber Review Program, GCR became aware that CVS was filling prescriptions from certain pill mill prescribers who wrote invalid prescriptions. Many of these prescribers were later criminally convicted, lost their licenses, or both, and have admitted to issuing prescriptions outside the practice of medicine and not for a valid medical purpose.

210. Nonetheless, rather than cutting off these known pill mill prescribers and stopping the flow of their illegal drug distribution through CVS pharmacies, GCR frequently permitted CVS pharmacies to continue filling prescriptions for these known pill mills with the knowledge that

pharmacists would continue to fill their prescriptions. The inevitable result of CVS executives' and managers' decisions was that CVS knowingly filled a stream of invalid prescriptions.

VII. CSA AND FCA VIOLATIONS BY CVS

211. As a result of CVS's inadequate staffing, pressure on staff to fill prescriptions quickly, and failure to implement recommended actions, as described above, between October 17, 2013, and the present, CVS pharmacists knowingly filled at least thousands of unlawful prescriptions for controlled substances. CVS filled these prescriptions knowing that the controlled substance prescriptions had at least one of the unresolved red flags discussed and/or were issued by prescribers CVS knew to be engaged in pill mill practices.

212. Filling these prescriptions violated the CSA because CVS knowingly filled them despite the fact that they were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice.

213. The claims for the prescriptions also violated the FCA. The claims were false because the prescriptions were not valid, were not for a medically accepted indication, and/or were not medically necessary. Rather than comply with its legal obligations to ensure that these prescriptions were legitimate, CVS filled these prescriptions and, where the customer had insurance through a Federal Healthcare Program, sought reimbursement from the government. In doing so, CVS knowingly presented and caused the presentation of false and fraudulent claims for payment or approval to these Federal Healthcare Programs, in violation of 31 U.S.C. § 3729(a)(1).

214. For each prescription reimbursed by Medicare, CVS caused PDE data to be submitted to CMS for the listed prescription and CMS made payments in reliance on this PDE data. These prescriptions were ineligible under Federal Healthcare Programs because they were not dispensed consistent with federal law. The PDE data were false, inaccurate, and incomplete.

CVS caused the false claims to be submitted and in turn caused CMS to make payments for the drugs. Similarly, CVS submitted or caused to be submitted to TRICARE and the state Medicaid programs data that were false, inaccurate, and incomplete, and CVS caused those programs to make payments for the prescription drugs.

215. As a direct, proximate, and foreseeable result of CVS's dispensing of controlled substances pursuant to prescriptions that were not valid, were not for a medically accepted indication, and/or were not medically necessary, CVS caused such false claims to be submitted to Federal Healthcare Programs and made or caused false statements to be made that were material to such claims.

216. By submitting and causing the submission of false billings and claims to these Federal Healthcare Programs, which sought reimbursement for prescriptions and dispensing services that did not satisfy the relevant payment criteria, CVS knowingly presented and/or caused the presentation of false and fraudulent claims for payment or approval to the United States, in violation of 31 U.S.C. § 3729(a)(1)(A)-(B), examples of which are included in Attachments 1 (False Claims for Prescriptions Written by Pill Mill Prescribers) and 2 (Additional Sample False Claims), which are incorporated by reference.

A. CVS Dispensed Prescriptions Written by Pill Mill Prescribers

217. Paragraphs 218 through 317 below provide examples of prescribers that CVS knew to be engaged in pill mill practices, but for whom it nonetheless continued to fill prescriptions that were not valid, not for a medically accepted indication, were not medically necessary, and/or were written outside the ordinary practice of medicine. Many such prescriptions raised egregious red flags and were submitted to and paid for by Federal Healthcare Programs, a sample of which are identified in Attachment 1. Each of these prescriptions were filled by CVS stores that had CVS DEA registration numbers and National Provider Identifier ("NPI") numbers (unique identification

numbers assigned by CMS to healthcare providers). The reimbursements for these prescriptions were sent into an account in CVS's control. The claims for the prescriptions that were reimbursed by Federal Healthcare Programs were false because they were not valid, were not for a medically approved indication, and/or were not medically necessary.

1. Prescriber Howard Diamond: "[H]e really needs to be investigated and shut down."

218. Howard Diamond was a doctor of family medicine who ran pain management clinics in Texas. In 2016, he ranked second in the State of Texas for the number of doses of hydrocodone and seventh for the number of oxycodone doses prescribed.

219. Diamond's prescribing practices and his patients raised numerous red flags, including, among others, questionable drug combinations, excessive quantities of controlled substances, cash-paying patients, and requests for early refills.

220. CVS knew early on from an internal report both that Diamond was engaged in improper prescribing practices and that pharmacists were receiving pressure from their supervisors to fill Diamond's prescriptions. A December 17, 2014, report alerted GCR that Diamond "never answers local phone" and that pharmacy staff at one CVS reported that they were told "to stop filling for him due to MD not verifying scripts but this lasted a couple of hours and then we were told to fill[.]" The report went on: "2 other pharmacies in the area will not fill for him he really needs to be investigated and shut down[.] [M]y direct supervisor wants me to fill for him."

221. Between 2014 and July 2017, CVS pharmacists and other business units escalated Diamond to GCR for review 13 separate times—the second-most times of any prescriber in the entire country.

222. Through one escalation, GCR learned that, in November and December 2016, Diamond had written and sent to CVS six controlled substance prescriptions for someone who

died in October 2016. The six controlled substance prescriptions included all three components of the trinity. Even the store that identified that Diamond had written prescriptions for a person who had died filled an additional 156 of his controlled substance prescriptions after that point.

223. Additional escalations to GCR concerning Diamond's prescribing practices also included the following:

224. On or about March 30, 2016, Diamond was identified for review by GCR with a note that Diamond "very rarely writes for non-controls" and that other national pharmacy chains had already blocked him.

225. On or about May 10, 2016, Diamond was "identified as a high hydromorphone prescriber" to GCR by a Texas CVS store.

226. On or about April 3, 2017, Diamond was identified to GCR as having "spread a stor[y] to local media" about "how no pharmacies are filling for his patients." The escalation report noted that "[other national pharmacies] as well as several local independents have a blanket ban on him as a prescriber," and that the individual reporting this information to GCR "had previously reached out" about Diamond.

227. On or about April 21, 2017, Diamond was reported to GCR as prescribing "[v]ery high amounts of Pain Meds," with a note that "most pharmacies are not filling his prescriptions."

228. On or about May 19, 2017, GCR learned that the DEA had served a search warrant on Diamond's office.

229. On or about June 6, 2017, GCR received an ethics line complaint from a CVS pharmacist that Diamond was writing "fraudulent prescriptions." The report stated that Diamond "is notorious for writing prescriptions for controlled substances in multiple cities around [T]exas."

Further, he "has a [DEA] investigation regarding this matter, but patients are still coming to cvs locations reque[s]ting their prescriptions by him filled."

230. On or about June 30, 2017, GCR received a report from a CVS store expressing that it was seeing "too many patients" from Diamond.

231. Additionally, in the second quarter of 2017, CVS's prescriber algorithm identified Diamond for GCR as one of the ten highest-volume prescribers nationwide for hydrocodone and hydromorphone.

232. CVS pharmacists also wrote notes in patient profiles demonstrating they knew Diamond was engaged in improper prescribing. These notes were available to GCR for review. Despite these notes, pharmacists continued to fill prescriptions written by Diamond, even in some instances for the very same patients in whose profiles the notes appeared. The following chart shows examples:

Note	Date	Number of Diamond Prescriptions Filled by CVS for the Patient After Note Date	Number of Diamond Prescriptions Filled by CVS After Note Date
CAN NOT FILL OPIOID DERIVATIVES FROM DR. DIAMOND!!	8/23/2015	35	8446
ESCRIBE FROM SUSPECTED PILL MILL	4/17/2017	2	1578
DR DIAMOND OFFICE IS UNDER INVESTIGATE BY DEA OFFICE	6/1/2017	3	769
NO CONTROL FROM DR DIAMOND. UNDER FDA INVESTIGATION; NO DR DIAMOND RX	6/8/2017	3	614

233. Despite possessing this information about Diamond's conduct, CVS continued to fill prescriptions for Diamond. In fact, in June 2017, after years of receiving repeated reports of Diamond's problematic prescribing, GCR staff finally recommended that CVS block pharmacists from filling further Diamond controlled substance prescriptions based on GCR's knowledge of

Diamond's unlawful prescribing. That recommendation was escalated to a CVS medical director, who directed the company to continue to allow pharmacists to fill those prescriptions, which they did.

234. Despite these repeated escalations flagging Diamond's inappropriate prescribing practices, CVS continued to permit pharmacists to continue filling Diamond's prescriptions, until weeks after a federal grand jury indicted Diamond for CSA violations and other federal crimes.

235. On October 5, 2018, Diamond pled guilty to illegal distribution of controlled substances through invalid prescriptions, and he was ultimately sentenced to 20 years' incarceration.

2. Prescriber Robert Ritchea: "DO NOT FILL ANY RITCHEA SCRIPTS!! !!"

236. Robert Ritchea was an internal medicine doctor who operated in Phenix City, Alabama, and was well known by prescribers, pharmacists, and others in his community to write prescriptions for excessive amounts of narcotics.

237. Ritchea's own office staff reported to law enforcement that he routinely prescribed controlled substances to patients who were drug addicts or engaged in drug seeking behavior. Indeed, Ritchea treated such patients, and prescribed controlled substances to them, even when they were visibly high on drugs. Ritchea's office staff also reported that Ritchea treated patients while Ritchea himself was visibly high.

238. Ritchea's prescriptions filled at CVS bore numerous red flags of diversion, including, among others, carloads of individuals from out of state arriving simultaneously with Ritchea's prescriptions; opioid patients appearing to be young, healthy, and not in obvious pain; and prescriptions for unusually high quantities of opioids.

239. CVS was alerted to Ritchea's inappropriate prescribing no later than January 2013, when a CVS pharmacist notified GCR that Ritchea was "being investigated by the DEA, and has been shut off by nearby pharmacies for over-prescribing oxy and Percocet."

240. A June 2013 CVS ethics line escalation reviewed by GCR stated:

> Dr. Ritchea's prescriptions are no longer accepted by different insurance companies due to unethical practices. Dr. Ritchea is not a pain physician, but is writing prescriptions for pain medications in great quantities. Dr. Ritchea provides the customers with three different prescriptions and asks the customers to take each prescription to a different pharmacy. Dr. Ritchea also requests that the customers pay for the medication in cash. . . . [C]ustomers come to the store with Dr. Ritchea's prescriptions on a daily basis, several times a day.

241. In August 2013, CVS GCR employees interviewed Ritchea. In preparation for that interview, GCR became aware of an online review of Ritchea's medical practice that stated: "Dr. Ritchea is nasty! . . . He FINALLY got caught filing false medicare claims. He is a poor excuse of a Doctor. His license should be pulled. All he does is dope up the world!!!"

242. During the August 2013 interview with CVS, Ritchea admitted that he only accepted payment in cash, that "half of his patients receive cocktails," and that he saw as many as forty-five patients a day. In addition, GCR employees knew Ritchea prescribed as many as 13,000 hydrocodone tablets per month and was in the 97th and 94th percentiles chainwide for the volume of hydrocodone and oxycodone prescribed, respectively. Nonetheless, CVS took no action to stop its pharmacists from continuing to fill Ritchea's prescriptions.

243. In early 2015, government investigators interviewed several CVS pharmacists regarding Ritchea's prescribing. One pharmacist explained that their store had stopped filling Ritchea's prescriptions due to "good faith issues." The pharmacist explained that they saw as many as ten to twenty patients per week with prescriptions written by Ritchea, with the majority of Ritchea's patients presenting prescriptions for very large quantities of opioids, appearing to be

addicted to pills, and paying in cash—all significant red flags of diversion. Another pharmacist stated that Ritchea "had a reputation for writing prescriptions for excessive amounts of narcotics." GCR was aware that the pharmacy supervisor in this region was "partnering with" law enforcement on their investigation, yet other CVS pharmacies nonetheless continued to fill Ritchea's prescriptions at that time.

244. Pharmacists also wrote notes in patient profiles indicating that Ritchea was engaged in suspicious prescribing. These notes were available to GCR for review. Despite these notes, CVS pharmacists continued to fill prescriptions written by Ritchea, even in some instances for the very same patients in whose profile the notes appeared. The following chart shows examples:

Note	**Date**	**Number of Ritchea Prescriptions Filled by CVS for the Patient After Note Date**	**Number of Ritchea Prescriptions Filled by CVS After Note Date**
DR RITCHEA BEING INVESTIGATED PER CVS 1824 DO NOT FILL CONTROLS	3/20/2015	5	845
DO NOT FILL NARCS...PILL MILL	4/20/2015	3	639
DO NOT FILL ANY RITCHEA SCRIPTS!!!!!!!!!!! !! !! !!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!	8/21/2015	7	361
DO NOT FILL FOR DR ROBERT RITCHEA, CVS IN ALABAMA DO NOT FILL FOR HIM EITHER. PT PAYS CASH ONLY HAS MULTIPLE RX FOR CIIS	8/25/2015	1	343

245. Thus, despite having information that demonstrated that Ritchea was prescribing outside the ordinary course of medicine, and despite its own pharmacists' determination that Ritchea was an illegal pill mill, CVS knowingly continued to fill Ritchea's invalid and red flag prescriptions, which lacked a legitimate medical purpose and were written outside the usual course of professional practice, until his arrest for illegal drug distribution in May 2016.

246. On or about January 30, 2017, Ritchea pled guilty to conspiracy to distribute controlled substances and was sentenced to 120 months' incarceration.

3. Prescriber Raymond Kraynak: "a pill pusher, and a drunk"; "the influx of patients and prescriptions is unbelievable"

247. Raymond Kraynak was a doctor of osteopathic medicine, who operated a family medicine practice in Mount Carmel and Shamokin, Pennsylvania. In 2014, 2015, and 2016, he was the top prescriber of opioids in Pennsylvania. From January 2014 to July 31, 2017, Kraynak prescribed approximately 9.5 million units of oxycodone, hydrocodone, oxycontin, and fentanyl to his patients.

248. It was common knowledge in Mount Carmel and Shamokin that patients could easily get narcotics from Kraynak. As one former patient explained, Kraynak was the "go to" for pain pills. Some patients referred to him as "the Maniac" or the "candy man" because of the large number of controlled substance prescriptions he wrote. A police detective from Coal Township, which surrounds Shamokin, reported in mid-2015 that Kraynak had prescribed most of the narcotic pills that ended up being sold and used on the streets of the township.

249. CVS was alerted to Kraynak's inappropriate prescribing at least as early as 2014 but continued to fill his prescriptions for years before finally blocking him in 2017, well after CVS learned that DEA had raided Kraynak's office.

250. By July 2014, CVS also knew about a public internet review of Kraynak's practice that stated: "This doctor writes scripts without seeing patient. He will refill without questioning why a patient needs an addictive drug due to supposed lose [sic]."

251. CVS was repeatedly made aware that Kraynak was engaged in unlawful prescribing. Before July 2017, pharmacists and other business units escalated Kraynak to CVS GCR for review 17 times, more times than any other prescriber in the entire country.

252. Kraynak escalations to GCR included the following:

253. On or about April 28, 2014, two CVS stores separately reported a concern that Kraynak was writing a high volume of prescriptions.

254. On or about July 27, 2015, a CVS business unit noted that Kraynak's prescribing was "questionable" due to his writing of "large amounts of controls."

255. On or about November 2, 2015, that same business unit noted Kraynak was "questionable" because he "writes for high qtys of high strengths of oxycodone."

256. On or about May 31, 2016, a CVS pharmacist reported that Kraynak "is a prescriber of concern" who "often writes prescriptions for frequencies above what is recommended and only has office hours daily from 6am-9am."

257. On or about August 29, 2016, a CVS pharmacist reported that Kraynak was "under investigation by DEA" and that another chain pharmacy "made a corporate wide decision not to fill his scripts anymore."

258. In October 2016, a CVS manager reported to GCR that "at least 5" of his pharmacists had separately reached out to the manager with concerns about Kraynak, as well as reporting that another chain pharmacy had "suspended filling as a company for this prescriber." One pharmacist "had already expressed concern with this prescriber prior to the decision [by another chain pharmacy to cease filling Kraynak's prescriptions] but now the influx of patients and prescriptions is unbelievable. They have refused to fill a ton of prescriptions and what they are filling still seems excessive."

259. On or about October 7, 2016, a CVS pharmacist reported that Kraynak's patients were pharmacy shopping; that one patient lied about their insurance coverage; and that two other pharmacy chains had stopped filling Kraynak's Schedule II prescriptions.

260. On or about October 18, 2016, a CVS business unit reported "regulatory concerns" with Kraynak; that two national pharmacy chains, and a third local pharmacy were refusing to fill for him; that Kraynak was steering his patients to CVS because it would fill his prescriptions; that patients were showing up with multiple hard copies for multiple strengths of the same Schedule II controlled substances; and that the "DEA office has been to this store location."

261. On or about October 27, 2016, a CVS pharmacist reported that Kraynak "gives patients multiple hard copies and guides them to pharmacy shop"; "writes for multiple short active and long active pain reliever" at the same time; and provides "incorrect diagnostic codes." This pharmacist also reported that two national pharmacy chains and another local pharmacy had stopped filling for Kraynak, and that pharmacists were "receiving threats via social media" for refusing to fill for Kraynak.

262. On or about January 24, 2017, a CVS pharmacist reported having "concerns with the excessive amount of Narcotics, controlled substances and cocktail shares prescriptions from [Kraynak]. The prescriber writes for the same drugs, same dosage and qty and keeps patients on these drugs on a long term."

263. On or about April 28, 2017, a CVS business unit reported that Kraynak "[w]rites for large quantities, too many too much," and "higher strengths than standard practice in the area." The reporting pharmacist did "not feel these are totally valid."

264. On or about June 2, 2017, a business unit reported that Kraynak prescribed a "[l]arge amounts of pain meds" and that he had faced Pennsylvania medical board action in 2012 for prescribing "large quantities of controls for multiple patients without proper indications/documentation/drug screening."

265. CVS pharmacists also wrote notes in patient profiles indicating that Kraynak was engaged in unlawful prescribing. These notes were available to GCR for review. Despite these notes, pharmacists continued to fill Kraynak's prescriptions, even in some instances for the very same patients in whose profiles the warning notes appeared. The following chart shows examples:

Note	Date	Number of Kraynak Prescriptions Filled by CVS for the Patient After Note Date	Number of Kraynak Prescriptions Filled by CVS After Note Date
[. . .] NO KRAYNAK GOING FORWARD...	10/28/2016	6	4351
DO NOT FILL RX'S FROM DR KRAYNAK	11/28/2016	19	3870
PT WAS INFORMED WE WILL NOT BE TAKING ANYMORE KRAYNAK PRESCRIPTIONS FILLED 1/25/17 FOR LAST TIME	1/25/2017	2	2890
PT WAS INFORMED WE WILL NOT BE TAKING KRAYNAK PRESCRIPTIONS FILLED 1/25/17 FOR LAST TIME	1/25/2017	3	2890
TOLD PT THE OCODONE WAS LAST CONTROLLED SUSBTANCE RX WE ARE FILLING FROM KRAYNAK, JAN IS LAST ONTH WE ARE ACCEPTING HIS CONTROLLS, BASED ON DISCUSSIONS WITH MANAGER AND SUPERVISER	1/27/2017	3	2865
AGREED TO FILL KRAYNAK 0N 2/8 FOR THE LAST TIME	2/8/2017	2	2650
WAD TOLD WE WILL NO LONGER TAKE CONTROLS FROM DR. KRAYNAK	2/27/2017	1	2350
TOLD HIM TODAY WAS LAST WE'D FILL KRAYNAK NARC, HE NEEDS TO TALK TO FAMILY DOCTOR	3/19/2017	1	2037

266. CVS interviewed Kraynak three times regarding his prescribing habits. During all three interviews, GCR staff expressly noted the enormous volume of opioid prescriptions Kraynak was writing. Before its first interview with Kraynak in 2014, GCR noted that Kraynak was in the 100th percentile chainwide for volume for both oxycodone and hydrocodone. During a second interview, in December 2016, interviewers addressed, but did not resolve, Kraynak's high volume

score. Finally, a May 2017 CVS analysis identified Kraynak as in the 100th and 99th percentiles for volume of oxycodone and hydrocodone prescribing, respectively.

267. Moreover, before the third interview, GCR was alerted to an online review of Kraynak's practice that stated: "He is a pill pusher, and a drunk. I was able to obtain Adderall and Xanax by answering five questions. I can bet shortly he will be locked up. . . ."

268. Despite CVS's documented awareness of Kraynak's unlawful prescribing, it did not block his controlled substance prescriptions until June 2017, shortly before he was indicted.

269. In December 2017, Kraynak was indicted for, among other things, unlawful distribution and dispensing of controlled substances, including violations resulting in the death of five patients. On September 23, 2021, Kraynak pled guilty and admitted that Schedule II opioid drugs that he prescribed resulted in the deaths of five patients. He was sentenced to fifteen years' incarceration.

4. Prescriber Gurpreet Bajwa: "DON'T FILL FROM DR BAJWA"

270. Gurpreet Bajwa was a doctor of family practice who operated in Fairfax, Virginia, and prescribed enormous quantities of controlled substances. For example, between January 2017 and October 2018, Bajwa issued approximately 16,000 controlled substance prescriptions to more than 1,000 patients. These prescriptions included 120,000 dosage units of narcotics, 320,000 dosage units of stimulants, and 550,000 dosage units of sedatives to patients in Virginia alone.

271. GCR was alerted to Bajwa's inappropriate prescribing no later than April 2012, when he was identified in a CVS store review as a prescriber of concern.

272. In November 2012, the Virginia Board of Medicine suspended Bajwa's medical license after he admitted to inappropriately prescribing opioids to 13 patients. Bajwa's license was reinstated in January 2013 after he completed continuing medical education and other requirements imposed by the Board.

273. Beginning in 2016, CVS's prescriber algorithm repeatedly identified Bajwa as a high-risk prescriber of alprazolam.

274. Due to Bajwa's alprazolam prescribing and concerns with his amphetamine prescribing, GCR interviewed Bajwa in February 2017. According to interview notes, Bajwa told GCR members that the Virginia Medical Board suspended his license in 2012 because "he was seeing a pt who was doctor shopping and he wasn't as diligent." CVS had the Medical Board's suspension order and knew that Bajwa actually had been suspended for inappropriately prescribing opioids to 13 patients. Nonetheless, GCR did not stop CVS pharmacists from continuing to fill Bajwa's prescriptions.

275. CVS pharmacists also wrote notes in patient profiles indicating that Bajwa was engaged in unlawful prescribing. These notes were available to GCR for review. Despite these notes, pharmacists continued to fill prescriptions for the very same patients, and the stores at which the pharmacists writing these notes worked, as set forth below:

Note	Date	Number of Bajwa Prescriptions Filled by CVS for the Patient After Note Date	Number of Bajwa Prescriptions Filled by CVS After Note Date
DON'T FILL FROM DR BAJWA	5/22/2017	4	3407
WE WILL NOT FILL RX'S FROM DR GURPREET BAJWA ANY LONGER	8/25/2017	4	2797
NO RXS FILLED FROM DR BAJWA	9/24/2017	3	2595
NOT FILLING CONTROLS FROM DR BAJWA	10/3/2017	2	2507

276. CVS did not block Bajwa until June 2018.

277. On or about March 4, 2020, Bajwa pled guilty to six counts of unlawful distribution of controlled substances. He was sentenced to ten years' incarceration.

5. Prescriber Randall Wade: "WE WILL NOT FILL CONTROLS FROM DR WADE'S OFFICE ANYMORE"

278. Randall Wade was a family medicine doctor practicing in McKinney, Texas.

279. CVS employees were aware of Wade's unlawful prescribing no later than 2011. A CVS pharmacy technician who worked at a location that filled Wade's prescriptions beginning in 2011 reported that the pharmacy filled significant numbers of Wade's prescriptions, including many trinity prescriptions—which came to be known at that pharmacy as the "Houston cocktail."

280. Beginning in 2015, CVS's prescriber algorithm repeatedly identified Wade as a high-risk hydrocodone prescriber. Wade was twice identified as a "tier 1" prescriber—the highest risk level for unlawful prescribing. An October 2015 analysis showed that Wade was the 10th highest prescriber of hydrocodone 10 mg (the highest commercially available dosage) across the entire CVS chain. In the second quarter of 2016, it also identified him as one of the ten highest prescribers of the drug nationwide. CVS's algorithm also flagged Wade as a high-risk prescriber of alprazolam.

281. CVS at the corporate level was repeatedly made aware that Wade was engaged in unlawful prescribing. Between May 2015 and May 2016, pharmacists and other business units escalated Wade to GCR for review three times. Nonetheless, CVS continued to permit pharmacists to fill Wade's invalid prescriptions until shortly before his arrest in June 2016.

282. Those escalations included the following:

283. On or about May 18, 2015, a pharmacist reported that Wade was writing excessive numbers of prescriptions for cocktails, that competitors were not filling his prescriptions, and that Wade had been advising patients to obtain multiple refills for alprazolam and carisoprodol at the same time.

284. On or about March 30, 2016, a pharmacist reported that Wade wrote prescriptions for large quantities of alprazolam and hydrocodone, and when called to validate prescriptions, Wade would sometimes "verbally cancel" the prescription.

285. On or about May 10, 2016, Wade was "identified as a high hydromorphone prescriber out of store 6821."

286. In addition, although prior to its December 2015 acquisition by CVS, Target pharmacy had blocked Wade, CVS undid that block after the acquisition.

287. CVS pharmacists also wrote notes in patient profiles indicating that Wade was engaged in unlawful prescribing, including a March 2015 note stating, "STOP FILLING FOR HIM!" and an April 2016 note stating "TOLD THAT WE WILL NOT FILL CONTROLS FROM DR WADE'S OFFICE ANYMORE. REFUSAL TO FILL COMPLETED. X/XX/XX ERP." These notes were available to GCR for review. Despite these notes, pharmacists continued to fill prescriptions for the very same patients and at the same stores at which the pharmacists writing these notes worked.

288. In June 2015, GCR interviewed Wade regarding his prescribing practices. At that time, GCR noted the enormous volume of opioid prescriptions Wade was writing: he was in the 100th percentile chainwide for hydrocodone and in the 95th or higher percentile for several other red flag metrics tracked by GCR. Moreover, during his interview, Wade told CVS that "he won't give Soma and Norco" together, a statement contradicted by a cursory analysis of CVS's dispensing data for Wade. Despite these warning signs, GCR recommended no action after the interview.

289. CVS did not suspend Wade until June 2016, after he had reached an agreement with the Texas Medical Board to no longer prescribe chronic opioids.

290. Wade ultimately pled guilty to possession with intent to distribute controlled substances outside the usual course of professional practice and without legitimate medical purpose, and related money laundering offenses, and was sentenced to 120 months in prison.

6. Prescriber Mark Lipetz: Picked Up His Patients' Prescriptions

291. Dr. Mark Lipetz was the owner and operator of a South Maui pain management clinic located next door to CVS #4492 in Maui, Hawaii.

292. For years, Lipetz turned CVS #4492 into his own illegal dispensary, writing hundreds of illegitimate prescriptions for controlled substances that were ostensibly for his patients. However, Lipetz picked these drugs up from the CVS himself, paying for them with his own credit card, for his own improper use—including for his own personal stockpile of opioids.

293. CVS pharmacists knew that a doctor picking up controlled substances on behalf of a patient is exceedingly rare, presents an obvious risk of diversion, and should never happen on an ongoing basis. Thus, the CVS pharmacists filling these prescriptions knew this situation required heightened scrutiny and special justifications but did not obtain or document such justifications.

294. Instead, CVS #4492 catered to Lipetz's illegal prescribing by allowing him to use a special, expedited payment mechanism for "Home Delivery" prescriptions—saving his credit card and ID on file for immediate processing—even though his illegal prescription pick-ups did not involve home delivery. They even kept a special bin reserved for Lipetz's ever-accumulating prescriptions.

295. Between 2014 and 2018, CVS #4492 filled at least 217 controlled substance prescriptions for 66 different patients that were written, picked up, and paid for by Lipetz. The sheer volume of the prescriptions picked up and paid for by Lipetz, along with the types of drugs, doses, strengths, quantities, and combinations, was overwhelming evidence of diversion.

296. Pharmacists at CVS #4492 admitted to DEA that they filled these prescriptions because they were afraid to risk the substantial business the store received from Lipetz. During the relevant years, Lipetz was a star prescriber for CVS #4492. From roughly 2014 through 2018, Lipetz wrote more than 60% of the prescriptions the store filled.

297. When a part-time pharmacist refused to fill several controlled substances prescriptions that Lipetz tried to pay for and pick up for patients, the pharmacist in charge overrode the decision and filled the prescriptions, citing pressure to retain Lipetz's business.

298. The pharmacist in charge admitted that the store disregarded red flags because of the pressure from CVS corporate to keep Lipetz's significant business. From 2014 through 2018, this pharmacist in charge filled the vast majority of Lipetz's prescriptions at CVS #4492, despite this pharmacist's own knowledge of the obvious red flags of diversion.

299. CVS's corporate employees, including GCR, were also aware of Lipetz's illegitimate prescribing. As early as March 2012, a CVS pharmacy review panel recommended that Lipetz be investigated due to concerning percentages of oxycodone prescribed with another "cocktail," early fills, and very high doses of oxycodone.

300. Between 2014 and 2019, Lipetz was escalated for review by GCR six times.

301. CVS #4492 also repeatedly elicited corporate concerns. The March 2012 pharmacy review panel flagged that the store may have warranted investigation based on concerning percentages of high-risk drug prescriptions and high-dosage oxycodone prescriptions. In July 2016, CVS #4492 was again reviewed for concerning opioid dispensing practices, and the review concluded that pharmacists were failing to use PDMP and ignoring clear red flags by filling trinities.

302. On or about April 20, 2018, the pharmacist in charge of CVS #4492 was notified by a pharmacist at another CVS that a patient on whose purported behalf Lipetz had picked up multiple alprazolam prescriptions from CVS #4492 had stated that they did not take alprazolam and had never had it picked up from CVS #4492. The other pharmacist knew Lipetz's misconduct was outside the usual course of prescribing practice and needed to be stopped. This pharmacist raised the situation to the District Leader, expressing regret that CVS had allowed Lipetz's fraud to go on for years. Even then, CVS declined to take any formal action to restrict Lipetz's prescribing.

303. Moreover, when a DEA investigator visited CVS #4492 in June 2018 to ask about Lipetz, a pharmacy supervisor claimed—despite the fact that Lipetz was a leading opioid prescriber at the store—that "we rarely fill any c2 rxs" for Lipetz patients.

304. CVS continued to fill Lipetz's prescriptions until July 2019, only a few days before he pled guilty to charges that he filled and used prescriptions for purposes other than legitimate medical treatment of his patients and submitted false claims to federal healthcare payors. Lipetz was sentenced to six months' imprisonment.

7. Prescriber David Betat: the "candy man"

305. David Betat was a doctor of family medicine in Lakeport, California. Between 2014 and 2017, he wrote over 40,000 controlled substance prescriptions containing over 3.8 million dosage units. During this time period, 64% of his prescriptions were for opioids, and another 23% of his total prescriptions were for benzodiazepines.

306. Betat was such a prolific prescriber that he was known as the "candy man" among the nursing staff where he practiced. One nurse reported that people in the community knew they could get a prescription from Betat to sell if they needed money to pay rent. This nurse could not

believe the high quantities of opioids that Betat put his patients on and thought the amount of drugs being prescribed could kill a person.

307. CVS was alerted to Betat's inappropriate prescribing by at least late 2013, when a pharmacist observed that Betat "prescribe[d] a ton of methadone, dilaudid and short acting oxy" even though he was a practitioner of family medicine. During a 2014 interview, Betat acknowledged that he was "not utilizing [PDMP]" or "doing pill counts," and that his patients were "asking for oxycodone" specifically. He also told CVS that he prescribed his patients immediate release opioids because they could not afford extended-release opioids, even though those are different medications that have different approved indications. CVS did not block him following that interview.

308. Between 2013 and June 2019, Betat was escalated to GCR for review an additional six times. Despite these repeated escalations, CVS decided to keep Betat active and continued to fill his invalid controlled substance prescriptions until March 2018. Those escalations included the following:

309. On or about August 2013, a business unit reported that a store had seen a large increase in controlled substance prescribing since Betat moved in, and that the majority of his prescriptions were for controlled substances.

310. On or about June 2014, a pharmacist reported that nearly a third of Betat's prescriptions were for methadone, and that many of them were written in the same way (*i.e.*, pattern prescribing).

311. Other CVS analyses also identified Betat as a prescriber of concern. In March 2015, an analysis of high MME prescribers flagged that he had written two prescriptions for methadone with an average daily MME of 1260. In July 2015, he was listed among the top 25 oxycodone 30

mg prescribers chainwide. In June 2016, he was flagged in an analysis of stores with high numbers of patients on high MME opioids doses. In June 2017, he was flagged as a high fentanyl prescriber.

312. CVS's prescriber algorithm also repeatedly flagged Betat as a prescriber of concern. In every quarter from the fourth quarter of 2015 through the first quarter of 2017, the algorithm identified Betat as a highest risk tier prescriber of oxycodone, and in every quarter from the first quarter of 2016 through the second quarter of 2017, he was one of the ten highest prescribers for hydromorphone nationwide.

313. Pharmacists at CVS #9943 in Lakeport, California were particularly aware of Betat's illegitimate prescribing. Between January 1, 2015, and March 19, 2018, CVS #9943 alone filled 6,521 controlled substance prescriptions written by Betat—an average of over five prescriptions every single day. Of this total amount of prescriptions, 3,810 (58%) were for Schedule II narcotic analgesics.

314. During an October 2016 internal audit of CVS #9943, multiple pharmacists expressed concern about the quantity of controlled substances prescriptions Betat wrote, telling auditors that "when doctor David Betat moved back to the area [the store's controlled substance] scripts increased;" that he prescribed the majority of oxycodone and hydrocodone filled by the store; and that it was "too easy to get prescriptions" from him.

315. Furthermore, when interviewed by federal investigators, a staff pharmacist at CVS #9943 stated that Betat prescribed "crazy combinations of opioids," including high quantities and unusual drug combinations and, when contacted, provided inadequate explanations for his prescribing. Multiple pharmacists at the store also told investigators they were "uncomfortable" filling for Betat.

316. Nevertheless, CVS did not implement a chainwide block of Betat until after March 19, 2018, when CVS surrendered its DEA registration for CVS #9943. CVS surrendered the store's registration after the pharmacist-in-charge, when presented by DEA investigators with specific prescriptions exhibiting red flags, was unable to explain why he had filled them.

317. In August 2019, DEA initiated administrative proceedings to revoke Betat's DEA registration, alleging that Betat wrote controlled substance prescriptions that were not for a legitimate medical purpose and/or were not issued in the usual course of professional practice. In April 2022, the DEA administrator revoked his license.

B. CVS Filled Invalid Prescriptions for Patients Who Died by Overdose

318. CVS also knowingly filled invalid prescriptions for patients who died by overdose with the very drugs dispensed by CVS still in their systems. These prescriptions were not valid, were not for a medically accepted indication, were not medically necessary, and/or were written by prescribers CVS knew had a history of acting outside the usual course of professional practice. Furthermore, because they ignored egregious red flags of diversion, CVS pharmacists who filled these prescriptions also knew or were willfully blind to the fact that these prescriptions were not valid, were not for a medically accepted indication, were not medically necessary, and/or were outside the usual course of professional practice. Paragraphs 319-354 below set forth examples of such patients and prescriptions:

Patient #1

319. Between January and May 2018, when Patient #1 died of an overdose, CVS filled 14 controlled substance prescriptions for Patient #1, a Virginia resident.

Fill Date	Drug	Quantity	Days Supply
1/18/2018	Oxycodone Hcl 30 mg	60	15
2/01/2018	Oxycodone Hcl 30 mg	60	15
2/07/2018	Morphine sulfate ER 100 mg	30	15
2/09/2018	Alprazolam 1 mg	120	30
2/15/2018	Oxycodone Hcl 30 mg	60	15
2/21/2018	Morphine sulfate ER 100 mg	30	15
3/01/2018	Oxycodone Hcl 30 mg	120	30
3/10/2018	Alprazolam 1 mg	120	30
3/26/2018	Oxycodone Hcl 30 mg	120	30
4/02/2018	Morphine sulfate ER 100 mg	60	30
4/09/2018	Alprazolam 1 mg	120	30
4/11/2018	Pregabalin 150 mg	20	5
4/25/2018	Oxycodone Hcl 30 mg	120	30
5/01/2018	Morphine sulfate ER 100 mg	60	30

320. Ten of these prescriptions were opioid prescriptions written by Dr. Verna Lewis, a prescriber who, in 2020, pled guilty to writing these ten opioid prescriptions (among others) outside the usual course of professional practice and without legitimate medical purpose in violation of the CSA. She was sentenced to 36 months' incarceration.

321. CVS had been repeatedly alerted to Lewis's inappropriate prescribing prior to Patient #1's overdose death. Multiple CVS pharmacists escalated concerns that Lewis wrote high quantity, high dose opioid prescriptions. Patients also traveled extremely long distances to visit Lewis. Further, CVS's data showed that, as of March 2015, Lewis was in the 99th percentile chainwide for oxycodone prescribing. CVS's prescriber algorithm also flagged Lewis as a high-risk hydromorphone prescriber in three consecutive quarters in 2016.

322. The prescriptions CVS filled for Patient #1 also bore egregious and obvious red flags of diversion. CVS simultaneously dispensed to Patient #1 two potent opioids that together

generated a cumulative daily MME of approximately 380. CVS filled many of Patient #1's controlled substance prescriptions one or more days early, and these repeated early fills generated an excess supply for Patient #1 of 32 oxycodone tablets and 12 morphine sulfate tablets in just four months.

323. Patient #1 also was evidently engaged in doctor shopping: at the same time CVS dispensed these powerful opioids from Lewis, CVS also dispensed to Patient #1 three high quantity alprazolam prescriptions and one pregabalin prescription written by different prescribers. PDMP also revealed that on March 7, 2018, Patient #1 filled an opioid prescription, also written by Lewis, at a non-CVS pharmacy.

324. At the time CVS dispensed the January 18, 2018, oxycodone prescription, it had not dispensed an opioid prescription to Patient #1 in nearly nine months, and Patient #1's PDMP revealed that they had not received any opioid prescriptions from any other pharmacy in Virginia during that timeframe. Because PDMP showed that Patient #1 had not received any opioid prescriptions for a significant length of time, the evidence available to the pharmacist indicated that Patient #1 was clinically opioid-naïve. It is extremely dangerous for an opioid-naïve patient to receive such a high dose of oxycodone—the package insert for oxycodone itself warns that "total daily doses greater than 80 mg [] may cause fatal respiratory depression when administered" to opioid-naïve patients. The January 18, 2018, prescription cumulatively provided for a daily dose of 120 mg of oxycodone. Such a high dose prescribed to an opioid naïve patient was an egregious red flag of illegitimacy, yet CVS filled it.

325. No pharmacist notes in CVS's dispensing system reflect that the dispensing pharmacists resolved any of these egregious red flags.

326. On May 5, 2018, only four days after filling an invalid morphine sulfate prescription at CVS, Patient #1 died of a mixed drug overdose including morphine toxicity.

Patient #2

327. Between December 5, 2017, and March 18, 2018, Patient #2, a Virginia resident, obtained the following prescriptions, despite the presence of obvious red flags. Each of these prescriptions was written by Gurpreet Bajwa, whom, as set forth above, CVS knew was not engaged in legitimate medical practice.

Pharmacy	Fill Date	Drug	Quantity	Days Supply
CVS	**12/5/2017**	**Alprazolam 2 mg**	**30**	**30**
CVS	**1/5/2018**	**Alprazolam 2 mg**	**60**	**30**
Other	1/15/2018	Alprazolam 2mg	46	23
Other	1/15/2018	Oxycodone Hcl 10 mg	14	7
Other	2/5/2018	Alprazolam 2 mg	60	30
Other	2/5/2018	Oxycodone HcL 30 mg	20	10
Other	2/19/2018	Oxycodone Hcl 30 mg	14	7
CVS	**2/20/2018**	**Alprazolam 2 mg**	**90**	**30**
Other	3/17/2018	Alprazolam 2 mg	90	30
Other	3/17/2018	Oxycodone Hcl 30 mg	14	7
CVS	**3/18/2018**	**Alprazolam 2 mg**	**21**	**7**

328. Each of the four prescriptions dispensed by CVS was for alprazolam 2 mg, the highest commercially available dose. The dosage increased from one tablet per day to three per day in only two months. This rapid titration is a serious red flag. Further, Patient #2 paid for one of the prescriptions with cash, even though the others were funded by insurance—another red flag.

329. Review of Patient #2's PDMP reveals additional serious red flags. Patient #2 was pharmacy shopping—between January and March 2018, Patient #2 also filled seven controlled substance prescriptions at a non-CVS pharmacy. Moreover, the prescriptions Patient #2 filled at

this other pharmacy—also written by Bajwa—included (i) high MME oxycodone prescriptions that create a risk of death when combined with high doses of alprazolam and (ii) more alprazolam.

330. Patient #2's repeated filling of alprazolam at CVS and the other pharmacy resulted in five early fills—including fills that were 21, 20, and 16 days early—and together generated an excess supply of 166 tablets in three months, another serious red flag.

331. No pharmacist notes in CVS's dispensing system reflect a resolution of any of these red flags.

332. Patient #2 died of a mixed drug overdose including alprazolam on March 28, 2018, only 10 days after CVS filled an alprazolam prescription for Patient #2.

Patient #3

333. Between in or about January 2015 and June 2018, CVS pharmacists filled 77 controlled substance prescriptions, including 52 opioid prescriptions, for Patient #3, a Virginia resident, despite the presence of numerous red flags, including but not limited to:

a. Overlapping oxycodone and fentanyl prescriptions exceeding 170 combined daily MMEs;

b. Numerous prescriptions paid in cash even though the patient was covered by insurance;

c. Early fills; and

d. A patient profile note in RxConnect that included a warning to "WATCH OUT FOR CV-C2," an apparent reference to controlled substances.

334. No pharmacist notes adequately justify this highly suspicious course of therapy.

335. Twice during this patient's last year of life, CVS filled high MME opioid prescriptions shortly after filling prescriptions for suboxone, a drug whose purpose is to treat opioid addiction:

a. On February 13, 2018, after filling suboxone prescriptions for Patient #3 for nearly two months, and only four days after filling a suboxone prescription, CVS filled prescriptions for ten 25 mcg/hr fentanyl patches to serve as a 30-day supply, and 75 oxycodone 15 mg tablets to serve as a 15-day supply, for a combined daily cumulative MME of 195.

b. On May 8, 2018, after filling suboxone and buprenorphine prescriptions for two months, and only five days after filling a buprenorphine-naloxone prescription, CVS filled an oxycodone-acetaminophen prescription for Patient #3. The oxycodone-acetaminophen prescription was written by a different prescriber than the buprenorphine-naloxone prescription.

336. Dispensing high-dose opioids to a patient actively being treated for opioid use disorder places the patient at high risk. No pharmacist notes reflect any attempt to resolve these red flags, and there was no legitimate medical basis for these prescriptions.

337. Patient #3 died of a mixed drug overdose, including oxycodone and fentanyl, on June 10, 2018—three days after CVS filled their prescription for oxycodone-acetaminophen.

Patient #4

338. Between January 2015 and March 2019, CVS filled 171 controlled substance prescriptions for Patient #4, a Virginia resident, despite the presence of serious red flags.

339. CVS pharmacists knew that Patient #4's prescriptions exhibited signs of diversion. On April 25, 2015, a CVS pharmacist wrote that Patient #4 had filed a police report for stolen medications. An August 24, 2015, a CVS pharmacist note warned other pharmacists: "DO NOT FILL ANY CONTROLS EARLY FOR PT!! HAS CALLED 3 MONTHS IN A ROW CLAIMING SOMEONE HAS STOLEN MED/ HAS POLICE RPT."

340. On April 4, 2016, a CVS pharmacist wrote on Patient #4's profile: "DO NOT FILL ANY C2S FROM THIS PATIENT." Other CVS pharmacists nonetheless filled 27 Schedule II prescriptions for Patient #4 after the date of this note.

341. Between March 2018 and March 2019, CVS filled 14 benzodiazepine prescriptions, 12 stimulant prescriptions, and 15 opioid prescriptions for Patient #4. This combination of drugs, known as the "stimulant trinity," raises egregious red flags. Moreover, Patient #4 received these stimulant trinity components from numerous different prescribers. CVS also filled 11 prescriptions for gabapentin, which raised additional concerns regarding the course of therapy. There are no pharmacist notes in CVS's system documenting the resolution of any of these red flags.

342. In the weeks prior to Patient #4's death, between February 19 and March 11, 2019, CVS dispensed the following prescriptions to Patient #4:

Fill Date	Drug	Quantity	Days Supply	Prescriber
2/19/2019	Phentermine 37.5 mg	30	30	J.F.
3/3/2019	Zolpidem tartrate 10 mg	30	30	S.R.
3/5/2019	Dextroamphetamine-amphetamine salts 25 mg	30	30	S.R.
3/7/2019	Tramadol Hcl 50 mg	90	30	J.F.
3/11/2019	Alprazolam 1 mg	60	30	S.R.

343. These five prescriptions presented egregious red flags, including but not limited to: dispensing of the stimulant trinity; duplicate stimulant therapies (phentermine and amphetamine salts); doctor shopping (multiple prescriptions written by two separate prescribers, including different prescribers for the two stimulants); and cash payments made by an insured patient (for the phentermine and tramadol).

344. No pharmacist notes in CVS's dispensing system reflect a resolution of any of these red flags.

345. On March 16, 2019, Patient #4 died after overdosing on a combination of intoxicants including alprazolam and amphetamines, just five days after CVS filled an alprazolam prescription, and 11 days after CVS filled an amphetamine salts prescription.

Patient #5

346. Between December 23, 2016, and January 19, 2017, Patient #5, a Florida resident, obtained the following prescriptions:

Pharmacy	Fill Date	Drug	Quantity	Days Supply
Other	12/22/2016	Oxycodone Hcl 30 mg	120	30
Other	12/23/2016	Fentanyl 75 mcg/hr	10	30
CVS	**1/19/2017**	**Fentanyl 75 mcg/hr**	**10**	**30**
CVS	**1/19/2017**	**Oxycodone Hcl 30 mg**	**120**	**30**

347. The January 19, 2017, prescriptions filled by CVS raised egregious red flags of diversion. Patient #5 filled identical prescriptions at a different pharmacy only weeks earlier. CVS then dispensed the January 19, 2017, oxycodone prescription two days early and the fentanyl prescription three days early. These prescriptions generated a cumulative daily MME of 720 until Patient #5 ran out of doses from the December 2016 fills.

348. No notes in CVS's dispensing system reflect resolution of these red flags.

349. On January 20, 2017, a day after filling fentanyl and oxycodone prescriptions at CVS, Patient #5 died of a mixed drug overdose including fentanyl.

Patient #6

350. Between February 2015 and October 2016, CVS filled 82 controlled substance prescriptions for Patient #6, a Texas resident. The prescriptions were written by Howard Diamond, whom, as set forth above, CVS knew was not prescribing in the legitimate practice of medicine.

351. These 82 prescriptions consisted of 45 opioid prescriptions, 24 benzodiazepine prescriptions, and 13 carisoprodol prescriptions and bore egregious red flags of diversion. CVS repeatedly filled prescriptions for these trinity drugs, with overlapping supply so that Patient #6 could take all three drugs simultaneously. CVS also repeatedly filled prescriptions for multiple powerful opioids on the same day, generating MMEs up to or greater than 150. CVS also filled 15

prescriptions for gabapentin, which raised additional concerns regarding the legitimacy of Patient #6's therapy.

352. Between October 2 and 27, 2016, CVS filled the following prescriptions for Patient #6, which together constituted the trinity:

Fill Date	Drug	Quantity	Days Supply
10/2/2016	Hydrocodone-Acetaminophen 10-325	150	30
10/14/2016	Morphine Sulfate ER 60 mg	90	30
10/25/2016	Alprazolam 0.25 mg	90	30
10/27/2016	Carisoprodol 350 mg	30	30
10/27/2016	Temazepam 30 mg	30	30

353. No pharmacist notes in CVS's dispensing system reflect resolution of these red flags.

354. On November 4, 2016, only days after filling carisoprodol and benzodiazepine prescriptions at CVS, and weeks after filling opioid prescriptions at CVS, Patient #6 was found dead. Patient #6's toxicology screen was positive for morphine and carisoprodol, among other substances.

C. CVS Submitted False Claims for Invalid Prescriptions to Federal Healthcare Programs

355. CVS also violated the CSA and FCA by knowingly filling at least thousands of controlled substance prescriptions bearing egregious red flags of diversion and that were not valid, were not for a medically accepted indication, or were not medically necessary.

356. Examples of unlawful prescriptions that were dispensed by CVS and billed to Federal Healthcare Programs include:

Patient #7

357. On October 22, 2020, CVS filled four prescriptions for Patient #7 for (1) 150 tablets of OxyContin 40 mg; (2) 120 tablets of oxycodone/apap 10/325 mg; (3) 90 tablets of carisoprodol

350 mg; and (4) 90 tablets of diazepam 10 mg. CVS filled these prescriptions, the combination of which constituted the trinity cocktail, and submitted claims to Medicare for reimbursement.

358. Between October 22, 2020, and at least June 15, 2022, CVS filled trinity cocktail prescriptions on the same day on at least 14 occasions:

Fill Date	Drug	Quantity	Days Supply
10/22/2020	Oxycontin Tab 40mg ER	150	30
10/22/2020	Oxycod/Apap Tab 10-325mg	120	30
10/22/2020	Carisoprodol Tab 350mg	90	30
10/22/2020	Diazepam Tab 10mg	90	30
11/20/2020	Diazepam Tab 10mg	90	30
11/20/2020	Carisoprodol Tab 350mg	90	30
11/20/2020	Oxycontin Tab 40mg ER	150	30
11/20/2020	Oxycod/Apap Tab 10-325mg	120	30
1/19/2021	Carisoprodol Tab 350mg	90	30
1/19/2021	Oxycod/Apap Tab 10-325mg	120	30
1/19/2021	Diazepam Tab 10mg	90	30
1/19/2021	Oxycontin Tab 40mg ER	150	30
3/20/2021	Carisoprodol Tab 350mg	90	30
3/20/2021	Oxycod/Apap Tab 10-325mg	120	30
3/20/2021	Diazepam Tab 10mg	90	30
3/20/2021	Oxycontin Tab 40mg ER	150	30
4/19/2021	Oxycod/Apap Tab 10-325mg	120	30
4/19/2021	Carisoprodol Tab 350mg	90	30
4/19/2021	Oxycontin Tab 40mg ER	150	30
4/19/2021	Diazepam Tab 10mg	90	30
6/18/2021	Diazepam Tab 10mg	90	30
6/18/2021	Oxycod/Apap Tab 10-325mg	120	30
6/18/2021	Oxycontin Tab 40mg ER	150	30
6/18/2021	Carisoprodol Tab 350mg	90	30
8/17/2021	Oxycod/Apap Tab 10-325mg	120	30
8/17/2021	Carisoprodol Tab 350mg	90	30
8/17/2021	Diazepam Tab 10mg	90	30
8/17/2021	Oxycontin Tab 40mg ER	150	30
9/16/2021	Oxycod/Apap Tab 10-325mg	120	30
9/16/2021	Oxycontin Tab 40mg ER	150	30
9/16/2021	Carisoprodol Tab 350mg	90	30
9/16/2021	Diazepam Tab 10mg	90	30
10/16/2021	Oxycontin Tab 40mg ER	150	30
10/16/2021	Oxycod/Apap Tab 10-325mg	120	30
10/16/2021	Diazepam Tab 10mg	90	30
10/16/2021	Carisoprodol Tab 350mg	90	30

11/15/2021	Oxycontin Tab 40mg ER	150	30
11/15/2021	Diazepam Tab 10mg	90	30
11/15/2021	Carisoprodol Tab 350mg	90	30
11/15/2021	Oxycod/Apap Tab 10-325mg	120	30
12/14/2021	Diazepam Tab 10mg	90	30
12/14/2021	Oxycod/Apap Tab 10-325mg	120	30
12/14/2021	Carisoprodol Tab 350mg	90	30
1/13/2022	Oxycod/Apap Tab 10-325mg	120	30
1/13/2022	Oxycontin Tab 40mg ER	150	30
1/13/2022	Diazepam Tab 10mg	90	30
1/13/2022	Carisoprodol Tab 350mg	90	30
2/14/2022	Diazepam Tab 10mg	90	30
2/14/2022	Oxycontin Tab 40mg ER	150	30
2/14/2022	Carisoprodol Tab 350mg	90	30
2/14/2022	Oxycod/Apap Tab 10-325mg	120	30
6/15/2022	Diazepam Tab 10mg	90	30
6/15/2022	Carisoprodol Tab 350mg	90	30
6/15/2022	Oxycontin Tab 40mg ER	150	30
10/16/2021	Carisoprodol Tab 350mg	90	30
11/15/2021	Oxycontin Tab 40mg ER	150	30
11/15/2021	Diazepam Tab 10mg	90	30
11/15/2021	Carisoprodol Tab 350mg	90	30
11/15/2021	Oxycod/Apap Tab 10-325mg	120	30
12/14/2021	Diazepam Tab 10mg	90	30
12/14/2021	Oxycod/Apap Tab 10-325mg	120	30
12/14/2021	Carisoprodol Tab 350mg	90	30
1/13/2022	Oxycod/Apap Tab 10-325mg	120	30
1/13/2022	Oxycontin Tab 40mg ER	150	30
1/13/2022	Diazepam Tab 10mg	90	30

359. Each of these prescriptions were filled by CVS stores that had CVS DEA registration numbers and NPI numbers. The reimbursements for these prescriptions were sent into an account in CVS's control. The claims for the prescriptions that were reimbursed by Federal Healthcare Programs were false because the prescriptions were not valid, were not for a medically accepted indication, and/or were not medically necessary.

Patient #8

360. On February 20, 2017, CVS filled three prescriptions for Patient #8 for (1) 120 tablets of oxycodone/apap 10/325 mg; (2) 120 tablets of carisoprodol 350 mg; and (3) 120 tablets

of diazepam 10 mg. CVS filled these prescriptions, the combination of which constituted the trinity cocktail, and submitted claims to Medicare for reimbursement.

361. Between February 20, 2017, and at least June 15, 2022, CVS filled trinity cocktail prescriptions on the same day on at least 53 occasions:

Fill Date	Drug	Quantity	Days Supply
2/20/2017	Oxycod/Apap Tab 10-325mg	120	30
2/20/2017	Carisoprodol Tab 350mg	120	30
2/20/2017	Diazepam Tab 10mg	120	30
3/20/2017	Carisoprodol Tab 350mg	120	30
3/20/2017	Oxycod/Apap Tab 10-325mg	120	30
3/20/2017	Diazepam Tab 10mg	120	30
4/18/2017	Carisoprodol Tab 350mg	120	30
4/18/2017	Diazepam Tab 10mg	120	30
4/18/2017	Oxycod/Apap Tab 10-325mg	120	30
5/17/2017	Diazepam Tab 10mg	120	30
5/17/2017	Oxycod/Apap Tab 10-325mg	120	30
5/17/2017	Carisoprodol Tab 350mg	120	30
6/17/2017	Carisoprodol Tab 350mg	120	30
6/17/2017	Oxycod/Apap Tab 10-325mg	120	30
6/17/2017	Diazepam Tab 10mg	120	30
7/14/2017	Oxycod/Apap Tab 10-325mg	120	30
7/14/2017	Carisoprodol Tab 350mg	120	30
7/14/2017	Diazepam Tab 10mg	120	30
9/13/2017	Carisoprodol Tab 350mg	120	30
9/13/2017	Oxycod/Apap Tab 10-325mg	120	30
9/13/2017	Diazepam Tab 10mg	120	30
10/11/2017	Oxycod/Apap Tab 10-325mg	120	30
10/11/2017	Diazepam Tab 10mg	120	30
10/11/2017	Carisoprodol Tab 350mg	120	30
11/11/2017	Diazepam Tab 10mg	120	30
11/11/2017	Carisoprodol Tab 350mg	120	30
11/11/2017	Oxycod/Apap Tab 10-325mg	120	30
2/8/2018	Diazepam Tab 10mg	120	30
2/8/2018	Carisoprodol Tab 350mg	120	30
2/8/2018	Oxycod/Apap Tab 10-325mg	120	30
3/8/2018	Carisoprodol Tab 350mg	120	30
3/8/2018	Diazepam Tab 10mg	120	30
3/8/2018	Oxycod/Apap Tab 10-325mg	120	30
4/7/2018	Diazepam Tab 10mg	120	30
4/7/2018	Carisoprodol Tab 350mg	120	30
4/7/2018	Oxycod/Apap Tab 10-325mg	120	30

5/7/2018	Diazepam Tab 10mg	120	30
5/7/2018	Carisoprodol Tab 350mg	120	30
5/7/2018	Oxycod/Apap Tab 10-325mg	120	30
6/5/2018	Diazepam Tab 10mg	120	30
6/5/2018	Carisoprodol Tab 350mg	120	30
6/5/2018	Oxycod/Apap Tab 10-325mg	120	30
8/3/2018	Diazepam Tab 10mg	120	30
8/3/2018	Oxycod/Apap Tab 10-325mg	120	30
8/3/2018	Carisoprodol Tab 350mg	120	30
10/3/2018	Carisoprodol Tab 350mg	120	30
10/3/2018	Oxycod/Apap Tab 10-325mg	120	30
10/3/2018	Diazepam Tab 10mg	120	30
11/2/2018	Carisoprodol Tab 350mg	120	30
11/2/2018	Oxycod/Apap Tab 10-325mg	120	30
11/2/2018	Diazepam Tab 10mg	120	30
12/2/2018	Oxycod/Apap Tab 10-325mg	120	30
12/2/2018	Diazepam Tab 10mg	120	30
12/2/2018	Carisoprodol Tab 350mg	120	30
1/1/2019	Diazepam Tab 10mg	120	30
1/1/2019	Carisoprodol Tab 350mg	120	30
1/1/2019	Oxycod/Apap Tab 10-325mg	120	30
1/31/2019	Carisoprodol Tab 350mg	120	30
1/31/2019	Oxycod/Apap Tab 10-325mg	120	30
1/31/2019	Diazepam Tab 10mg	120	30
3/2/2019	Carisoprodol Tab 350mg	120	30
3/2/2019	Diazepam Tab 10mg	120	30
3/2/2019	Oxycod/Apap Tab 10-325mg	120	30
4/1/2019	Oxycod/Apap Tab 10-325mg	120	30
4/1/2019	Diazepam Tab 10mg	120	30
4/1/2019	Carisoprodol Tab 350mg	120	30
5/31/2019	Oxycod/Apap Tab 10-325mg	120	30
5/31/2019	Diazepam Tab 10mg	120	30
5/31/2019	Carisoprodol Tab 350mg	120	30
7/1/2019	Carisoprodol Tab 350mg	120	30
7/1/2019	Diazepam Tab 10mg	120	30
7/1/2019	Oxycod/Apap Tab 10-325mg	120	30
7/30/2019	Diazepam Tab 10mg	120	30
7/30/2019	Carisoprodol Tab 350mg	120	30
7/30/2019	Oxycod/Apap Tab 10-325mg	120	30
10/28/2019	Diazepam Tab 10mg	120	30
10/28/2019	Oxycod/Apap Tab 10-325mg	120	30
10/28/2019	Carisoprodol Tab 350mg	120	30
11/27/2019	Oxycod/Apap Tab 10-325mg	120	30
11/27/2019	Diazepam Tab 10mg	120	30
11/27/2019	Carisoprodol Tab 350mg	120	30

12/27/2019	Diazepam Tab 10mg	120	30
12/27/2019	Oxycod/Apap Tab 10-325mg	120	30
12/27/2019	Carisoprodol Tab 350mg	120	30
1/26/2020	Oxycod/Apap Tab 10-325mg	120	30
1/26/2020	Carisoprodol Tab 350mg	120	30
1/26/2020	Diazepam Tab 10mg	120	30
2/25/2020	Diazepam Tab 10mg	60	30
2/25/2020	Carisoprodol Tab 350mg	120	30
2/25/2020	Oxycod/Apap Tab 10-325mg	120	30
3/24/2020	Carisoprodol Tab 350mg	120	30
3/24/2020	Diazepam Tab 10mg	120	30
3/24/2020	Oxycod/Apap Tab 10-325mg	120	30
4/22/2020	Carisoprodol Tab 350mg	120	30
4/22/2020	Oxycod/Apap Tab 10-325mg	120	30
4/22/2020	Diazepam Tab 10mg	120	30
5/22/2020	Oxycod/Apap Tab 10-325mg	104	26
5/22/2020	Carisoprodol Tab 350mg	104	26
5/22/2020	Diazepam Tab 10mg	104	26
6/16/2020	Diazepam Tab 10mg	60	15
6/16/2020	Carisoprodol Tab 350mg	60	15
6/16/2020	Oxycod/Apap Tab 10-325mg	60	15
7/1/2020	Carisoprodol Tab 350mg	120	30
7/1/2020	Diazepam Tab 10mg	120	30
7/1/2020	Oxycod/Apap Tab 10-325mg	120	30
8/30/2020	Oxycod/Apap Tab 10-325mg	120	30
8/30/2020	Carisoprodol Tab 350mg	120	30
8/30/2020	Diazepam Tab 10mg	120	30
9/29/2020	Oxycod/Apap Tab 10-325mg	120	30
9/29/2020	Diazepam Tab 10mg	120	30
9/29/2020	Carisoprodol Tab 350mg	120	30
1/28/2021	Oxycod/Apap Tab 10-325mg	120	30
1/28/2021	Diazepam Tab 10mg	120	30
1/28/2021	Carisoprodol Tab 350mg	120	30
3/29/2021	Oxycod/Apap Tab 10-325mg	120	30
3/29/2021	Carisoprodol Tab 350mg	120	30
3/29/2021	Diazepam Tab 10mg	120	30
4/28/2021	Diazepam Tab 10mg	120	30
4/28/2021	Oxycod/Apap Tab 10-325mg	120	30
4/28/2021	Carisoprodol Tab 350mg	120	30
9/27/2021	Diazepam Tab 10mg	120	30
9/27/2021	Carisoprodol Tab 350mg	120	30
9/27/2021	Oxycod/Apap Tab 10-325mg	120	30
10/27/2021	Carisoprodol Tab 350mg	120	30
10/27/2021	Oxycod/Apap Tab 10-325mg	120	30
10/27/2021	Diazepam Tab 10mg	120	30

11/27/2021	Oxycod/Apap Tab 10-325mg	120	30
11/27/2021	Carisoprodol Tab 350mg	120	30
11/27/2021	Diazepam Tab 10mg	120	30
12/27/2021	Oxycod/Apap Tab 10-325mg	120	30
12/27/2021	Carisoprodol Tab 350mg	120	30
12/27/2021	Diazepam Tab 10mg	120	30
1/26/2022	Diazepam Tab 10mg	120	30
1/26/2022	Carisoprodol Tab 350mg	120	30
1/26/2022	Oxycod/Apap Tab 10-325mg	120	30
2/25/2022	Oxycod/Apap Tab 10-325mg	120	30
2/25/2022	Carisoprodol Tab 350mg	120	30
2/25/2022	Diazepam Tab 10mg	120	30
3/27/2022	Diazepam Tab 10mg	120	30
3/27/2022	Oxycod/Apap Tab 10-325mg	120	30
3/27/2022	Carisoprodol Tab 350mg	120	30
9/24/2022	Carisoprodol Tab 350mg	120	30
9/24/2022	Diazepam Tab 10mg	120	30
9/24/2022	Oxycod/Apap Tab 10-325mg	120	30
10/24/2022	Oxycod/Apap Tab 10-325mg	120	30
10/24/2022	Carisoprodol Tab 350mg	120	30
10/24/2022	Diazepam Tab 10mg	120	30
11/23/2022	Oxycod/Apap Tab 10-325mg	120	30
11/23/2022	Diazepam Tab 10mg	120	30
11/23/2022	Carisoprodol Tab 350mg	120	30
12/23/2022	Oxycod/Apap Tab 10-325mg	120	30
12/23/2022	Diazepam Tab 10mg	120	30
12/23/2022	Carisoprodol Tab 350mg	120	30
1/22/2023	Oxycod/Apap Tab 10-325mg	120	30
1/22/2023	Carisoprodol Tab 350mg	120	30
1/22/2023	Diazepam Tab 10mg	120	30
2/21/2023	Diazepam Tab 10mg	120	30
2/21/2023	Oxycod/Apap Tab 10-325mg	120	30
2/21/2023	Carisoprodol Tab 350mg	120	30
3/23/2023	Carisoprodol Tab 350mg	120	30
3/23/2023	Oxycod/Apap Tab 10-325mg	120	30
3/23/2023	Diazepam Tab 10mg	120	30

362. Each of these prescriptions were filled by CVS stores that had CVS DEA registration numbers and NPI numbers. The reimbursements for these prescriptions were sent into an account in CVS's control. The claims for the prescriptions that were reimbursed by Federal

Healthcare Programs were false because the prescriptions were not valid, were not for a medically accepted indication, and/or were not medically necessary.

Patient #9

363. On November 3, 2015, CVS filled a 30-day prescription for Patient #9 for 120 tablets of OxyContin 60 mg, equating to a daily MME of 360. On November 16, 2015, CVS filled a 30-day prescription for Patient #9 for 120 tablets of OxyContin 80 mg, increasing the daily MME by 480 to a combined daily MME of 840. CVS filled these prescriptions and submitted claims to Medicare for reimbursement.

364. Between November 3, 2015, and at least May 19, 2017, CVS continued to fill these two high MME prescriptions at least 38 times:

Fill Date	Drug	Quantity	Days Supply
11/3/2015	Oxycontin Tab 60mg ER	120	30
11/16/2015	Oxycontin Tab 80mg ER	120	30
11/30/2015	Oxycontin Tab 60mg ER	120	30
12/13/2015	Oxycontin Tab 80mg ER	120	30
12/28/2015	Oxycontin Tab 60mg ER	120	30
1/26/2016	Oxycontin Tab 60mg ER	120	30
2/4/2016	Oxycontin Tab 80mg ER	120	30
2/23/2016	Oxycontin Tab 60mg ER	120	20
3/21/2016	Oxycontin Tab 80mg ER	120	30
3/21/2016	Oxycontin Tab 60mg ER	120	30
4/18/2016	Oxycontin Tab 80mg ER	120	30
4/18/2016	Oxycontin Tab 60mg ER	120	30
5/16/2016	Oxycontin Tab 80mg ER	120	30
5/16/2016	Oxycontin Tab 60mg ER	120	30
6/13/2016	Oxycontin Tab 80mg ER	120	30
6/13/2016	Oxycontin Tab 60mg ER	120	30
7/11/2016	Oxycontin Tab 80mg ER	120	30
7/11/2016	Oxycontin Tab 60mg ER	120	30
8/8/2016	Oxycontin Tab 60mg ER	120	30
8/8/2016	Oxycontin Tab 80mg ER	120	30
10/3/2016	Oxycontin Tab 80mg ER	120	30
10/3/2016	Oxycontin Tab 60mg ER	120	30

10/31/2016	Oxycontin Tab 80mg ER	120	30
10/31/2016	Oxycontin Tab 60mg ER	120	30
11/28/2016	Oxycontin Tab 80mg ER	120	30
11/28/2016	Oxycontin Tab 60mg ER	120	30
12/23/2016	Oxycontin Tab 80mg ER	120	30
12/23/2016	Oxycontin Tab 60mg ER	120	30
1/23/2017	Oxycontin Tab 60mg ER	120	30
1/30/2017	Oxycontin Tab 80mg ER	120	30
2/20/2017	Oxycontin Tab 60mg ER	120	30
2/26/2017	Oxycontin Tab 80mg ER	120	30
3/20/2017	Oxycontin Tab 60mg ER	120	30
3/25/2017	Oxycontin Tab 80mg ER	120	30
4/18/2017	Oxycontin Tab 60mg ER	120	30
4/22/2017	Oxycontin Tab 80mg ER	120	30
5/15/2017	Oxycontin Tab 60mg ER	120	30
5/19/2017	Oxycontin Tab 80mg ER	120	30

365. Each of these prescriptions were filled by CVS stores that had CVS DEA registration numbers and NPI numbers. The reimbursements for these prescriptions were sent into an account in CVS's control. The claims for the prescriptions that were reimbursed by Federal Healthcare Programs were false because the prescriptions were not valid, were not for a medically accepted indication, and/or were not medically necessary.

Patient #10

366. On November 1, 2013, CVS filled a 30-day prescription for Patient #10 for 90 tablets of morphine sulfate 100 mg, equating to a daily MME of 300. CVS filled this prescription and submitted a claim to Medicaid for reimbursement.

367. Between November 1, 2013, and at least March 1, 2016, CVS continued to fill this high MME prescriptions at least 26 times:

Fill Date	Drug	Quantity	Days Supply
11/1/2013	Morphine Sul Tab 100mg ER	90	30
11/25/2013	Morphine Sul Tab 100mg ER	90	30
12/18/2013	Morphine Sul Tab 100mg ER	90	30
3/4/2014	Morphine Sul Tab 100mg ER	90	30
4/1/2014	Morphine Sul Tab 100mg ER	90	30
4/29/2014	Morphine Sul Tab 100mg ER	90	30
5/30/2014	Morphine Sul Tab 100mg ER	90	30
6/27/2014	Morphine Sul Tab 100mg ER	90	30
7/24/2014	Morphine Sul Tab 100mg ER	90	30
8/21/2014	Morphine Sul Tab 100mg ER	90	30
9/18/2014	Morphine Sul Tab 100mg ER	90	30
10/15/2014	Morphine Sul Tab 100mg ER	90	30
12/10/2014	Morphine Sul Tab 100mg ER	90	30
1/7/2015	Morphine Sul Tab 100mg ER	90	30
2/3/2015	Morphine Sul Tab 100mg ER	90	30
3/2/2015	Morphine Sul Tab 100mg ER	90	30
5/26/2015	Morphine Sul Tab 100mg ER	90	30
6/22/2015	Morphine Sul Tab 100mg ER	90	30
7/22/2015	Morphine Sul Tab 100mg ER	90	30
8/19/2015	Morphine Sul Tab 100mg ER	90	30
9/16/2015	Morphine Sul Tab 100mg ER	90	30
10/14/2015	Morphine Sul Tab 100mg ER	90	30
12/8/2015	Morphine Sul Tab 100mg ER	90	30
1/4/2016	Morphine Sul Tab 100mg ER	90	30
2/2/2016	Morphine Sul Tab 100mg ER	90	30
3/1/2016	Morphine Sul Tab 100mg ER	90	30

368. Each of these prescriptions were filled by CVS stores that had CVS DEA registration numbers and NPI numbers. The reimbursements for these prescriptions were sent into an account in CVS's control. The claims for the prescriptions that were reimbursed by Federal Healthcare Programs were false because the prescriptions were not valid, were not for a medically accepted indication, and/or were not medically necessary.

369. Attachments 1 and 2 identify examples of claims CVS submitted to Federal Healthcare Programs for unlawful prescription that were paid for by Federal Healthcare Programs and that presented with one or more of three of the red flags discussed above: excessive quantities of opioids, trinity cocktails, and early fills of opioids. Each of these prescriptions were filled by

CVS stores that had CVS DEA registration numbers and NPI numbers. The reimbursements for these prescriptions were sent into an account in CVS's control. The claims for the prescriptions that were reimbursed by Federal Healthcare Programs were false because the prescriptions were not valid, were not for a medically accepted indication, and/or were not medically necessary.

VIII. CLAIMS FOR RELIEF

COUNT ONE
Controlled Substances Act: Unlawful Dispensing of Controlled Substances: 21 U.S.C. §§ 842(a)(1), (c)(1)(A) & 829

370. The United States realleges the above and below paragraphs as if set forth herein.

371. From on or about January 7, 2015, to the present, CVS dispensed controlled substances without valid prescriptions, in violation of 21 U.S.C. §§ 829 and 842(a)(1); knowingly dispensed controlled substances without prescriptions, or pursuant to purported prescriptions that were issued without a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice, in violation of 21 U.S.C. §§ 829(a)-(b), 842(a)(1); and 21 C.F.R. § 1306.04; and dispensed controlled substances other than for a medical purpose, in violation of 21 U.S.C. §§ 829(c) and 842(a)(1).

372. From in or about January 7, 2015, to the present, CVS also dispensed Schedule III and IV prescriptions in violation of the CSA's restrictions on refills of such prescriptions, in violation of 21 U.S.C. §§ 829(b) and 842(a)(1) and 21 C.F.R. § 1306.22.

373. As a result of the foregoing, CVS is liable to the United States for a civil penalty in the amount of not more than $25,000 for each violation occurring before November 2, 2015, and not more than $80,850 for each violation occurring after November 2, 2015, to be proven at trial, pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

374. The United States also requests that the Court issue an order granting appropriate injunctive relief to restrain CVS's violations of 21 U.S.C. § 842, pursuant to 21 U.S.C. §§ 843(f), 882.

COUNT TWO
False Claims Act: Presentation of False Claims: 31 U.S.C. § 3729(a)(1)(A)

375. The United States realleges the above and below paragraphs as if set forth herein.

376. From at least October 17, 2013, through the present, CVS knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval, in violation of the FCA, 31 U.S.C. § 3729(a)(1)(A). Specifically, CVS knowingly presented, or caused to be presented, materially false or fraudulent claims for reimbursement for the dispensation of prescription drugs that were not valid, were not for a medically accepted indication, and/or not medically necessary, and consequently not eligible for reimbursement.

377. The Federal Healthcare Programs paid CVS's claims for these false or fraudulent claims.

378. If the Federal Healthcare Programs had known that the claims presented for payment were for the dispensation of prescription drugs that violated Federal Healthcare Program requirements, they would not have paid the claims.

379. Because of CVS's acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the FCA, plus a civil penalty for each violation.

COUNT THREE
False Claims Act: False Records or Statements: 31 U.S.C. § 3729(a)(1)(B)

380. The United States realleges the above and below paragraphs as if set forth herein.

381. CVS, from at least October 17, 2013, to the present, knowingly made, used, or caused to be made or used false records or statements in violation of the FCA, 31 U.S.C.

§ 3729(a)(1)(B)—in the form of, *inter alia*, false claims data, false certifications, and false attestations—that were material to the payment of false or fraudulent claims for reimbursement by Federal Healthcare Programs for the dispensation of prescription drugs that were not valid, were not for a medically accepted indication, and/or were not medically necessary.

382. If the Federal Healthcare Programs had known that the records and statements were false, they would not have paid CVS's claims.

383. Because of CVS's acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the FCA, plus a civil penalty for each violation.

COUNT FOUR
Fraud

384. The United States realleges the above and below paragraphs as if set forth herein.

385. As described above, CVS made misrepresentations to Federal Healthcare Programs by submitting claims for reimbursement for controlled substance prescriptions from at least October 17, 2013, through the present that were dispensed pursuant to prescriptions that were not valid, were not for medically accepted indications, and/or were not medically unnecessary.

386. CVS made these misrepresentations knowing of their falsity. CVS's misrepresentations were the direct and proximate causes of the United States' injuries because they led the United States to make payments that it would not have made otherwise. As a result of CVS's material misrepresentations, the United States was damaged in an amount to be determined at trial.

COUNT FIVE
Payment by Mistake

387. The United States realleges the above paragraphs as if set forth herein.

388. The United States seeks relief against CVS to recover monies paid under mistake of fact. From at least October 17, 2013, through the present, the Federal Healthcare Programs paid CVS for claims in connection with the dispensation of prescription drugs based on the mistaken and erroneous belief that the dispensations complied with federal rules and regulations governing the dispensing of prescriptions. This mistaken and erroneous belief, as well as the false representations and records made by CVS concerning the claims, were material to the determination to pay for the claims.

389. If the Federal Healthcare Programs had known that the claims were for the dispensation of prescription drugs not for medically accepted indications and/or not authorized by valid prescriptions, they would not have paid the claims, resulting in damages to the United States in an amount to be determined at trial.

COUNT SIX
Unjust Enrichment

390. The United States realleges the above and below paragraphs as if set forth herein.

391. From at least October 17, 2013, through the present, the United States paid CVS for the dispensing of prescriptions that CVS should not have received. CVS retained and used these monies from the United States to which CVS were not entitled and therefore were unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, CVS should not retain those payments from the United States, the amount of which is to be determined at trial.

IX. PRAYER FOR RELIEF

WHEREFORE, the United States seeks against CVS the following:

(a) Civil penalties for violations of 21 U.S.C. § 842(a)(1), *see* 21 U.S.C. § 842(c)(1)(A); 28 C.F.R. § 85.5;

(b) Entry of a preliminary and permanent injunction to restrain future violations, pursuant to 21 U.S.C. §§ 843(f), 882, and enjoining CVS from obtaining, processing, administering, distributing, or dispensing controlled substances in a manner inconsistent with their legal obligations as set forth above;

(c) Damages to the United States, trebled, as mandated by 31 U.S.C. § 3729(a)(1);

(d) Civil penalties of between $5,500 and $11,000 for each false claim presented to a Federal Healthcare Program on or before November 2, 2015, 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.3(a)(9); and of between $11,803 and $23,607 for each false claim presented to a Federal Healthcare Program after November 2, 2015, 28 C.F.R. § 85.5;

(e) For payment by mistake, the amount of damages sustained by the United States as a result of its payment by mistake, to be proven at trial;

(f) For unjust enrichment, the sums by which CVS has been unjustly enriched, to be proven at trial;

(g) Pre-judgment interest, post-judgment interest, costs, and such other and further relief as the Court deems just and equitable.

Respectfully submitted,

Dated: December 13, 2024

UNITED STATES OF AMERICA,

By its Attorneys,

ZACHARY A. CUNHA
United States Attorney for the
District of Rhode Island

/s/ Kevin Love Hubbard
SARA MIRON BLOOM
KEVIN LOVE HUBBARD
RACHNA VYAS
Assistant United States Attorneys
One Financial Plaza, 17th Floor
Providence, RI 02903
(401) 709-5078
Kevin.Hubbard@usdoj.gov

JESSICA D. ABER
United States Attorney for the
Eastern District of Virginia
JOHN E. BEERBOWER
Special Assistant U.S. Attorney
2100 Jamieson Avenue
Alexandria, VA 22314
(703) 299-3700
John.Beerbower@usdoj.gov

CLARE E. CONNORS
United States Attorney for the
District of Hawaii
SYDNEY SPECTOR
TRACY J. WEINSTEIN
Special Assistant U.S. Attorneys
300 Ala Moana Blvd, Room 6-100
Honolulu HI 96850
(808) 440-9291
Tracy.Weinstein@usdoj.gov

DAMIEN DIGGS
United States Attorney for the
Eastern District of Texas
ADRIAN GARCIA
JAMES GILLINGHAM
Special Assistant U.S. Attorneys
110 N. College, Ste. 700
Tyler, TX 75702
(903) 510-9346
James.Gillingham@usdoj.gov

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

BURDEN H. WALKER
Acting Deputy Assistant Attorney General
Civil Division

AMANDA N. LISKAMM
Director
LISA K. HSIAO
Senior Deputy Director, Civil Litigation
AMY L. DELINE
C.B. BUENTE
Assistant Directors
DONALD LORENZEN
Senior Litigation Counsel
BEN CORNFELD
AMANDA K. KELLY
Trial Attorneys
United States Department of Justice
Consumer Protection Branch
450 Fifth Street, N.W.
Washington, D.C. 20530
(202) 598-7276
Benjamin.a.cornfeld2@usdoj.gov

MICHAEL GRANSTON
Deputy Assistant Attorney General

JAMIE A. YAVELBERG
Director
NATALIE A. WAITES
Assistant Director
CLAIRE L. NORSETTER
JOSHUA BARON
MEGAN F. ENGEL
Trial Attorneys
U.S. Department of Justice
Commercial Litigation Branch, Fraud Section
175 N Street, N.E.
Washington, D.C. 20002
(202) 307-1112
Claire.L.Norsetter@usdoj.gov