GEOFFREY S. BERMAN
United States Attorney
By: CHRISTOPHER B. HARWOOD
Assistant United States Attorney
86 Chambers Street, 3rd Fl.
New York, NY 10007
Tel.: (212) 637-2728
Email: Christopher.Harwood@usdoj.gov

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al. ex rel.* MARC D. BAKER, Plaintiffs, v. WALGREENS, INC., Defendant.	12 Civ. 0300 (JPO)

UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. WALGREEN CO., Defendant.	12 Civ. 0300 (JPO)

Plaintiff United States of America ("United States" or "Government"), by its attorney, Geoffrey S. Berman, United States Attorney for the Southern District of New York, brings this action against Walgreen Co. ("Walgreens"), alleging upon information and belief as follows:

PRELIMINARY STATEMENT

1. This is a civil action brought by the United States against Walgreens under the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), and the common law to recover damages sustained by, and civil penalties owed to, the United States based on Walgreens' violation of the FCA in connection with its submission of false claims for reimbursement to Medicaid for prescription drugs that it sold through its Prescription Savings Club program ("PSC program"), a discount drug program.

2. As set forth more fully below, from January 2008 through December 2017 ("Covered Period"), Walgreens violated the FCA by (1) submitting claims to the Medicaid programs of 39 states[1] and the District of Columbia (collectively, "States") in which the prices it identified as the usual and customary ("U&C") prices for certain prescription drugs that it sold through the PSC program were higher than the prices it charged for those drugs pursuant to the PSC program, and thereby (2) obtaining more money in reimbursements from the States' Medicaid programs for sales of such drugs than it was entitled to receive.

3. As a result of this conduct, Walgreens submitted false claims for payment to Medicaid, and it is liable under the FCA and the common law for damages and penalties for those false claims, as discussed in detail below.

---

[1] The 39 states referenced above are Alabama, Alaska, Arkansas, California, Connecticut, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, Washington, and Wisconsin.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the remaining common law claims pursuant to 28 U.S.C. § 1345.

5. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because Walgreens does business in this district and some of the false or fraudulent acts occurred in this district.

PARTIES

6. Plaintiff is the United States of America suing on its own behalf and on behalf of the United States Department of Health and Human Services, and its component agency, the Centers for Medicare and Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which is responsible for overseeing the Medicaid program.

7. Relator was employed by Walgreens as a Pharmacy Manager from April 2001 through December 2011. In January 2012, Relator filed a *qui tam* complaint against Walgreens in the United States District Court for the Southern District of New York, alleging, among other things, that Walgreens violated the FCA by submitting false claims for reimbursement to federal health care programs for prescription drugs that it sold through the PSC program. Relator filed an amended complaint in December 2013.

8. Defendant Walgreens is a nationwide retail pharmacy chain, which during the Covered Period, owned and operated thousands of retail pharmacies located across the United States, including in the Southern District of New York. At various times during the Covered Period, Walgreens submitted false claims for reimbursement to Medicaid for prescriptions drugs sold through the PSC program in the Southern District of New York.

FACTUAL ALLEGATIONS

I. Walgreens' Prescription Savings Club Program

9. Walgreens launched the PSC program in 2007. By 2008, Walgreens was offering the PSC program at its stores across the United States.

10. Throughout the Covered Period, customers who enrolled in the PSC program ("PSC program members") were eligible to receive discounts on thousands of generic and brand-name prescription drugs.

11. The specific drugs for which PSC program members were eligible to receive discounts were identified on Walgreens' PSC program formulary.

12. During the Covered Period, Walgreens offered a savings guarantee pursuant to which PSC program members could recoup (in the form of a store credit) the difference between the amount they paid to enroll in the program in a given year and the amount they received in discounted savings under the program in that year.

II. The Medicaid Program

13. When a physician prescribes a pharmaceutical product to a patient, the patient is provided with a prescription that is filled at a pharmacy. When the patient is a Medicaid beneficiary, the pharmacy then submits a claim for payment to Medicaid for reimbursement.

14. Medicaid is a joint federal-state program created in 1965 that provides healthcare benefits for certain groups, primarily the poor and disabled. Each participating state administers its own Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specified 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 — including the States at issue here — provide reimbursement for prescription drugs.

15. 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. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and can be significantly higher. 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." 42 U.S.C. § 1396b(a)(1).

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

III. Medicaid's Usual and Customary Pricing Requirement

17. During the Covered Period, most states (including the States at issue here) required that, when Walgreens — or any other pharmacy — submitted a claim for

reimbursement in connection with the sale of a prescription drug, the amount that the pharmacy would be reimbursed was to be the lowest of certain price points, one of which was the pharmacy's U&C price for the drug.

18. During the Covered Period, most states (including the States at issue here) had or adopted specific formulations for how pharmacies should identify their U&C prices.

19. Many of the formulations required that, in submitting claims for reimbursement to the States, pharmacies should identify their drug discount program prices as their U&C prices. The following are examples of such formulations:

- ***Alabama.*** In or about October 2006, Alabama issued a Pharmacy Provider Alert that stated, "*In response to pharmacy retailers' recent announcements of reduced prices for specific generic drugs, the Alabama Medicaid agency will consider these reduced prices to be the 'usual and customary' price for these retailers*." Alert Re: Reimbursement for Covered Drugs (emphasis added).

- ***Alaska.*** At all times relevant to this case, Alaska's Administrative Code provided, "Regardless of the payment methodology or payment rate adopted under 7 AAC 105 – 7 AAC 160, and except as provided in 7 AAC 155.010 with regard to tribal health programs, *the department will pay a provider for a covered service at the lowest of the . . . provider's lowest charge that is advertised, quoted, posted, billed, or discounted for any other purchaser of services for that unit of service and provided on the same date*, determined in accordance with (b) of this section." Alaska Admin. Code tit. 7, § 145.020(a) (emphasis added); *see* Alaska Admin. Code tit. 7, § 43.040.

- ***Colorado.*** In or about September 2008, Colorado issued a Medicaid Provider Bulletin, which has been in effect since then and states, "*Pharmacies who offer*

prescription discount programs must use their discounted prices as the usual and customary charge on Medicaid claims. Pharmacies should not submit higher prices on Medicaid claims than prices offered to the general public." Colorado Medicaid Provider Bulletin B0800252 (emphasis added).

- ***Georgia.*** At all times relevant to this case, the Georgia Medicaid Provider Manual stated, "For-profit providers must submit their usual and customary charge when billing the Division for Medicaid prescriptions. The Division defines usual and customary as the lower of the lowest price reimbursed to the pharmacy by other third party payers (including HMO's); *or, the lowest price routinely offered to any segment of the general public*." Georgia Medicaid Provider Manual § 602.1, VI-3 (emphasis added).

- ***Idaho.*** At all times relevant to this matter, Idaho's Medicaid regulations stated, "*A pharmacy's billed charges are not to exceed the usual and customary charges defined as the lowest charge by the provider to the general public for the same service including advertised specials.*" IDAPA 16.03.09.665.03 (emphasis added).

- ***Indiana.*** Since at least March 2009, Indiana's Medicaid Provider Manual has stated, "When billing the program for any covered service, the provider submits only the provider's usual and customary charge to the general public for the covered service. *This includes any special pricing that is offered to the general public, such as $4 generic programs.*" Indiana Health Coverage Programs Provider Manual, Ch. 9, § 4, p. 9-20 (emphasis added).

- ***Maryland.*** At all times relevant to this case, Maryland's Medicaid Provider Manual stated, "It is illegal to submit reimbursement requests for . . . amounts greater than your usual and customary charge for the service. *If you have more than one*

charge for a service, the amount billed to the Maryland Medical Assistance Program should be the lowest amount billed to any person, insurer, health alliance or other payor." Maryland Medicaid Provider Manual at 62 (emphasis added).

- ***Massachusetts.*** During the Covered Period, the Code of Massachusetts Regulations defined "Usual and Customary Charge" as "*[t]he lowest price that a provider charges or accepts from any payer for the same quantity of a drug on the same date of service*, in Massachusetts, including but not limited to the shelf price, sale price, or advertised price for any drug including an over-the-counter drug." 101 Mass. Code Regs. 331.02 (emphasis added).

- ***Nebraska.*** During the Covered Period, Nebraska's Administrative Code provided, "*Any loss leader prices, shelf prices, sale prices, cash only prices, coupon certificates, newspaper or brochure ad prices that are in effect on the date the prescription is dispensed will be considered the pharmacy's usual and customary charge to the general public.*" 471 Neb. Admin. Code 16-005.03A (emphasis added).

- ***Oregon.*** During the Covered Period, the Oregon Administrative Rules defined "Usual and Customary Price" as "a pharmacy's charge to the general public *that reflects all advertised savings, discounts, special promotions, or other programs including membership based discounts initiated to reduce prices for product costs available to the general public, a special population, or an inclusive category of customers*." Or. Admin. R. 410-121-00000(3)(LL) (emphasis added).

- ***Pennsylvania.*** At all times relevant to this case, the Pennsylvania Administrative Code defined "usual and customary charge" as: "The pharmacy's lowest net charge an MA recipient would pay for a prescription as a non-Medicaid patient at the

time of dispensing for the same quantity and strength of a particular drug or product, *including applicable discounts*, such as special rates to nursing home residents, senior citizens, *or other discounts extended to a particular group of patients*." 55 Pa. Code § 1121.2 (emphasis added). In 2012, the phrase "including generic drug discount savings programs" was added to the above language after the phrase "or other discounts extended to a particular group of patients." *Id.* The new language did not reflect a substantive change to prior policy, but rather was meant to "clarify payment for pharmaceutical services that have been in effect under the MA Program, based upon Federal Medicaid requirements and MA payment policies . . . ." 2012 Pa. Reg. Text 289896 (NS).

- ***Tennessee.*** Since at least October 2008, Tennessee's Pharmacy Provider Agreement has included the following definition of the term "Usual and Customary Charge": "The reasonable, usual and customary fees charged by the Pharmacy which do not exceed the fees the Pharmacy would charge any other person regardless of whether the person is a TennCare enrollee, *inclusive of any special marketing or prescription drug programs offered by the Pharmacy*." Network Participation Agreement for Ambulatory and Long Term Care Pharmacy Providers, § 1.1 (emphasis added).

- ***Utah.*** Since at least January 2012, Utah's Medicaid Provider Manual for Pharmacy Services has stated, "*Pharmacies must submit their lowest usual and customary charges to Medicaid, including promotional rates such as $4.00 generics, if they are offered to the general public.*" Utah Medicaid Provider Manual, Pharmacy Reimbursement, § 1-2 (emphasis added).

- ***Vermont.*** Since at least March 2007, the Vermont Medicaid Provider Manual has included the following language: "USUAL AND CUSTOMARY RATE

(UCR) – Various claim forms (1500, UB-92, and 837) require the submission of 'Charge' or 'Total Charges' or 'Charge Amount' to be reported for each service billed. The provider's 'usual and customary charge' or 'uniform charge' is a dollar amount in effect at the time of the specific date or service. This is the amount to be reported on the claim. This usual and customary charge is the amount that the provider bills to insured and private-pay persons for the same service. *If the provider has more than one charge for a service, the lowest charge will be reported to Vermont Medicaid*; except, if the charge has been reduced on an individual basis because of a sliding-fee scale based on the patient's documented inability to pay." Office of Vermont Health Access Provider Manual § 1, p. 9 (emphasis added).

IV. Walgreens Failed to Identify Its PSC Program Prices as its Usual and Customary Prices

20. Throughout the Covered Period, in submitting claims for reimbursement for prescription drugs to the States, Walgreens did not identify its PSC program prices as its U&C prices for the drugs on the PSC program formulary.

21. As a result, the States paid Walgreens more money in reimbursements than they would have paid if Walgreens had identified its PSC program prices as its U&C prices. Walgreens thus received more money in reimbursements from the States than it was entitled to received, and a portion of that money consisted of federal, FMAP funds.

22. Walgreens referred to a transaction in which a customer paid for a prescription drug out of pocket (*i.e.*, without using third-party insurance) as a "cash transaction."

23. The only circumstance in which a customer might pay what Walgreens identified as its U&C price for a drug (in its claims for reimbursement to Medicaid) was in connection with a cash transaction.

24. For Walgreens' cash transactions involving a drug on the PSC program formulary, the price that the customer paid for the drug frequently was less than the price that Walgreens identified as its U&C price for the drug.

FIRST COUNT

Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

25. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

26. The United States seeks relief against defendant under 31 U.S.C. § 3729(a)(1) (2006) and, as amended, 31 U.S.C. § 3729(a)(1)(A).

27. As set forth above, Walgreens violated the FCA by submitting claims for reimbursement to the States in which it failed to identify its PSC program prices as its U&C prices for the drugs on the PSC program formulary. As a result, Walgreens knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

28. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

SECOND COUNT

Violations of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))

29. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

30. The United States seeks relief against defendant under the False Claims Act, 31 U.S.C. § 3729(a)(2)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

31. As set forth above, Walgreens violated the FCA by submitting claims for reimbursement to the States in which it failed to identify its PSC program prices as its U&C prices for the drugs on the PSC program formulary. In connection with these claims, Walgreens knowingly made or used, or caused others to make or use, false records or statements that were material to false or fraudulent claims for payment submitted to the States' Medicaid programs.

32. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

THIRD COUNT

Unjust Enrichment

33. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

34. As set forth above, in submitting claims for reimbursement to the States, Walgreens did not identify its PSC program prices as its U&C prices for the drugs on the PSC program formulary. As a result, the States paid Walgreens more money in reimbursements than they would have paid if Walgreens had identified its PSC program prices as its U&C prices. The circumstances of Walgreens' receipt of this money are such that, in equity and good conscience, Walgreens should not retain the money, the amount of which is to be determined at trial.

WHEREFORE, the United States respectfully requests judgment against Walgreens as follows:

a. On Counts One and Two (FCA), a judgment against Walgreens for treble damages and civil penalties to the maximum amount allowed by law;

b. On Count Three (common law), a judgment for damages to the extent allowed by law.

Dated: December 27, 2018
New York, New York

GEOFFREY S. BERMAN
United States Attorney for the
Southern District of New York

By: /s/Christopher B. Harwood
CHRISTOPHER B. HARWOOD
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Telephone: (212) 637-2728
Facsimile: (212) 637-2786

Attorney for the United States of America