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

THE UNITED STATES OF AMERICA; and the STATE OF CALIFORNIA, the STATE OF COLORADO, the STATE OF CONNECTICUT, the STATE OF DELAWARE, the DISTRICT OF COLUMBIA, the STATE OF FLORIDA, the STATE OF GEORGIA, the STATE OF HAWAII, the STATE OF ILLINOIS, the STATE OF INDIANA, the STATE OF LOUISIANA, the STATE OF MARYLAND, the STATE OF MASSACHUSETTS, the STATE OF MICHIGAN, the STATE OF MINNESOTA, the STATE OF MONTANA, the STATE OF NEVADA, the STATE OF NEW JERSEY, the STATE OF NEW MEXICO, the STATE OF NEW YORK, the STATE OF NORTH CAROLINA, the STATE OF OKLAHOMA, the STATE OF RHODE ISLAND, the STATE OF TENNESSEE, the STATE OF TEXAS, the STATE OF VIRGINIA, and the STATE OF WISCONSIN, *ex rel.*, FOX RX, INC., Plaintiffs, v. WALGREEN COMPANY, Defendant.	Civil Action No. _____ **COMPLAINT** **UNDER SEAL** **Pursuant to 31 U.S.C. § 3730(b)(2)**

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The United States of America (the United States or the Government), the District of Columbia, and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin (collectively, the Plaintiff States), by and through their *qui tam* Relator, Fox Rx, Inc. (Fox, Plaintiff or Relator) bring this action under the Federal False Claims Act, 31 U.S.C. §§ 3729-3733, *et seq.* and the States' False Claims Acts as enumerated below, against Walgreen Company ("Walgreens" or "Defendant") to recover all damages, penalties, and other remedies provided by the False Claims Acts on behalf of the United States, the States, and the Relator, and for their Complaint allege:

I. INTRODUCTION

1. Walgreens is one of the nation's largest retail pharmacy chains providing prescription drug services to patient beneficiaries under the Medicare Part D and Medicaid insurance programs.

2. Since the commencement of the Part D program in 2006, Walgreens has routinely overcharged Fox, other sponsors of Medicare Part D plans, and the Medicare and Medicaid programs by: (1) failing to substitute generic drugs for brand-name drugs in states which have laws mandating such substitution; and (2) dispensing drugs after their shelf-life expiration date in states which have laws prohibiting pharmacies from doing so.

II. PARTIES

3. Plaintiff and Relator Fox Rx, Inc., is a Delaware Corporation, and is the parent corporation of Fox Insurance, Inc. (Fox), a Delaware corporation that was, from 2006 to 2010, engaged in the business of sponsoring insurance plans under Medicare Part D.

4. Plaintiff United States of America, acting through the Department of Health and Human Services (HHS), and its Centers for Medicare and Medicaid Services (CMS) administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.* (Medicare), and Grants to States for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.* (Medicaid).

5. Plaintiffs the District of Columbia, and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin (hereinafter, the "Plaintiff States"), are States participating in the Medicaid program which have adopted laws or regulations requiring pharmacists filling prescriptions of Medicaid beneficiaries to substitute generic drugs for branded ones, and which have also adopted State False Claims Acts which permit a relator such as Fox to sue on their behalf to recover for false and fraudulent claims made to their Medicaid programs. In addition, the States of Florida, Hawaii, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Washington, and West Virginia have enacted statutes that generally require pharmacies to substitute a generic version of a branded drug whenever the branded drug is prescribed, including brand drug prescriptions of Medicare Part D beneficiaries. Also, the District of Columbia and the States of Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Wisconsin, and Wyoming have enacted statutes

prohibiting pharmacies from dispensing drugs after the shelf-life expiration date, including prescriptions dispensed to Medicare Part D beneficiaries.

6. Defendant Walgreen Company is an Illinois corporation with its headquarters located in Deerfield, Illinois and is one of the nation's largest provider of retail pharmacy services operating more than 7,800 drugstores in all 50 U.S. states, the District of Columbia, Guam, and Puerto Rico, as well as two mail-order facilities with $72.2 billion in sales in FY 2011 (ending August). Prescription drugs account for about two-thirds of Walgreens' sales; the rest comes from general merchandise, over-the-counter medications, cosmetics, and groceries.

III. JURISDICTION AND VENUE

7. Jurisdiction in this Court is proper pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This Court also has jurisdiction pursuant to 28 U.S.C. § 1331.

8. The Court may exercise personal jurisdiction over the Defendant, and venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391 because the acts proscribed by 31 U.S.C. §§ 3729 *et seq.*, and complained of herein took place in part in this district and the Defendant transacted business in this district.

9. Jurisdiction in this Court over all State laws alleged herein is proper under 31 U.S.C. § 3732(b).

10. Venue is proper in this Court for the additional reason that for the 2010 plan year, Fox Insurance, Inc., held a contract with CMS to provide prescription drug plan services under Medicare Part D in the State of New York.

11. Venue is proper in this Court for the additional reason that from 2006 to the present, Defendant provided retail pharmacy services to residents in the State of New York.

12. Pursuant to 31 U.S.C. § 3730(b)(2), the Plaintiff prepared and has served with this Complaint on the Attorney General of the United States, the United States Attorney for the Southern District of New York, and the Attorneys General of the Plaintiff States a written disclosure of all material evidence and information currently in its possession.

13. This action is not based upon prior public disclosure of allegations or transactions in a Federal criminal, civil, or administrative hearing, in which the Government or its agent is a party. Nor have Relator's allegations or transactions herein been publicly disclosed in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or in news media; or in any other form as the term "publicly disclosed" is defined in 31 U.S.C. § 3730(e)(4)(A) and parallel provisions of the State False Claims Acts.

14. To the extent there has been a public disclosure unknown to Relator of any of the allegations herein, Relator is the original source of those allegations within the meaning of 31 U.S.C. § 3730(e)(4)(B) and parallel provisions of the State False Claims Acts.

IV. LEGAL BACKGROUND

A. The False Claims Act

15. The False Claims Act provides, in pertinent part:

> (a) Liability for certain acts.—
>
> > (1) In general.—Subject to paragraph (2), any person who—
> >
> > > (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> >
> > > (B) 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 a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(b) Definitions.—For purposes of this section—

(1) the terms "knowing" and "knowingly" —

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term "claim"—

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual

> as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;
>
> (3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and
>
> (4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

31 U.S.C. § 3729(a), (b).

16. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 28 C.F.R. § 85.1, the False Claims Act civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

17. Each of the Plaintiff States have adopted False Claims Acts that provide comparable relief to the States for the submission of false and fraudulent claims. These include:

a. California: Cal. Govt Code §12651, et seq.

b. Colorado: Colo. Rev. Stat. § 25.5-4-303.5, et seq.

c. Connecticut: Conn. Gen. Stat. § 17b-301, et seq.

d. Delaware: Del. Code Ann. Tit. 6 § 1201, et seq.

e. District of Columbia: D.C. Code § 2-308.14, et seq.

f. Florida: Fla. Stat. § 68.081, et seq.

g. Georgia: Ga. Code Ann. § 49-4-168, et seq.

h. Hawaii: Haw. Rev. Stat. § 661-21, et seq.

i. Illinois: 740 Ill. Comp. Stat. §175, et seq.

j. Indiana: Ind. Code § 5-11-5.5-1, et seq.

k. Louisiana: La Rev. Stat. Ann § 46:438.3

l. Maryland: Md. Code Ann., Health-Gen. § 2-601, et seq.

m. Massachusetts: Mass. Gen. Laws Ch. 12 § 5A, et seq.

n. Michigan: MCL 400.607

o. Minnesota: Minn. Stat. § 15C.01, et seq.

p. Montana: Mont. Code Ann. § 17-8-401, et seq.

q. Nevada: Nev. Rev. Stat. § 357.010, et seq.

r. New Jersey: N.J. Stat. Ann. § 2A:32C-1, et seq.

s. New Mexico: N. M. S. A. 1978, §§ 27-14-1, et seq.

t. New York: N.Y. St. Fin. Law § 187, et seq.

u. North Carolina: N.C. Gen. Stat. § 1-605, et seq.

v. Oklahoma: Okla. Stat. tit. 63 § 5053, et seq.

w. Rhode Island: R.I. Gen. Laws § 9-1.1-1, et seq.

x. Tennessee: Tenn. Code Ann. § 71-5-181, et seq.

y. Texas: Tex. Hum. Res. Code § 32.039, et seq. and § 36.001, et seq.

z. Virginia: Va. Code Ann. § 8.01-216.1, et seq.

aa. Wisconsin: Wis. Stat. § 20.931, et seq.

B. Overview of Medicare Part D

18. Medicare is a federally funded and administered health insurance program for certain groups of persons, primarily the elderly and the disabled. HHS administers the Medicare program through CMS.

19. Medicare Part D is a voluntary prescription drug benefit program for Medicare enrollees that became effective on January 1, 2006. 42 U.S.C. § 1395w-101 *et seq.*

20. Medicare Part D coverage is offered through private companies, known as Part D sponsors, which contract with CMS to administer prescription drug plans (PDPs).

21. CMS gives each Part D sponsor advance monthly payments consisting of the PDP's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§ 423.315, 423.320.

22. Beneficiaries' coverage varies by their cost of drug usage over the course of a plan year:

- Deductible: As with most insurance plans, beneficiaries do not receive any benefits under Medicare Part D until their out-of-pocket costs for prescription drugs meets a modest deductible amount ($320 for 2012).
- Initial Coverage: Once a beneficiary meets his or her deductible, they receive prescription drug benefits up to an annual cap ($2930 for 2012).
- Coverage Gap (the "Doughnut Hole"): After the beneficiary reaches the cap of the initial coverage, they fall into a coverage gap until their total out-of-pocket costs reach a threshold for catastrophic coverage ($4700 for 2012).
- Catastrophic Coverage: After the beneficiary meets the threshold amount, they are again entitled to prescription drug benefits under a reinsurance scheme in which the United States Treasury pays 80% of drug costs, the Part D sponsor pays 15% and the beneficiary pays 5%.

23. Throughout the plan year, each time a Medicare beneficiary has a prescription filled under Part D, the sponsor receives a claim from the pharmacy and notifies CMS of the event, including the cost the sponsor has incurred. At the end of the plan year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred.

24. If CMS underpaid the Part D Sponsor for low-income subsidies or reinsurance costs, CMS makes up the difference. If CMS overpaid the Part D Sponsor for these costs, it recoups the overpayment from the Sponsor. 42 C.F.R. § 423.343.

25. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to

what degree a plan's allowable costs per beneficiary exceeded or fell below a target amount for the plan by certain threshold percentages (commonly called the Part D risk corridor). 42 C.F.R. § 423.336.

26. Although CMS and beneficiaries together pay a monthly insurance premium to the Part D sponsor (this is called a "capitated" rate), there are circumstances under which prescriptions dispensed to an individual beneficiary may cause CMS to make additional payments to (or collect monies from) a Part D sponsor, including:

a. A beneficiary with a low income may be subsidized by CMS (Low Income Subsidy or "LIS" beneficiary), causing the government to pay costs that otherwise the beneficiary would bear, such as copayments and, within the coverage gap, out-of-pocket prescription costs.

b. When a beneficiary is entitled to catastrophic coverage, the government pays 80% of the beneficiary's drug costs through reinsurance paid to the PDP sponsor. In essence, CMS reimburses the plan for prescriptions for such beneficiaries on a nearly fee-for-service basis.

27. Under the MMA, the federal government does not bear the entire expense of the Part D coverage. Rather, the Part D benefit is funded in two ways: (1) by traditional Medicare funding through enrollee payments and the Health Insurance Trust Fund; and (2) by phased-down state payments made directly to the federal government (commonly referred to as the "clawback"). *See* A. Grady & C. Scott, Congressional Research Service, "Implications of the Medicare Prescription Drug Benefit for State Budgets," CRS-1 (2004), at 2.

28. The clawback payments represent a portion of the costs associated with providing Part D coverage to persons eligible for both Medicare and Medicaid. 42 U.S.C. § 1396u-

5(c)(1)(A), (B). The phased-down contribution reflects the percentage of the expected state costs of Medicaid drug coverage for dual-eligible beneficiaries, as determined by the MMA. Starting in 2006 when the Part D program began, that contribution was 90 percent of the states' expected costs in providing Medicaid drug coverage for dual eligibles. The percentage declines each year for all of the States from 90 percent in 2006 to 75 percent after 2014. *See* 42 U.S.C. § 1396u-5(c)(5). For 2012, the states' contribution is 80 percent. *Id.* If a State fails to make the required clawback payments, the federal government will offset that amount, plus interest, against Medicaid payments that it otherwise would have made to the State. 42 U.S.C. § 1396u-5(c)(1)(A), (B), (C).

1. Sponsors, Pharmacy Benefit Managers, and Pharmacies Under Part D

29. Part D Sponsors enter into contracts with pharmacies (including retail pharmacies, such as Walgreens) to provide prescription drugs to their plan members.

30. Part D Sponsors also frequently contract with a pharmaceutical benefits manager ("PBM") to administer their prescription drug programs. PBMs work with Sponsors to develop and implement a prescription drug formulary, and provide automated processing services for Sponsors to "adjudicate" claims submitted by pharmacies on a real-time basis.

31. From 2006 to 2010, Fox entered into contracts with PBMs to assist in operating its Part D plans.

32. Walgreens has entered into subcontracts with the majority of Medicare Part D sponsors, including Fox, either directly, or through PBMs.

2. Medicare's Requirements of Participants in Part D

33. Medicare Part D requires all participants in the program – PDP Sponsors, PBMs, and pharmacies – to adhere to all federal laws and regulations, including those designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1).

34. Under CMS regulations, PDP Sponsors' subcontracts with PBMs and pharmacies must contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. §§ 423.505(h)(1), (i)(3)(v).

35. Services performed by or delegated to such "first-tier" and "downstream" entities must meet the standards required of the Part D Sponsor. *Id.*, §§ 423.505(h)(1), (h)3), (i)(3(v), 423.505(i)(4)(iv).

C. Overview of the Medicaid Program

36. The Medicaid Program, as enacted by Title XIX of the Social Security Act of 1965, 42 U.S.C. § 1396, *et seq.*, is a joint federal-state program that provides health care benefits for certain groups, primarily indigent and disabled individuals. The federal Medicaid statute establishes the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

37. All of the Plaintiff States have elected to participate in the Medicaid program, and all have elected to offer prescription drug coverage to Medicaid beneficiaries.

38. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b).

39. The Medicaid statute requires each participating state to implement and administer a state plan for medical assistance services which contains certain specified minimum

criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). These requirements include a comprehensive description of the State Medicaid agency's payment methodology for prescription drugs. 42 C.F.R. § 447.518.

40. Although the MMA transferred prescription drug coverage for dual eligibles to Part D, states are still obligated to finance a portion of the Part D coverage through clawback payments to the federal government. As mentioned above, the MMA's clawback provision requires states to pay the federal government a significant portion of the money they save by no longer providing prescription drug coverage to dual eligibles.

41. Most states continue to include the clawback payments as part of the state Medicaid budget, but these payments are not matched with federal funds and they are not included in calculations of federal Medicaid spending. The federal government accounts for these payments as Medicare revenue. The Congressional Budget Office estimated that the clawback payments from states to the federal government will total $124 billion between 2006 and 2015. *See* Robert Pear, States Protest Contributions to Drug Plan, N.Y. TIMES, Oct. 18, 2005.

D. Medicare Part D and Medicaid Prohibit Billing for Brand Drugs in Lieu of Their Generic Substitutes

1. Overview of Generic and Branded Drugs

42. When a brand pharmaceutical manufacturer receives approval from the Food & Drug Administration (FDA) to market a new pharmaceutical, the manufacturer typically receives a period of "exclusivity" during which it has the sole right to market the drug in the United States. In addition to the FDA exclusivity period, the brand manufacturer typically holds patent rights that prevent competitors from producing and marketing the same chemical compound. Because brand manufacturers market their drugs under a proprietary name rather than the name

of the drug's generic active ingredient (e.g., Zocor is the brand name given by Merck & Co., Inc., to the drug's active ingredient simvastatin), they are referred to as brand-name drugs.

43. After the exclusivity period and patent rights expire, however, other pharmaceutical manufacturers may submit to the FDA an Abbreviated New Drug Application and receive approval to market a generic version of the brand drug. Generic drugs contain the same active ingredient and are bioequivalent to their branded counterparts in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Generic drugs are typically sold at substantial discounts from the price of their branded counterparts.

44. Physicians writing prescriptions for drugs frequently use the brand drug even after a generic has become available on the market. Physicians may continue to use the brand drug, for example, because they have become familiar with that brand during the period of exclusivity, or because they do not know that a generic version of the drug has become available.

45. In a small number of circumstances, the physician may decide that only the brand-name drug is suitable for the patient. In those cases, the physician indicates their preference for the brand-name drug by noting it on the prescription form. There are several methods for indicating brand-name preference, including writing "dispense as written" (or its shorthand, DAW) or "brand medically necessary" (or its shorthand, BMN).

46. In the absence of a statement by the prescriber to the pharmacist that the brand-name drug alone must be dispensed, the pharmacist must, for Medicaid claims in the Plaintiff States and for all claims (including those under Medicare Part D) in Florida, Hawaii, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island,

Tennessee, Washington, and West Virginia, substitute an equivalent generic drug when one is available.

2. CMS Requires Pharmacies to Properly Report Their Generic Substitution Instructions as Part of Each Part D Claim

47. When retail pharmacies, such Walgreens, dispense drugs to a Medicare Part D enrollee, the pharmacies submit a claim electronically to the enrollee's Part D sponsor (often via a PBM) comprised of several pieces of information, including the ingredient cost (the cost of the drug itself), a dispensing fee, and any sales or similar taxes paid, less any payments received from the enrollee and any rebates received from the drug's manufacturer or distributor. If a pharmacy dispenses a brand-name multisource drug, it also provides the basis for its decision not to substitute a generic in the form of a "Dispense as Written/Product Selection Code," or "DAW Code," as described below in Paragraphs 84 through 90.

48. The Part D sponsor then uses the information provided by the pharmacies, reformats it, and submits it to CMS as a Prescription Drug Event (PDE). CMS uses the PDE information at the end of the payment year when it reconciles its advance payments to the Part D sponsor with the costs the sponsor has incurred throughout the year, as described in Paragraph 25.

49. Medicare Part D requires that, as a condition of payment, all Part D sponsors must submit data and information necessary for CMS to carry out Part D's payment provisions, including claims information provided by the pharmacy for use in the PDE. 42 U.S.C. § 1395w-115(c)(1)(C), (d)(2); 42 C.F.R. § 423.322.

50. Part D sponsors and retail pharmacies are "Health Care Providers" and "Covered Entities" under the Health Insurance Portability and Accountability Act ("HIPAA"). 42 U.S.C. 1320(d); 45 C.F.R. § 160.103.

51. As HIPAA Covered Entities, Part D sponsors and retail pharmacies like Walgreens are required to comply with certain electronic data transmission standards that CMS has adopted by regulation for pharmacy claims processing, including standards developed by the National Council for Prescription Drug Programs ("NCPDP"), as described in Paragraphs 84 through 90, below. *See* 45 C.F.R. §§ 162.1102, 162.920.

52. Relying on the integrity of the claim information provided by the retail pharmacy, the Part D sponsor certifies to CMS that the PDE information is accurate, complete, and truthful. 42 C.F.R. § 423.505(k)(3).

53. CMS specifically relies upon and uses the following PDE cost and payment fields in its year end reconciliation: gross drug cost above out-of-pocket threshold, gross drug cost below out-of-pocket threshold, low-income cost-sharing subsidy, and covered Part D Plan paid amount (the four PDE data elements). The Part D sponsor, or its PBM, calculates the four data elements from the point-of-sale claims data submitted by the pharmacy using instructions provided by CMS.

54. In order to receive Part D finds from CMS, Part D sponsors, their authorized agents, employees, and contractors (including pharmacies, such as Walgreens) are required to comply with all applicable Federal laws, regulations, as well as CMS instructions. 42 U.S.C. § 1860D-12(b)(1); 42 C.F.R. § 423.505(i)(4)(iv).

55. Additionally, as Part D subcontractors/downstream entities, retail pharmacies are required to "certify, (based on best knowledge, information and belief) the accuracy, completeness, and truthfulness of the data [transmitted to the PDE] and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

56. In conformance with this provision, Walgreens enters into Electronic Data Interchange ("EDI") Agreements directly with CMS and expressly certify, among other things, that any data Walgreens transmits to the PDE would be "accurate and complete" to its "best knowledge, information and belief."

3. The Plaintiffs States' Medicaid Programs Mandate Generic Substitution

57. The Plaintiff States have instituted Medicaid plans requiring that generic drugs be substituted for branded ones. The State Medicaid laws or regulations mandating generic substitution include:

a. Colorado: Colo. Rev. Stat. § 25.5-5-501; 10 Colo. Code Regs. § 2505-10 8.800.4.H;

b. Connecticut: Conn. Gen. Stat. § 17b-274; § 20-619;

c. Delaware: Del. Code Ann. Tit. 31 § 503; Del. Med. Assist. Prog. Pharm. Provider Manual § 3.1.1.3;

d. District of Columbia: DCMR, tit. 29 § 2704;

e. Florida: Fla. Stat. §§ 409.906, 465.025 (general state requirement);

f. Georgia: Ga. Code Ann. § 26-4-81; Ga. Dept. of Comm. Health Div. of Med. Assist. Pt. II: Policies and Procedures for Pharm. Services § 1002;

g. Hawaii: Haw. Medicaid Manual § 19.1.7.4(b)(3); Haw. Rev. Stat. § 328-92 (general state requirement);

h. Indiana: Ind. Code § 16-42-22-10;

i. Kentucky: Ky. Rev. Stat. Ann. § 217.822 (general state requirement);

j. Maryland: Md. Code Ann., Health-Gen. § 15-124;

k. Massachusetts: Mass. Gen. Laws, Pt. I, Tit. XVII, ch. 118E § 17; 130 Code of Mass. Reg. § 406.413; Mass. Gen. Laws, Pt. I, Tit. XVI, ch. 112 § 12D (general state requirement);

l. Minnesota: Minn. Health Care Programs Provider Manual, "Dispense as Written – Brand Necessary;" Minn. Stat. § 151.21 (general state requirement);

m. Montana: Mont. Admin. R. 37.86.1105 (2011);

n. Nevada: Nev. Rev. Stat. § 639.2583 (general state requirement);

o. New Jersey: N.J. Admin. Code § 10:51-2.9; N.J. Stat. Ann. 24:6E-7 (general state requirement);

p. New Mexico: N.M. Admin. Code § 8.324.4.12;

q. New York: N.Y. Soc. Servs. Law § 365-a(5)(a-1); N.Y. Educ. Law §6816-a (general state requirement);

r. North Carolina: N.C. Adult Medicaid Manual § XXII(C)(4);

s. Oklahoma: Okla. Admin. Code § 317:30-5-76;

t. Oregon: Or. Rev. Stat. § 414.325;

u. Pennsylvania: 35 Pa. Cons. Stat. § 960.3 (general state requirement);

v. Rhode Island: R.I. Gen. Laws § 40-8-24; R.I. Dept. of Hum. Servs. Code of Reg. §§ 0348.45.05.05, 0374.65; R.I. Gen. Laws §§ 5-19.1-19, 21-31-16.1 (general state requirement);

w. Tennessee: Tenn. Code Ann. § 53-10-205 (general state requirement);

x. Texas: 22 Tex. Admin. Code § 309.3; Tex. H.H.S. Vendor Drug Pharmacy Provider Handbook §§ 354.1851, 355.8545 355.8546; Tex. H.H.S. Comm. Vendor Drug Program Pharmacy Provider Procedures Manual 4.4;

y. Virginia: 12 Va. Admin. Code § 30-50-210;

z. Washington: WAC 182-530-4125; RCW 69.41.100, et seq. (general state requirement);

aa. W.Va. Code § 30-5-12b (general state requirement);

bb. Wisconsin: Wis. Admin. Code D.H.S. § 107.10 (2009);

4. State Pharmacy Laws Require Generic Substitution, Including For Medicare Part D Claims

58. Medicare Part D requires that PDP sponsors require pharmacies providing services to the plan comply with minimum standards for pharmacy practice as established by the States. 42 C.F.R. § 423.153.

59. The States of Florida, Hawaii, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Washington, and West Virginia require that generic drugs be substituted for brand name ones for all payors, including Medicare Part D.

60. These States' laws mandating generic substitution constitute the minimum standards for pharmacy practice with which Medicare Part D requires compliance.

61. The relevant State laws include:

a. Florida: Fla. Stat. § 465.025;

b. Hawaii: Haw. Rev. Stat. § 328-92;

c. Kentucky: Ky. Rev. Stat. Ann. § 217.822;

d. Massachusetts: Mass. Gen. Laws, Pt. I, Tit. XVI, ch. 112 § 12D;

e. Minnesota: Minn. Stat. § 151.21;

f. Nevada: Nev. Rev. Stat. § 639.2583;

g. New Jersey: N.J. Stat. Ann. §24:6E-7, N.J. Admin. Code §10:51:11(b)(2);

h. New York: N.Y. Educ. Law §6816-a;

i. Pennsylvania: 35 Pa. Cons. Stat. § 960.3;

j. Rhode Island: R.I. Gen. Laws §§ 5-19.1-19, 21-31-16.1;

k. Tennessee: Tenn. Code Ann. § 53-10-205;

l. Washington: RCW 69.41.100, et seq.; and

m. West Virginia: W.Va. Code § 30-5-12b.

5. Medicare Part D Sponsors' Contracts Require Generic Substitution

62. When Medicare Part D sponsors enter into contracts with PBMs and pharmacies, they typically require substitution of generics for brand-name drugs.

63. Moreover, any downstream entity (including pharmacies such as Walgreens) are contractually obligated to "comply with all applicable Federal laws, regulations, and CMS instructions." 42 C.F.R. § 423.505(i)(4)(iv).

E. Medicare Part D and Medicaid Prohibit Billing for Expired Drugs

1. Overview of National Drug Codes and Terminated Drugs

64. The Drug Listing Act of 1972 requires registered drug establishments (including pharmaceutical manufacturers) to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. 21 U.S.C. § 360. Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for human drugs.

65. Each listed drug product is assigned a unique 11-digit, 3-segment NDC, identifying the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including repackagers or relabelers), or distributes (under its own name) the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug marketed by a particular labeler. Different formulations, or different strengths of the same formulation, should be assigned different product codes. The third segment, the package code, identifies package sizes and types. Both the product and package codes are assigned by the labeler.

66. Pursuant to 21 C.F.R. § 211.137, prescription drug labelers must assign each drug produced an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use. The expiration date effectively establishes a shelf-life for the drug.

67. CMS defines a drug's NDC termination date generally as (1) the shelf-life expiration date of the last batch of a discontinued drug sold by the manufacturer, or (2) the date that the Food and Drug Administration (FDA) or the manufacturer withdraws a drug from the market for health and safety reasons or orders such withdrawal. *Medicaid Drug Rebate Operational Training Guide*, page F7 (Sept. 2001); *Medicaid Drug Rebate Program Release No. 19*, at 5.

68. NDCs may become terminated in several circumstances. For example, the labeler may adopt the use of a new NDC for the drug, making the old NDC obsolete. The labeler (and thus, the drug) may also have been acquired by another firm (e.g., Pfizer, Inc.'s recent acquisitions of Wyeth and King Pharmaceuticals) whereby, subsequent to the acquisition, the drugs of the acquired firm would be identified and reported under the acquiring firm's labeler code and assigned product and package codes.

69. Any claims submitted to Medicare and Medicaid for drugs dispensed after the NDC termination date are invalid and are not reimbursable.

70. CMS reports NDC termination dates to private companies, including First Data Bank, Inc., a provider of drug database services, and to the states in the quarterly updates tape (also, referred to as "quarterly drug tapes") for each state's purpose of carrying out its respective Medicaid Rebate Program.

2. Medicare Part D Prohibits Dispensation of Expired Drugs

71. When pharmacies, such as Walgreens, dispense drugs to a Medicare Part D enrollee, the NDC of the dispensed drug is included in a field (Field 15, the Product/Service ID) of the PDE processed by the pharmacy, as described in Paragraphs 48-49.

72. As described in Paragraph 58, Medicare Part D obligates Defendant to comply with minimum standards for pharmacy practice as established by the states.

73. For example, the District of Columbia and the states of Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Wisconsin, and Wyoming are among those states that prohibit dispensing expired drugs for all payors, including Medicare Part D.

74. These states' laws, which require the quarantine, destruction, return of, or directly prohibit dispensing expired drugs, constitute the minimum standards for pharmacy practice with which Medicare Part D requires compliance.

75. The relevant State laws, rules, or regulations include:

a. Alaska: Alaska Admin. Code tit. 12, § 52.410;

b. Arizona: Arizona Admin. Code §§ R4-23-611, R4-23-701;

c. Arkansas: Ark. Code R. § 070.00.5-05-00-0003;

d. California: Cal. Admin. Code tit. 16, § 1718.1;

e. Colorado: 3 Colo. Code Regs. § 719-1:3.00.40;

f. Delaware: 24 Del. Code Regs. § 2500-2;

g. District of Columbia: DCMR, tit. 22, 1901.6;

h. Florida: Fla. Stat. §§ 499.0121, 499.005-.006;

i. Georgia: Ga. Comp. R. & Regs. 480-10-.11; 480-28-.07;

j. Hawaii: Haw. Admin. Rules § 16-95-96(3)(A);

k. Idaho: Idaho Admin. Code r. 54-1758, Rules of the Idaho State Board of Pharmacy, IDAPA 27.01.01.326 (2008);

l. Illinois: 77 Ill. Admin. Code §§ 725.20, 725.41, 725.60;

m. Indiana: 856 Ind. Admin. Code § 1-20-1;

n. Iowa: Iowa Admin. Code r. 657-8.8, 657-23.16;

o. Louisiana: La. Admin. Code. tit. 46, § 2501;

p. Maine: Me. Code R. 02-392-30 § 1;

q. Maryland: Md. Code Regs. 10.34.12;

r. Massachusetts: 247 Mass. Code Regs. 9.01;

s. Minnesota: Minn. Admin. R. 6800.0100, Minn. Stat. § 151.415;

t. Mississippi: Miss. Code R. 30-20-1:XI, XXX;

u. Missouri: 20 Mo. Code Regs. Ann. §§ 2220-2.010, 2220-2.090;

v. Nevada: Nev. Rev. Stat. § 639.282;

w. New Jersey: N.J. Admin. Code. § 13:39-7.18;

x. New York: N.Y. Codes R. & Regs. tit. 8, § 29.7;

y. North Carolina: 21 N.C. Admin. Code 46.1411(7), 46.2502;

z. Ohio: Ohio Rev. Code Ann. § 3715.521;

aa. Oklahoma: Okla. Admin. Code §§ 535:10-3-1.2(25), 535:15-3-11(c);

bb. Oregon: Or. Admin. R. 855-041-0036;

cc. Pennsylvania: 49 Pa. Code § 27.14;

dd. Rhode Island: R.I. Code R. 5-19.1-PHAR § 13.3.1;

ee. South Carolina: S.C. Code Ann. § 40-43-86 (1976);

ff. Tennessee: Tenn. Comp. R. & Regs. 1140-03-.11;

gg. Texas: 22 Tex. Admin. Code §§ 281.7(29)(B), 281.8(4), 291.33, 291.54, 291.72;

hh. Utah: Utah Code Ann. § 58-17b-502 (1953);

ii. Wisconsin: Wis. Admin. Code Phar. 10.03(4); and

jj. Wyoming: Wyo. Stat. Ann § 33-24-101 (1977), 8 Wyo. Code. R. Pharm. § 15.

76. Expired drugs are not "reasonable and necessary" for medical diagnosis or treatment, and as such may be excluded from Medicare coverage. Social Security Act, §§ 1862(a)(1)(A) & D-2(e)(3); Centers for Medicare and Medicaid Services, "Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements," Rev.10, 02-19-2010 at 15-16.

77. Expired drugs are also non-reimbursable by Medicare Part D because they amount to "worthless services," the performance of which "is so deficient that for all practical purposes it is the equivalent of no performance at all," *Mikes v. Strauss*, 274 F.3d 687, 703 (2d. Cir. 2001).

78. CMS has identified dispensation of expired drugs as a pharmacy practice constituting Medicare fraud, waste, and abuse. Centers for Medicare and Medicaid Services, "Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse," Rev.2, 04-25-2006 at 58.

3. Medicaid Prohibits Dispensation of Expired Drugs

79. The Social Security Act and its implementing regulations mandates that States must require providers to report the NDC codes when submitting Medicaid prescription drug claims. 42 U.S.C. § 1396r-8(b); 42 C.F.R. § 456.722 (requiring States that employ a point-of-sale electronic claims management (ECM) system as the means of processing claims for covered outpatient drugs to include, among other data, the drug's NDC, which is part of the "Minimum data set (as defined in Part 11 of the State Medicaid Manual)"); State Medicaid Manual, Part 11, ch. 3, section 11375. In order to implement this requirement, several states have prohibited, by statute or regulation, the payment of Medicaid prescription drug claims for pharmaceuticals with dates of service beyond the drugs' NDC termination dates.

80. Examples of relevant State Medicaid laws, rules, or regulations include:

a. Alaska: 7 Alaska Admin. Code § 12.680;

b. Arkansas: Arkansas Dept. of Human Servs., Div. of Medical Servs., Pharmacy Official Notice DMS-2007-Q-3, "Implementation of the Federal Deficit Reduction Act of 2005, Requiring National Drug Code (NDC) When Billing Drug Procedure Codes" dated Oct. 24, 2007.

c. District of Columbia: DCMR, tit. 29 § 2706.3.

d. Illinois: Illinois Department of Healthcare and Family Services, Handbook for Pharmacy Services, ch. P-206.3;

e. Louisiana: Louisiana Medicaid Program Provider Manual, Ch. 37 Pharmacy Benefits Management Services, 37.6.1;

f. Maine: 02-392-101 Me. Code R. § 90;

g. Michigan: Michigan Department of Community Health, Medicaid Provider Manual: Pharmacy, Section 6;

h. Minnesota: Minnesota Health Care Programs' Provider Manual, available at http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_008992#P158_13542 (last accessed March 18, 2012);

i. Mississippi: 23 Miss. Code R. § 214, Rule 1.3;

j. Montana: Prescription Drug Program Provider Manual, Montana Dept. of Health and Human Services (May 2011), at http://medicaidprovider.hhs.mt.gov/pdf/pharmacy.pdf (last accessed March 18, 2012);

k. North Dakota: Medical Services Division, North Dakota Department of Human Services, Provider Manual for Pharmacies, 9 (Apr. 2010);

l. Oklahoma: Okla. Health Care Authority, Policies and Rules 317:30-5-80, National Drug Code;

m. Oregon: Oregon Health Authority, Pharmaceutical Services Provider Guide, 4 (Sept. 2011);

n. Tennessee: Bureau of TennCare Policy Manual, BTC-Pol-Enc-200701-001, at 3 (Feb. 2008), http://www.tn.gov/tenncare/forms/ndcsubmissionforhcpcs.pdf (last accessed April 4, 2012);

o. Virginia: 12 Va. Admin. Code § 30-50-520, 18 Va. Admin. Code § 110-20-200, Medicaid Pharmacy Manual, Ch. IV: Covered Services and Limitations (revised July 2, 2008) at 37 at http://websrvr.dmas.virginia.gov/ProviderManuals/ManualChapters/RX/chapterIV_rx.pdf (last accessed March 18, 2012);

p. Washington: Wash. Admin. Code § 182-530-2100;

q. West Virginia: Medicaid Provider Manual, Ch. 518 – Covered Services, Limitations, and Exclusions for Pharmacy Services, Section 518.7;

r. Wisconsin: Topic 1943, Wisconsin Medicaid and BadgerCare Information for Providers, Pharmacy, Covered and Noncovered Services: Codes, https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=48&s=2&c=10&nt=National+Drug+Codes.

81. Expired drugs are also non-reimbursable by Medicaid because they amount to "worthless services," the performance of which "is so deficient that for all practical purposes it is the equivalent of no performance at all," *Mikes v. Strauss*, 274 F.3d 687, 703 (2d. Cir. 2001).

V. DEFENDANT'S FRAUDULENT SCHEMES

82. Since 2006, Walgreens has routinely overcharged the Medicare Part D and Medicaid programs in violation of the federal and States' False Claims Acts by billing for branded drugs when state laws, incorporated into the Medicare program by the Social Security Act and CMS regulations, required Walgreens pharmacies instead to substitute equivalent generic drugs.

83. Since 2006, Walgreens has, in violation of the Federal and States' False Claims Acts, routinely dispensed drug products to Medicare Part D and Medicaid beneficiaries well after the particular drug's shelf-life expiration, or after a date the FDA withdrew or ordered the withdrawal of the drug from the market for health and safety reasons, as indicated by the particular drug's NDC termination date. No such terminated drugs are reimbursable under either Medicare Part D or Medicaid. because state laws, incorporated into the Medicare program by the

Social Security Act and CMS regulations, required Walgreens pharmacies to dispense drugs that were not terminated.

A. Walgreens Has Failed to Substitute Generic Drugs in Contravention of the Medicare Part D and Medicaid Programs

1. Walgreens Has Misrepresented Its Generic Substitution Instructions Reported on the PDE Using the DAW Code

84. The PDE includes several NCPDP-derived data elements the use of which, as described in Paragraph 51 above, is required by CMS regulations for pharmacy claims processing.

85. One such data element derived from the NCPDP standard and contained in each PDE submitted by a Part D sponsor to CMS, as described in Paragraphs 47 to 49, is Field 17, the "Dispense as Written/Product Selection Code" (DAW Code).

86. The DAW Code indicates whether a generic drug was substituted for a brand-name one, and if not, why no substitution was made.

87. NCPDP has defined ten numbers for filling the DAW Code:

0 = No Product Selection Indicated

1 = Substitution Not Allowed by Prescriber

2 = Substitution Allowed – Patient Requested Product Dispensed

3 = Substitution Allowed – Pharmacist Selected Product Dispensed

4 = Substitution Allowed – Generic Drug Not in Stock

5 = Substitution Allowed – Brand Drug Dispensed as Generic

6 = Override

7 = Substitution Not Allowed – Brand Drug Mandated by Law

8 = Substitution Allowed – Generic Drug Not Available in Marketplace

9 = Other

88. NCPDP's official "value meaning" of DAW "0", which the United States Department of Health and Human Services ("HHS") has adopted, provides: "This is the field default value that is appropriately used for prescriptions where the product selection is not an issue. Examples include prescriptions written for single source brand products and prescriptions written using the generic name and a generic product is dispensed."[1]

89. HHS's definitions of the DAW code values are consistent with those of the pharmaceutical industry, in which it is universally understood that a DAW value of "0" in a prescription drug claim submitted by a pharmacy is appropriate only when an explanation for the product's selection is unnecessary or irrelevant. This is true in only two circumstances: first, when there is no approved generic equivalent available on the market at the time the drug is dispensed; or second, when a generic equivalent does exist and has in fact been substituted.

90. In all other circumstances when a brand-name drug is dispensed, pharmacies must provide another DAW Code to explain why no generic was substituted.

91. CMS has specifically identified as an example of potential pharmacy fraud, waste and abuse the "inappropriate use of dispense as written ("DAW") codes." Centers for Medicare and Medicaid Services, "Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse," Rev.5, 09-26-08 at page 58.

92. On hundreds of occasions, Walgreens pharmacies have utilized a "0" for the DAW Code when, in fact, they themselves have chosen not to substitute a generic under

[1] *See* http://ushik.ahrq.gov/ViewItemDetails?&system=mdr&itemKey=71459000&item=Dispense%20As%20Written%20(DAW)/%20Product%20Selection%20Code_CD&show=details%20view. The Agency for Healthcare Research and Quality (AHRQ) is 1 of 12 agencies within HHS and supports research that helps people make more informed decisions and improves the quality of health care services. AHRQ was formerly known as the Agency for Health Care Policy and Research.

circumstances required by Medicare Part D either through incorporation of state pharmacy law or by contract with the Part D sponsor.

2. Walgreens Has Submitted False Claims For Unsubstituted Brand Drugs Under Medicare Part D and Medicaid

93. Walgreens pharmacies repeatedly have failed to substitute generic drugs for more costly brand-name ones, and have submitted claims for payment to the Medicare Part D program through Part D plan sponsors in violation of State laws and contracts with Part D plan sponsors mandating substitution.

94. Attachment A to this Complaint is a spreadsheet that includes the PDE data Walgreens submitted as required by CMS regulations for pharmacy claims processing, for a sample of 10 prescription drug claims of Fox Part D enrollees (with identifying information redacted). For each of these claims, a brand-name drug was dispensed when Walgreens knew, or should have known that a generic equivalent was available, and that substitution was mandated under the laws of Florida, Hawaii, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Tennessee, and West Virginia. These claims likewise violate Medicare Part D sponsors' contractual provisions mandating generic substitution.

95. For example, Walgreens submitted for payment under Part D claim numbers 4736933 and 15746111, each of which was for a prescription of Cosopt Eye Drops as identified in Attachment A by the brand drug's NDC number (00006362836, Merck & Co.). The prescription for claim number 4736933 was filled by the Walgreens located at 4049 Pine Tree Drive in Miami Beach, Florida on July 22, 2009. The prescription for claim number 15746111 was filled by the Walgreens located at 20340 Old Cutler Road in Miami, Florida on August 11, 2009. At the time these prescriptions were filled, a generic form of Cosopt (Dorzolamide HCI - Timolol Maleate Opthalmic Solution, Hi-Tech Pharma) was available on the market.

96. Claim numbers 4736933 and 15746111 submitted by Walgreens were false in that the DAW code on each of these claims was "0" (i.e., no approved generic equivalent available) despite the fact that Walgreens knew, or was reckless in not knowing, that a much cheaper generic form of Cosopt was available, at the time these prescriptions were filled.

97. Walgreens' failure to substitute the prescribed brand Cosopt for a generic form violated state law mandating such substitution as well as the applicable Federal laws, regulations, and CMS instructions, which expressly conditioned payment upon, among other things, Walgreens' compliance with the state law mandating generic substitution and Medicare's requirements to comply with the state's mandate.

98. For the cases described in Paragraphs 92 to 97 and as set forth in the representative examples in Attachment A, Walgreens failed to accurately report DAW information on the PDE, utilizing a "0" code (for "No Product Selection Indicated") instead of a "3" (for "Substitution Allowed – Pharmacist Selected Product Dispensed"). Had Walgreens identified these decisions accurately, Part D sponsors and CMS would have been able to recognize that Walgreens itself was unlawfully steering patients towards high-cost brand-name drugs.

99. In addition, for all of these cases, Walgreens impliedly certified that the data transmitted to the PDE and submitted in connection with each claim for payment, including the DAW code, not only were accurate, complete and truthful, but also that Walgreens itself had complied the state law mandating generic substitution and Medicare's requirements to comply with the state's mandate.

100. As a result, all such claims so submitted by Fox for reimbursement by Medicare were caused to be false as a result of Walgreens' unlawful conduct in steering patients towards high-cost brand-name drugs.

101. Not only has Walgreens impliedly certified that the information submitted in connection with the claims for payment, including the DAW code, was truthful and complied with state generic substitution laws and Medicare's requirements to follow such laws, by virtue of its Electronic Data Interchange Agreement with CMS, as described above in Paragraph 56, Walgreens also expressly certified, among other things, that the data it transmitted in the PDE was "accurate and complete" to their "best knowledge, information and belief."

102. On information and belief, Walgreens has submitted similar illegal claims to other Medicare Part D sponsors in violation of the laws of the States of Florida, Hawaii, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Washington, and West Virginia.

103. On information and belief, Walgreens has submitted similar claims to the Medicaid programs in the Plaintiff States for beneficiaries who were eligible only for benefits under the Medicaid program.

3. Unnecessary Brand-Name Drugs' Impact on the U.S. Treasury

104. The high cost of brand-name prescription drugs under both the Medicare Part D and Medicaid programs exacts a heavy toll on the United States Treasury.

a. Walgreens' Misconduct Directly Impacted the U.S. and State Treasuries

105. Although the conduct alleged against Walgreens in Paragraphs 92 through 102 occurred in the context of a capitated insurance program, many of the company's false claims directly affected the United States and Plaintiff States' treasuries.

106. A significant portion of Part D enrollees each year qualify to receive additional subsidies from the government because of their low income (i.e., LIS beneficiaries), of which an overwhelming majority reach the annual catastrophic coverage trigger (for 2012, $4,700.00), after which the federal government reinsures the Part D sponsor on an individual enrollee basis against 80% of further prescription drug costs.

107. Consequently, although many Part D enrollees' drug costs are covered by the capitated (per enrollee) premium subsidy, a significant percentage of Part D enrollees have the bulk of their claims individually reimbursed by the federal government through individual catastrophic coverage reinsurance, or through low-income cost-sharing payments.

108. A review of Fox's member population reveals that during the 2009 plan year, there were 19,316 Fox enrollees who had their prescriptions filled by Walgreens, of which 13.87% entered into Catastrophic Coverage. However, within the Fox Walgreens population, 89.71% were LIS eligible; and of those that were LIS eligible, 14.03% entered into Catastrophic Coverage. Out of the total Fox Walgreens population who reached Catastrophic stage, 91% were LIS eligible.

109. The U.S. Treasury is not the only public fisc that has been affected by Walgreen's false claims as the Plaintiff States themselves have similarly suffered due to their responsibility to pay for a portion of the Part D coverage given to dual-eligible patients.

110. This is so because the MMA requires States to pay a portion of the costs associated with providing federal Medicare drug coverage to persons eligible for both Medicare and Medicaid. 42 U.S.C. § 1396u-5(c)(1)(A), (B). If a State fails to make the required payments, commonly referred to as "clawback" payments, the federal government will offset that

amount, plus interest, against Medicaid payments that it otherwise would have made to the State. *Id.* § 1396u-5(c)(1)(C). To this end:

> About 8.8 million elderly and persons with disabilities participate in both the Medicare and Medicaid programs. These "dual eligibles," accounted for only 15 percent of Medicaid enrollment, but just over 40 percent of Medicaid expenditures for medical service prior to the transfer of prescription drugs to Medicare. These same individuals account for over 25 percent of Medicare spending. The duals rely on Medicaid to pay Medicare premiums, cost sharing, and to cover critical benefits not covered by Medicare, such as long-term care. Because dual eligibles have significant medical needs and a much higher per capita cost than other Medicaid beneficiaries, they are a major issue for both Medicare and Medicaid and for both state and federal governments.

Kaiser Commission on Medicaid and the Unisured, *Headed for a Crunch: An Update on Medicaid Spending, Coverage and Policy Heading into an Economic Downturn--Results from a 50 State Medicaid Budget Survey for State Fiscal Years 2008 and 2009* (dated September 2008) at p. 13 (*available at* http://www.kff.org/medicaid/upload/7815.pdf).

111. To demonstrate how the high cost of Walgreens' fraud can be identified and measured, Attachment B summarizes the prescription drug utilization of a small sample of anonymous Part D beneficiaries who had their prescriptions filled by Walgreens. For each prescription, the chart summarizes the cost to each stakeholder: the beneficiary-member (with identifying information redacted), Fox, and the federal government. Each prescription of a brand-name, multisource drug for the beneficiaries during the 2009 plan year is shown, color coded to indicate the phase (initial, donut hole, and catastrophic) of Part D coverage in which it fell. The rightmost columns provide a running total of the costs born by the member, Fox, and the United States Treasury.

112. For enrollees who have reached the level of catastrophic reinsurance, Walgreens caused each and every of the previously alleged false or fraudulent costs to be submitted by Part D sponsors for reimbursement, and Walgreens ultimately received payment.

b. Brand Drugs Cost the Government and the Plaintiff States Large Multiples of the Cost of Their Generic Substitutes

113. Attachment C to this Complaint is a spreadsheet that lists seven sample cases of brand-name drugs for which Walgreens submitted prescription drug claims for Fox Part D enrollees in 2009 for which a generic equivalent was available. In these seven cases, the claim for reimbursement submitted to Medicare Part D for the brand-name prescription drug cost between 15% and 545% more than the generic equivalent.

B. Walgreens Has Dispensed Expired Drugs In Contravention of the Medicare Part D and Medicaid Programs

1. Walgreens Has Submitted Claims for Expired Drugs Under Medicare Part D

114. In many cases, Walgreens has dispensed and submitted claims to Part D sponsors for drugs beyond their NDC Terminate Date, in violation of applicable State laws, and at great cost to the United States Treasury.

115. Attachment D to this Complaint is a spreadsheet listing representative examples that include the PDE data Walgreens submitted as required both by CMS regulations for pharmacy claims processing, and by its contracts with PBMs, for the prescriptions of 10 Fox Part D enrollees for whom Walgreens claims for drugs that were dispensed after the NDC termination date.

116. For example, the Walgreens pharmacy located at 2395 Kennedy Boulevard in Jersey City, New Jersey, submitted for payment under Part D claims for Patient 9's prescriptions

of Spiriva 18 mcg cp Handihaler as identified in Attachment D by the drug's unique NDC number (00597007537) that were filled on November 9 and December 10, 2009, respectively. At the time these prescriptions were filled, the drug had an NDC termination date of July 31, 2008. In other words, the drug had a shelf-life expiration date of July 31, 2008, or was withdrawn from the market for health and safety reasons or the FDA ordered the drug's withdrawal, as of that date – a date that was at least 466 days ***before*** the date these prescriptions were filled. The filling of these prescriptions were therefore improper and in violation of New Jersey's pharmacy law prohibiting the dispensing of expired drugs as well as its obligations as a downstream entity to Fox, which expressly conditioned payment upon, among other things, Walgreens' compliance with the state law prohibiting dispensing drugs that have expired, are obsolete, or are have an inactive NDC number, and Medicare's requirements to comply with such state laws.

2. Walgreens Has Submitted Claims for Expired Drugs Under Medicaid

117. In many cases, Walgreens has submitted claims to State Medicaid programs for drugs dispensed beyond their NDC terminate date, in violation of applicable State laws, and at great cost to the States and the United States Treasury.

118. Attachment D to this Complaint also lists representative examples of claims for payment of prescription drugs that were dispensed after the NDC termination date that Walgreens submitted on behalf of Fox Part D enrollees, who were also eligible for Medicaid (i.e., dual eligibles).

119. For example, the Walgreens pharmacy located at 280 Main Street in Security, Colorado, submitted for payment a claim for Patient 3's prescription of Norvir 100 mg capsules as identified in Attachment D by the drug's unique NDC number (00074663322) that was filled

on December 1, 2009. At the time this prescription was filled, the drug had an NDC termination date of July 1, 2007. In other words, the drug had a shelf-life expiration date of July 1, 2007, or was withdrawn from the market for health and safety reasons or the FDA ordered the drug's withdrawal, as of that date – a date that was 884 days ***before*** the date it was dispensed. The filling of this prescription therefore was improper and in violation of state Medicaid law and/or regulations prohibiting the dispensing of drugs that have expired, are obsolete, or are have an inactive NDC number.

3. Walgreens Benefits from Dispensing Expired Drugs Through Dispensing Fees

120. Walgreens stands to lose revenue by not exploiting the opportunity to earn dispensing fees generated by prescription claims for expired drugs.

121. Under its PBM contracts, Walgreens does not receive dispensing fees on rejected claims. Nor does Walgreens recoup those lost dispensing fees by returning expired drugs to the manufacturer or wholesaler for credit. Instead, these efforts add to Walgreens' administrative costs.

4. Expired Drugs' Impact on the U.S. Treasury

122. The cost of expired drugs under both the Medicare Part D and Medicaid programs exacts a heavy toll on the United States Treasury.

123. Walgreens' dispensation of drugs after their NDC termination date has defrauded the Medicare Part D and Medicaid programs of these drugs' entire cost because claims for such expired drugs are not reimbursable.

124. The Department of Health and Human Services Office of the Inspector General ("HHS-OIG") has identified tens of millions of dollars in improper reimbursement claims for

expired drugs. For example, HHS-OIG has reported the significant amounts of expenditures by Medicaid programs in 14 states – $58,140,937 (Federal share) – for terminated drugs that are not reimbursable under the states' own Medicaid rules. *See* HHS-OIG "Multi-State Review of Centers for Medicare & Medicaid Services Medicaid Drug Expenditure Controls," Oct. 2011 at http://oig.hhs.gov/oas/reports/region7/71006003.pdf.

125. As the examples described in Paragraphs 114-119 and in Attachment D demonstrate, Walgreens submitted claims for Fox enrollees for drugs that were dispensed well after their NDC termination date as defined by CMS.

126. Accordingly, all claims submitted for reimbursement of drugs for Walgreens customers beyond the NDC termination date are improper claims for payment caused by Walgreens.

127. As described above, given the standardized contracts which PBMs use with PDP sponsors and network retail pharmacies, it is beyond doubt that Walgreens submitted similar illegal claims to other Medicare Part D sponsors and State Medicaid programs.

COUNT I – SUBMISSION OF FALSE CLAIMS TO MEDICARE PART D IN VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(A)

128. Plaintiff and Relator repeats each and every allegation of Paragraphs 1 through 127 of this Complaint with the same force and effect as if set forth herein.

129. As a result of the foregoing conduct, Walgreens knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

130. The claims relevant to this Count include all claims for reimbursement of brand-name drugs submitted by Walgreens to Part D plan sponsors from 2006 to the present for beneficiaries in the States of Florida, Hawaii, Kentucky, Massachusetts, Minnesota, Nevada,

New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Washington, and West Virginia, where a generic drug was available and State pharmacy law required it be substituted.

131. The claims relevant to this Count also include all claims for reimbursement of brand-name drugs submitted by Walgreens to Part D plan sponsors where a generic drug was available and the Part D plan sponsor's contract required it be substituted. (Together, the claims described in Paragraphs 130 and 131 are the "Part D Brand Drug Claims.")

132. The claims relevant to this Count also include all claims for reimbursement of drugs submitted by Walgreens which were dispensed after the NDC termination date as defined by CMS, from 2006 to the present for beneficiaries in the District of Columbia and the States of Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island South Carolina, Tennessee, Texas, Utah, Wisconsin, and Wyoming (the "Part D Expired Drug Claims").

133. Walgreens submitted the Part D Brand Drug Claims and the Part D Expired Drug Claims to Part D plan sponsors, including Fox, knowing that those private entities were agents for the federal government, that the prescription drug claims would be submitted by the Part D plan sponsors as Prescription Drug Events (PDE) to CMS, and that in many cases, the federal government would base its payments to Part D plan sponsors on those PDEs.

134. Walgreens' Part D Brand Drug Claims were false as described above in Paragraphs 92-102 because the record information Walgreens submitted in connection with all such claims for payment, including the DAW code, was false.

135. Walgreens' Part D Brand Drug Claims and Part D Expired Drug Claims were false as described above in Paragraphs 92-102 and 114-116, respectively because they violated Walgreens' implied certification of compliance with State law regulating pharmacies.

136. Walgreens' Part D Brand Drug Claims and Part D Expired Drug Claims were false as described above in Paragraphs 92-102 and 114-116, respectively because they violated Walgreens' implied certification of compliance with its contracts with the Part D plan sponsor or its Pharmacy Benefit Manager.

137. Walgreens had knowledge (as defined by the False Claims Act, 31 U.S.C. § 3729(b)(1)(A)) of the Part D Brand Drug Claims' falsity because Walgreens' pharmacies possessed the prescription that did not mandate the use of a brand-name drug, and they knew that a less expensive generic drug was available and that State law or contract required it be substituted.

138. Walgreens had knowledge (as defined by the False Claims Act, 31 U.S.C. § 3729(b)(1)(A)) of the Part D Expired Drug Claims' falsity because the expiration of the drugs Walgreens' pharmacies dispensed was obvious from the drug container, and they knew that State law or contract prohibited those drugs' dispensation.

COUNT II – SUBMISSION OF FALSE CLAIMS TO THE PLAINTIFF STATES' MEDICAID PROGRAMS IN VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(A)

139. Plaintiff and Relator repeats each and every allegation of Paragraphs 1 through 127 of this Complaint with the same force and effect as if set forth herein.

140. As a result of the foregoing conduct, Walgreens knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

141. The claims relevant to this Count include all claims for reimbursement of brand-name drugs submitted by Walgreens to the Plaintiff States' Medicaid agencies from 2002 to the present, where a generic drug was available and State Medicaid law required it be substituted (the "Medicaid Brand Drug Claims").

142. The claims relevant to this Count also include all claims for reimbursement of drugs submitted by Walgreens which were dispensed after the NDC termination date as defined by CMS, from 2006 to the present for beneficiaries in the District of Columbia and the States of Alaska, Arkansas, Illinois, Louisiana, Maine, Michigan, Minnesota, Mississippi, Montana, North Dakota, Oklahoma, Oregon, Tennessee, Virginia, Washington, West Virginia, and Wisconsin (the "Medicaid Expired Drug Claims").

143. Walgreens' Medicaid Brand Drug Claims were false as described above in Paragraph 103 because the record information Walgreens pharmacies submitted in connection with all such claims for payment, including the DAW code, was false.

144. Walgreens' Medicaid Brand Drug Claims and Medicaid Expired Drug Claims were false because they violated State Medicaid laws, as enumerated in Paragraphs 57 and 80, respectively.

145. Walgreens' Medicaid Brand Drug Claims and Medicaid Expired Drug Claims were false as described above in Paragraphs 103 and 117, respectively because they violated Walgreens' implied certification of compliance with State law regulating pharmacies.

146. Walgreens' Medicaid Brand Drug Claims and Medicaid Expired Drug Claims were false as described above in Paragraphs 103 and 117, respectively because they violated Walgreens' implied certification of compliance with its contracts with the Part D plan sponsor or its Pharmacy Benefit Manager.

147. Walgreens had knowledge (as defined by the False Claims Act, 31 U.S.C. § 3729(b)(1)(A)) of the Medicaid Brand Drug Claims' falsity because Walgreens' pharmacies possessed the prescription that did not mandate the use of a brand-name drug, and they knew that a less expensive generic drug was available and that State law or contract required it be substituted.

148. Walgreens had knowledge (as defined by the False Claims Act, 31 U.S.C. § 3729(b)(1)(A)) of the and Medicaid Expired Drug Claims' falsity because the expiration of the drugs Walgreens' pharmacies dispensed was obvious from the drug container, and they knew that State law or contract prohibited those drugs' dispensation.

COUNT III – USE OF FALSE RECORDS AND STATEMENTS MATERIAL TO THE PAYMENT OF FALSE CLAIMS IN VIOLATION OF FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(B)

149. Plaintiff and Relator repeats each and every allegation of Paragraphs 1 through 148 of this Complaint with the same force and effect as if set forth herein.

150. As a result of the foregoing conduct, Walgreens knowingly made, used, or caused to be made or used false records and statements material to false or fraudulent claims paid or approved in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

151. The claims relevant to this Count include all claims for reimbursement of brand-name drugs submitted by Walgreens to Part D plan sponsors from 2006 to the present for beneficiaries in the States of Florida, Hawaii, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Washington, and West Virginia, where a generic drug was available and State pharmacy law required it be substituted.

152. The claims relevant to this Count also include all claims for reimbursement of brand-name drugs submitted by Walgreens to Part D plan sponsors where a generic drug was

available and the Part D plan sponsor's contract required it be substituted. (Together, the claims described in Paragraphs 151 and 152 are the "Part D Brand Drug Claims.").

153. Walgreens submitted the Part D Brand Drug Claims to Part D plan sponsors, including Fox, knowing that those private entities were agents for the federal government, that the prescription drug claims would be submitted by the Part D plan sponsors as Prescription Drug Events (PDE) to CMS, and that in many cases, the federal government would base its payments to Part D plan sponsors on those PDEs.

154. The claims relevant to this Count further include all claims for reimbursement of brand-name drugs submitted by Walgreens to the Plaintiff States' Medicaid agencies from 2002 to the present, where a generic drug was available and State Medicaid law required it be substituted (the "Medicaid Brand Drug Claims").

155. Walgreens' Part D Brand Drug Claims and Medicaid Brand Drug Claims were false as described above in Paragraphs 92-103 because the record information Walgreens submitted in connection with all such claims for payment, including the DAW code, was false. In reliance on that record information, Walgreens caused the submission of claims to the Medicare and Medicaid programs containing false record information material to the United States and Plaintiff States' decision to reimburse all such claims.

156. Walgreens had knowledge (as defined by the False Claims Act, 31 U.S.C. § 3729(b)(1)(A)) of the falsity of the Part D Brand Drug Claims and Medicaid Brand Drug Claims because Walgreens' pharmacies possessed the prescription that did not mandate the use of a brand-name drug, and they knew that a less expensive generic drug was available and must be substituted under State pharmacy and/or Medicaid laws.

157. The claims relevant to this Count also include all claims for reimbursement of drugs submitted by Walgreens which were dispensed after the NDC termination date as defined by CMS, from 2006 to the present for Medicare Part D beneficiaries in the District of Columbia and the States of Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Wisconsin, and Wyoming (the "Part D Expired Drug Claims").

158. The claims relevant to this Count further include all claims for reimbursement of drugs submitted by Walgreens which were dispensed after the NDC termination date as defined by CMS, from 2006 to the present for Medicaid beneficiaries in the District of Columbia and the States of Alaska, Arkansas, Illinois, Louisiana, Maine, Michigan, Minnesota, Mississippi, Montana, North Dakota, Oklahoma, Oregon, Tennessee, Virginia, Washington, West Virginia, and Wisconsin (the "Medicaid Expired Drug Claims").

159. Walgreens' Part D Expired Drug and Medicaid Expired Drug Claims were false as described above in Paragraphs 114-119 because they violated Walgreens' implied certification of compliance with State law and/or Medicaid laws.regulating pharmacies.

160. Walgreens' Part D Expired Drug and Medicaid Expired Drug Claims were false as described above in Paragraphs 114-119 because they violated Walgreens' implied certification of compliance with its contract with the Part D plan sponsor or its Pharmacy Benefit Manager.

161. Walgreens had knowledge (as defined by the False Claims Act, 31 U.S.C. § 3729(b)(1)(A)) of the falsity of the Part D Expired Drug and Medicaid Expired Drug Claims

because the expiration of the drugs Walgreens' pharmacies dispensed was obvious from the drug container, and they knew that State law or contract prohibited it from being dispensed.

COUNT IV – SUBMISSION OF FALSE CLAIMS TO CALIFORNIA'S MEDICAID PROGRAM IN VIOLATION OF CALIFORNIA FALSE CLAIMS ACT, CAL. GOV'T CODE §12651(a)(1), (2)

162. Plaintiff and Relator repeats each and every allegation in the preceding Paragraphs with the same force and effect as if set forth herein.

163. As a result of the foregoing conduct, Walgreens knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval, in violation of the California False Claims Act, Cal. Gov't Code § 12651(a)(1).

164. As a result of the foregoing conduct, Walgreens knowingly made, used, or caused to be made or used false records and statements material to the payment or approval of such false and fraudulent claims, in violation of the California False Claims Act, Cal. Gov't Code § 12651(a)(2).

165. The claims relevant to this Count include all claims for reimbursement of brand-name drugs submitted by Walgreens to the State of California Medicaid agency (Medi-Cal) from 2002 to the present, where a generic drug was available and California's Medicaid law required it be substituted (the "California Brand Drug Claims").

166. Walgreens' California Brand Drug Claims were false because they violated California's pharmacy laws applicable to its Medicaid program, Cal. Admin. Code tit. 22, § 51313.

167. Walgreens had knowledge (as that term is used in the California False Claims Act, Cal. Gov't Code § 12650(b)(3)) of the California Brand Drug Claims' falsity because Walgreens' pharmacies possessed the prescription that did not mandate the use of a brand-name