



JOSH STEIN
ATTORNEY GENERAL

STATE OF NORTH CAROLINA
DEPARTMENT OF JUSTICE

SETH DEARMIN
CHIEF OF STAFF

March 19, 2019

North Carolina Senate President Pro Tempore Phil Berger
North Carolina House of Representatives Speaker Tim Moore
Co-Chairs, Joint Legislative Commission on Governmental Operations

Senator Danny Earl Britt, Jr.
Senator Warren Daniel
Senator Norman W. Sanderson
Representative James Boles, Jr.
Representative Ted Davis, Jr.
Representative Allen McNeill
Representative Rena W. Turner
Co-Chairs, Appropriations Subcommittee on Justice and Public Safety

North Carolina General Assembly
Raleigh, North Carolina 27601-1096

RE: G.S. §114-2.5; Report on Settlement Agreement for Walgreens Boots Alliance

Dear Members:

Section 114-2.5 of the North Carolina General Statutes requires the Attorney General to report to the Joint Committee on Governmental Operations and the Chairs of the Appropriations Subcommittees on Justice and Public Safety regarding all settlements and court orders which result in more than \$75,000.00 being paid to the State. Pursuant to that statute, I am writing regarding the settlement of claims for Medicaid reimbursement to the state and federal governments in the above-referenced matter. Pursuant to federal law (42 C.F.R. § 433.320) recoveries in these cases are shared on a pro rata basis by the state and federal governments.

A settlement has been executed between Walgreens Boots Alliance and the State of North Carolina.

The settlement resolves allegations that from January 1, 2006 through December 31, 2017, Walgreens Boots Alliance under-reported the days of supply (*i.e.*, the number of days that insulin pens should last if the patient used insulin strictly according to the prescriber's directions for use);

and that, due to this under-reporting, the federal government and State Medicaid programs paid for more insulin than certain patients needed.

Under the terms of North Carolina's settlement, the State of North Carolina will recover \$2,316,372.93. Of that amount the federal government will receive \$1,327,388.55 for North Carolina's federal portion of Medicaid recoveries. Pursuant to G.S. § 1-610, the qui tam plaintiffs whose whistleblower actions brought this matter to the government's attention will receive \$189,948.93 of North Carolina's recovery. The North Carolina Medicaid Program will receive \$375,815.79 as restitution and interest. In addition, pursuant to Article IX, Section 7 of the North Carolina Constitution and G.S. § 115C-457.1, the penalty portion of the settlement in the amount of \$355,770.65 will be paid to the Civil Penalty Forfeiture Fund for the support of North Carolina public schools. Pursuant to G.S. § 115C-457.2 and G.S. § 1-608(c), the North Carolina Department of Justice will receive \$67,449.01 for investigative costs and costs of collection.

We will be happy to respond to any questions you may have regarding this report.

Very truly yours,



Seth Dearmin
Chief of Staff

SD:ng

cc: John Poteat, NCGA Fiscal Research Division

STATE SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the “Agreement”) is entered into between the State of North Carolina (“the State”) and Walgreens Boots Alliance, Inc. (“Walgreens”), collectively, “the Parties.”

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Walgreens is a Delaware corporation with its principal place of business in Deerfield, Illinois. Walgreen Co., a wholly owned subsidiary of Walgreens, owns a series of retail pharmacies throughout the United States.

B. On July 21, 2015 Adam (a/k/a Azam) Rahimi and S. Christopher Schulte (together, the “Relators”) filed a *qui tam* action in the United States District Court for the Southern District of New York, captioned *United States of America et al., ex rel. Adam Rahimi et al. v. Walgreens Boots Alliance, Inc.*, Civil Action No. 15-CV-5686. The Relators alleged, *inter alia*, that Walgreens engaged in a pattern of submitting false claims to Medicaid that sought payments for more insulin pens of the types relevant here than patients needed in the time periods specified in the claims.¹ On or about November 16, 2018, Relators filed an amended complaint, which did not substantively modify the allegations in their original complaint. This *qui tam* action is referred to as the “Civil Action.”

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

Rahimi Walgreens II

Case # 16-04-01

C. Walgreens entered into a separate civil Stipulation and Order of Settlement and Dismissal (the “Federal Settlement Agreement”) with the United States of America (the “United States”) as that term is defined in the Federal Settlement Agreement.

D. The State alleges that Walgreens caused claims for payment to be submitted to the State’s Medicaid program (42 U.S.C. Chapter 7 Subchapter XIX), including “managed care entities” as defined by 42 U.S.C. § 1396u-2.

E. The State alleges that it has certain civil and administrative causes of action against Walgreens for engaging in the following conduct (the “Covered Conduct”):

From on or about January 1, 2006, to on or about December 31, 2017, Walgreens violated state law by obtaining reimbursement from the State Medicaid program for insulin pen prescriptions based on false claims that under-reported the days of supply (*i.e.*, the number of days that insulin pens should last if the patient used insulin strictly according to the prescriber’s directions for use); and that, due to this under-reporting, the State Medicaid program paid for more insulin than certain patients needed. The conduct described in this paragraph shall be defined as the “Covered Conduct” for purposes of this Agreement.

F. The Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Walgreens admits, acknowledges, and accepts responsibility for the following facts:

- a. Insulin “pens” are a common way for diabetic patients, including federal health program beneficiaries, to self-administer insulin. Manufacturers distribute the insulin pens relevant here in tamper-evident cartons containing five individual pens and with labeling approved by the U.S. Food and Drug Administration (“FDA”). Each pen consists of a syringe, which contains 3 milliliters of insulin solution, inside a hard plastic case.

- b. The FDA classifies the insulin pens relevant here as prescription drug products. Pharmacies can only dispense such pens to patients with valid prescriptions from licensed prescribers. Valid insulin prescriptions must set forth the “directions for use,” which typically designate both how much insulin to administer (e.g., 10 units) and when to administer it (e.g., at bedtime).
- c. At all relevant times, Walgreens’s regular practice was to record the prescribers’ “directions for use” in its electronic pharmacy management system – called Intercom Plus or IC+ – and to print out a copy of those directions for patients when they picked up prescription fills. The “directions for use” for insulin recorded in the IC+ system typically referred to “units” of insulin. For almost all of the insulin pens relevant here (*i.e.*, the types in Exhibit A), one milliliter of insulin solution contains 100 units of insulin; one pen (3 ml) contains 300 units of insulin; and each carton (15 ml) contains 1,500 units of insulin.² Further, Walgreens’s IC+ system recorded the quantity of insulin dispensed by milliliters of insulin solution (*e.g.*, one carton of pens is recorded as 15 ml).
- d. At all relevant times, when Walgreens sought reimbursements for insulin pens from relevant state Medicaid programs, it was required to report, among other data fields, the quantity dispensed and the days of supply. In pharmacy billing, “quantity dispensed” specifies the amount of medication being dispensed to a patient when she fills her prescription, and “days of supply” refers to the number of days that the quantity of medication dispensed should last if the patient uses the medication strictly according to the directions for use. To calculate days of supply, a pharmacist divides the total quantity of medication being dispensed to a particular patient by that patient’s “daily dose,” *i.e.*, the amount of medication that the prescriber directs the patient to use each day.
- e. State Medicaid programs, and/or pharmacy benefit managers (“PBMs”) working on their behalf, typically establish procedures to calculate the date on which a prescription refill would be needed (the “refill due date”) based on the date when a patient last filled a prescription and the days of supply reported by the pharmacy for that prior fill. The state Medicaid programs and/or PBMs also typically establish automated processes to deny refill claims too far in advance of the refill due dates. The reliability of these procedures and processes depends on the accuracy of the days of supply reported by pharmacies.
- f. According to company policy, Walgreens pharmacists generally are not permitted to dispense a refill too far in advance of the refill due date absent a specific reason. The IC+ system was configured to issue a “refill too soon” warning if a

² Certain of the insulin pen products listed in Exhibit A contain higher concentrations of insulin and are marketed in packages that contain fewer than five pens of 3 ml each. For instance, two of the Toujeo and Tresiba insulin pen brands, which were not marketed in the United States until 2015, contain 3 pens each and with higher concentration of insulin units per milliliter of insulin solution, and the Toujeo pens each have a capacity of only 1.5 ml.

patient requested a refill too far in advance of the refill due date, which the IC+ system calculated based on the date of the last fill and the days of supply.

- g. Until early 2018, Walgreens programmed the IC+ system to define a full carton of five pens as the appropriate minimum package size of the relevant types of insulin pens. This definition prevented Walgreens pharmacists from being able to dispense fewer than five pens at a given time.
- h. Walgreens was aware that certain payors – including state Medicaid programs – had established dispensing limits for prescription drug products in terms of quantity and days of supply and that such payors would deny a claim if the reported days of supply exceeded the payor's days of supply limit.
- i. At all relevant times, when a state Medicaid program denied a claim from Walgreens because the reported days of supply for a full carton of five insulin pens exceeded the Medicaid program's days of supply limit, it was Walgreens's practice to dispense and bill for the full carton, and reduce the reported days of supply to conform to the program's days of supply limit. Thus, Walgreens repeatedly reported days of supply data to state Medicaid programs that were different from, and lower than, the days of supply calculated according to the standard pharmacy billing formula of dividing the quantity of insulin being dispensed by the daily dose.
- j. As result of this practice, state Medicaid programs approved and paid a substantial number of claims submitted by Walgreens for insulin pen refills that the programs would not have approved if Walgreens had reported the days of supply for previous fills calculated according to the standard pharmacy billing formula of dividing the quantity dispensed by the daily dose. Specifically, the practice of reducing the reported days of supply without changing the quantity of insulin dispensed prevented the Medicaid programs from calculating reliable refill due dates and checking refill claims against those refill due dates.
- k. Similarly, because the "refill too soon" warning within Walgreens's IC+ system also depended on the accuracy of the reported days of supply, the practice of reporting days of supply for certain insulin pens sales based on payors' days of supply limit, instead of the calculation according to the standard pharmacy billing formula of dividing the quantity dispensed by the daily dose, prevented this warning from functioning effectively to notify pharmacists regarding premature refills.
- l. During the relevant times, Walgreens received audit reports in which PBMs acting on behalf of federal health programs sought refunds for insulin pen prescriptions due to inaccurate days of supply reporting. In early 2018, and after this investigation began, Walgreens modified its IC+ system to provide its pharmacists with the ability to dispense individual insulin pens.

2. Walgreens agrees to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) and subject to the non-participating state deduction provision of sub-paragraph (d) below), collectively, the total amount of \$209,200,000.00 (the "Settlement Amount"), plus interest. The Settlement Amount shall constitute a debt due and owing to the United States and the Medicaid Participating States on the "effective date" of the Federal Settlement Agreement, as defined therein and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States under the following terms and conditions:

(a) As provided in the Federal Settlement Agreement, Walgreens shall pay to the United States the sum of \$168,035,813.56 plus accrued interest pursuant to the terms of the Federal Settlement Agreement, of which \$84,017,906.78, plus 50% of the accrued interest, constitutes restitution to the United States.

(b) The total Medicaid recovery for the Covered Conduct is \$89,185,625.10 consisting of \$41,164,186.44 for the states pursuant to this Agreement and \$48,021,438.66 for the United States pursuant to the Federal Settlement Agreement. Walgreens shall pay to the Medicaid Participating States the sum of \$41,164,186.44 plus accrued interest, which shall be compounded annually, on that amount at the rate of 2.87% commencing on November 20, 2018 and continuing through December 31, 2018 (the "Medicaid State Settlement Amount"). However, if payment is made later than three business days after the date the Federal Agreement is accepted by the Court, additional interest will accrue for each day until paid. The Medicaid State Settlement Amount shall be paid within twenty days of the date the Federal Agreement is accepted by the Court by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the state negotiating team (the "State Team"), which

written instructions shall be delivered to counsel for Walgreens. This electronic funds transfer shall constitute tender and negotiation of the State Amount as defined in Paragraph 2(d) below.

(c) Walgreens shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which Walgreens and the State Team have agreed, or in a form otherwise agreed to by Walgreens and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to Walgreens's attorneys within 60 days of receiving this Agreement. If this condition is not satisfied within 60 days, Walgreens's offer to resolve this matter with the individual State shall become *null and void* absent written agreement between counsel for Walgreens and the State Team to extend the 60-day period.

(d) The total portion of the amount paid by Walgreens in settlement for the Covered Conduct for the State is \$2,314,136.24, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of \$986,747.69 (the "State Amount"), plus applicable interest, of which 50%, or \$493,373.84, plus 50% of the accrued interest, constitutes restitution to the State under Section 162 of the U.S. Internal Revenue Code. If the State does not execute this Agreement within 60 days of receiving this Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall be returned to Walgreens absent written agreement between counsel for Walgreens and the State Team to extend the time-period for executing this Agreement.

3. Contingent upon receipt of the State Amount, the State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against Walgreens or Walgreen Co. in State or Federal Courts for the Covered Conduct including any

supplemental state law claims asserted in the Civil Action. Contingent upon receipt of the State Amount, the State, if served with the Civil Action and otherwise liable to pay a relator's share, agrees to pay the Relators the amount of \$189,948.93 plus applicable interest. This amount is to be paid through the State Team and has been addressed via side letter agreement executed by and between the Relators and the State Team (on behalf of the Medicaid Participating States) in the Civil Action.

4. Subject to the exceptions in Paragraph 5 below, in consideration of the obligations of Walgreens set forth in this Agreement, and conditioned upon tender and negotiation of the State Amount, the State agrees to release Walgreens, including its subsidiaries, divisions, affiliates, corporate predecessors, successors, transferees, heirs, and assigns (collectively, the "Walgreens Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State's Medicaid program as a result of the Covered Conduct.

5. Notwithstanding the releases given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims of the State are specifically reserved and are not released:

- (a) any criminal, civil, or administrative liability arising under state revenue codes;
- (b) any criminal liability;
- (c) any civil or administrative liability that any person or entity, including the Walgreens Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation, or rule not expressly covered by the release in Paragraph 4 above or Paragraph 6 below, including, but not limited to, any and all of the following

claims: (i) State or federal antitrust violations; and (ii) claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability based upon obligations created by this Agreement;

(f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

(g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services, including quality of goods and services;

(h) any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(i) any liability for failure to deliver goods or services due; or

(j) any liability of individuals.

6. In consideration of the obligations of Walgreens set forth in this Agreement, and the Corporate Integrity Agreement (the "CIA") that Walgreens has entered into with the Office of the Inspector General of the United States Department of Health and Human Services in connection with this matter, and conditioned on receipt by the State of the State Amount, the State agrees to release and refrain from instituting, recommending, directing, or maintaining any administrative action seeking exclusion from the State's Medicaid program against Walgreens Released Entities for the Covered Conduct, except as reserved in Paragraph 5 above. Nothing in this Agreement precludes the State from taking action against Walgreens in the event that Walgreens is excluded by the federal government, or for conduct and practices other than the Covered Conduct.

7. Walgreens waives and shall not assert any defenses it may have to criminal prosecution or administrative action for the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the U.S. Constitution or the Excessive Fines Clause of the Eighth Amendment of the U.S. Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

8. In consideration of the obligations of the State set forth in this Agreement, the Walgreens Released Entities waive and discharge the State and any of its agencies, departments, and personnel, including, but not limited to, officials, employees, and agents, whether current or former in their official and individual capacities from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Walgreens Released Entities have against the State and any of its agencies, departments, and personnel, including, but not limited to officials, employees, and agents, whether current or former in their official and individual capacities arising from the State's investigation and prosecution of the Covered Conduct.

9. The amount that Walgreens must pay to the State pursuant to Paragraph 2. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid program, or any other state program payor, for the Covered Conduct; and Walgreens agrees not to resubmit to the State's Medicaid program or any other state program payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of, or not to appeal or cause the appeal of, any such denials of claims.

10. Walgreens agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents,

sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

11. Walgreens expressly warrants that it has reviewed its financial condition and that it is currently solvent, meaning that a fair valuation of its property (exclusive of exempt property) exceeds the sum of its debts.

12. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

13. Walgreens agrees to cooperate fully and truthfully with any investigation by the State related to the Covered Conduct of individuals or entities not released in this Agreement. Upon reasonable notice of such an investigation, Walgreens shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals and of Walgreens. Upon request, Walgreens agrees to furnish to the State complete and unredacted copies of all non-privileged documents including, but not limited to, reports, memoranda of interviews, and records in its possession, custody or control, concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

14. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

15. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any liability as to any other person or entity.

16. Except as identified in Paragraph 2(d), nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

17. In addition to all other payments and responsibilities under this Agreement, Walgreens agrees to pay the State Team's reasonable expenses and fees, including travel costs, consultant expenses, and administrative fees. Walgreens will pay this amount by separate check or wire made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

18. This Agreement is governed by the laws of the State, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions of the CIA, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

19. The undersigned Walgreens signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

20. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles and electronic transmissions of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

21. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

22. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

23. This Agreement may be executed in counterparts, each of which shall constitute an original, and all of which shall constitute one and the same Agreement.

24. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by the Parties to this Agreement and shall not, therefore, be construed against any of the Parties for that reason.

STATE OF NORTH CAROLINA

By: F. Edward Kirby, Jr.

F. Edward Kirby, Jr.
Director, Medicaid Investigations Division
Office of the Attorney General

Dated: 1-24-19

By: DAVE RICHARD

DAVE RICHARD
Deputy Secretary, NC Medicaid
Division of Health Benefits

Dated: 1/15/2019

WALGREENS BOOTS ALLIANCE, INC.

PRW By: Elena Kraus
ELENA KRAUS
Senior Vice President & General Counsel
Walgreen Co.

DATED: December 21, 2018
Deerfield, Illinois

DEBEVOISE & PLIMPTON LLP

By: _____
JOHN KIERNAN, ESQ.
KRISTIN KIEHN, ESQ.
919 Third Avenue
New York, NY 10022

ROPES & GRAY LLP

By: _____
STEPHEN A. WARNKE, ESQ.
LAURA HOEY, ESQ.
1211 Avenue of the Americas
New York, NY 10036

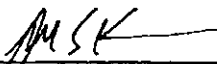
DATED: December __, 2018
New York, New York

WALGREENS BOOTS ALLIANCE, INC.

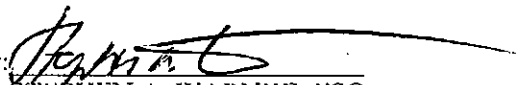
By: _____
ELENA KRAUS
Senior Vice President & General Counsel
Walgreen Co.

DATED: December __, 2018
Deerfield, Illinois

DEBEVOISE & PLIMPTON LLP

By:  _____
JOHN KIERNAN, ESQ.
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919 Third Avenue
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ROPES & GRAY LLP

By:  _____
STEPHEN A. WARNKE, ESQ.
LAURA HOEY, ESQ.
1211 Avenue of the Americas
New York, NY 10036

DATED: December 21, 2018
New York, New York

Exhibit A
Insulin Pen Brands Relevant to the Agreement

Brand Name	National Drug Code
APIDRA	00088250205
HUMALOG	00002771227
HUMALOG	00002879759
HUMALOG	00002879859
HUMALOG	00002879959
HUMALOG	00002751659
HUMALOG	00002872559
HUMALOG	00002879459
HUMULIN	00002880359
HUMULIN	00002882427
HUMULIN	00002880559
LANTUS	00088221905
LANTUS	00088222052
LANTUS	00088222060
LEVEMIR	00169643910
LEVEMIR	00169643810
NOVOLOG	00169369619
NOVOLOG	00169633910
NOVOLOG	00169330312
TOUJEO	00024586903
TRESIBA	00169255013
TRESIBA	00169266015