

SETTLEMENT AGREEMENT

This Settlement Agreement is made and entered into this 7th day of August, 2015 by and between the United States Attorney's Office for the District of Rhode Island, acting on behalf of the United States, the Drug Enforcement Administration ("DEA"), Providence Resident Office and CVS Health and all of its subsidiaries, entities, and affiliates, to the extent of their existence as a component or affiliate of CVS Health during the time period provided of the DEA Investigation as defined in Recital Paragraph I, herein (collectively "CVS") (each a "Party" and collectively the "Parties").

I. Recitals

A. CVS Health is a Delaware corporation with its corporate headquarters in Woonsocket, Rhode Island. CVS Health, directly or through its retail pharmacy subsidiaries and affiliates, and through its CVS/pharmacy division, operates retail pharmacies in the State of Rhode Island that dispense prescription drugs, including controlled substances, to retail consumers (hereafter referred to as "CVS/pharmacy retail stores").

B. Each CVS/pharmacy retail store in Rhode Island is separately registered with DEA and is assigned a unique DEA registration number that authorizes it to dispense controlled substances pursuant to the provisions of the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* ("the Act"), and its implementing regulations. The CVS/pharmacy retail stores physically located in the State of Rhode Island will be referred to collectively herein as "Rhode Island CVS/pharmacy retail stores."

C. Pharmacies registered with DEA as chain pharmacies are permitted to dispense prescriptions, including controlled substances.

D. CVS acknowledges that all of its DEA-registered CVS/pharmacy retail stores were and are required to comply with the CSA and the regulations promulgated thereunder.

E. The Act, specifically 21 U.S.C. § 842(a), forbids dispensing drugs on Schedules II through IV without a prescription that conforms to, *inter alia*, two requirements: first, that the prescription be issued for a “legitimate medical purpose in the usual course of professional practice . . . by a practitioner,” 21 U.S.C. § 829(e)(2)(A), and (2) that the issuing practitioner be “licensed by law to administer such drug.” 21 U.S.C. § 353(b); *see also* 21 C.F.R. § 1306.03(a)(1). A prescription that does not satisfy these criteria is not a valid prescription within the meaning of the Act.

F. CVS acknowledges that it has a corresponding responsibility to dispense only those prescriptions that have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and that knowingly filling a prescription not issued in the usual course of professional treatment or by a prescriber not licensed to prescribe the substance dispensed subjects the pharmacy filling the prescription to penalties under the Act. 21 C.F.R. § 1306.04.

G. In addition, the Act requires that individuals and entities registered to prescribe, administer or dispense controlled substances observe various recordkeeping requirements with respect to those substances, including but not limited to accurately labelling controlled substance prescriptions that are dispensed to patients and consumers. 21 U.S.C. § 842 (a)(5) and 21 C.F.R. § 1306.24.

H. At all times relevant to this agreement, the Act authorized the imposition of civil penalties and/or administrative sanctions for each of the categories of Covered Conduct as described in Recital Paragraph J below

I. Between October 18, 2013 and March 2, 2015, the DEA Providence Resident Office conducted an investigation into CVS' dispensing of prescriptions from Rhode Island CVS/pharmacy retail stores (the "DEA Investigation").

J. The United States contends that it has certain civil and administrative claims under the Act and its implementing regulations based on CVS' conduct at its Rhode Island CVS/pharmacy retail stores between March 3, 2010 and the date of this agreement, which conduct was the subject of the DEA Investigation, to wit:

- (1) Filling prescriptions with invalid prescriber DEA numbers, or under circumstances where the pharmacist filling the prescription knew or had reason to know that the prescription in question was invalid or unauthorized, in violation of 21 U.S.C. § 842 (a)(1) and CVS' corresponding responsibility pursuant to 21 C.F.R. § 1306.04;
- (2) Filling prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by the terms of their DEA registration to issue such prescriptions, in violation of 21 U.S.C. § 842 (a)(1) and 21 C.F.R. § 1306.03(a)(1);
- (3) Entering, creating, or maintaining CVS dispensing records, including prescription vial labels, in which the DEA registration numbers of non-prescribing practitioners, including non-prescribing practitioners who were not legally authorized to prescribe the substances dispensed, were substituted for the DEA registration numbers of prescribing practitioners, in violation of 21 U.S.C. § 842 (a)(5) and 21 C.F.R. § 1306.24.

The conduct described above in this paragraph is hereinafter referred to as the "Covered Conduct".

K. CVS denies that any provision of the Act and the regulations thereunder have been violated, or that it is liable to the United States.

L. The United States and CVS desire to reach a mutual agreement that settles, compromises, and resolves all claims based on alleged violations of the Act identified in the

course of the DEA Investigation, without any admission of liability or wrongdoing in this or any other proceeding, in order to avoid the delay, uncertainty, and expense of litigation.

II. Terms of Agreement

In accordance with the mutual covenants and agreements herein, and with full authority to enter into this Settlement Agreement and to be bound thereby, the United States, through the Office of the United States Attorney for the District of Rhode Island and its Drug Enforcement Administration, Providence Resident Office, and CVS agree as follows:

1. CVS shall pay the United States the sum of FOUR HUNDRED AND FIFTY THOUSAND DOLLARS (\$450,000.00) (the "Settlement Amount"), which shall be paid within five business days of the execution of this Settlement Agreement by all parties. The payment described in this Settlement Agreement is made in compromise of disputed claims and is not an admission and/or acknowledgment by CVS of liability and/or wrongdoing, nor by the United States or the DEA that their claims are not well founded.

2. Payment of the Settlement Amount shall be by electronic funds transfer in accordance with written instructions from the Office of the US Attorney, with written notice to said Office at the time of payment.

3. In exchange for, and in consideration of, the foregoing, including specifically CVS' agreement to pay the United States the Settlement Amount, the United States agrees to settle, release, and relinquish all civil and administrative claims, causes of action, suits, debts, in law or equity, against CVS based upon the Covered Conduct as described in Recital Paragraph J.

4. This Settlement Agreement, and the conditions contained herein, in no way alters or restricts the United States' rights to enforce the Act and regulations promulgated thereunder by commencing an administrative or civil action against CVS for any violations of the Act which do

not arise out of the Covered Conduct identified in this Settlement Agreement, or for any violations which occur after the date of the signing of this Settlement Agreement.

5. In addition to the foregoing, specifically reserved and excluded from the scope and terms of this agreement and the release it provides are the following:

- a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Any civil or administrative liability to the United States (or its agencies) for any conduct other than the Covered Conduct, and/or any civil or administrative liability to the United States for conduct outside the District of Rhode Island;
- d. Any liability based upon such obligations as are created by this Settlement Agreement.

6. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

7. This Agreement binds and is intended to benefit only the Parties. This Agreement is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein. This Agreement is specifically limited to the Office of the United States Attorney for the District of Rhode Island and the DEA for the Providence Resident Office and cannot bind other federal, state, or local authorities and jurisdictions.

8. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

9. Each Party and signatory to this Agreement represents that he, she, or it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

10. The parties agree that any dispute regarding this Settlement Agreement shall be filed and heard in the United States District Court for the District of Rhode Island, including but not limited to any proceeding to enforce the terms of this Settlement Agreement, and no party shall challenge the jurisdiction or venue of that Court over such proceedings.

11. CVS fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which CVS could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct, or arising from the DEA Investigation and resolution of claims based upon the Covered Conduct.

12. This document contains the entire agreement between CVS and the United States regarding the claims at issue herein.

13. This Settlement Agreement shall become final and binding only upon signing by all parties hereto.

14. This Settlement Agreement may be executed in one or more counterparts, each of which shall constitute an original and all of which shall together constitute one and the same agreement, and for purposes of this agreement, facsimile signatures shall be treated as equivalent to originals.

15. This Settlement Agreement may only be modified by a writing signed by both parties.

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16. Nothing in this Settlement Agreement or elsewhere shall be deemed to render this agreement confidential or otherwise exempt or restricted from public disclosure.

FOR THE UNITED STATES:

Dated: Providence, Rhode Island

Aug. 7, 2015

PETER F. NERONHA
United States Attorney
50 Kennedy Plaza, 8th Floor
Providence, RI 02903

By: 

Zachary A. Cunha
Bethany N. Wong
Assistant U.S. Attorneys
(401) 709-5000

FOR CVS:

Dated: Woonsocket, Rhode Island

July __, 2015

CVS HEALTH
One CVS Drive
Woonsocket, RI 02895

Elizabeth S. Ferguson
Senior Vice President & Assistant General Counsel

Nancy Coffey
DEA Diversion Program Manager
New England Field Division

Michael J. Ferguson
DEA Special Agent in Charge
New England Field Division

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