#### SETTLEMENT AGREEMENT

## I. PARTIES

This Settlement Agreement ("Settlement Agreement") is entered into by and between (i) the United States of America, acting through the United States Attorney's Office for the Eastern District of California, on behalf of the Drug Enforcement Administration ("DEA") (collectively, the "United States"); (ii) The Medicine Chest, LLC (also referred to as The Medicine Chest Pharmacy DEA #FT6916576) ("Medicine Chest" or "the Pharmacy"); and (iii) Diane Muller in her individual capacity and as the sole member of the Medicine Chest ("Muller"). The United States, Medicine Chest, and Muller are collectively referred to herein as "the Parties," and each is individually referred to as a "Party."

### II. PREAMBLE

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

A. Medicine Chest was, at all times pertinent to this agreement, a small family pharmacy in which Diane Muller (the "Owner") is the sole member and comprised of a single location at 1300 N. Fresno St. Suite 200B, Fresno California, in the Eastern District of California. During 2018-19, the Medicine Chest dispensed prescription drugs at its Fresno Street facility.

B. At all times pertinent to the agreement, Medicine Chest was required to conduct its operations in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 et seq. ("the CSA"), and the regulations promulgated thereunder.

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C. The DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating violations of the CSA.

D. The United States Attorney General, through the United States Attorney's Office, has primary authority to bring civil actions to enforce the CSA in this District. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

E. In September 2018, pursuant to 21 U.S.C. § 822(f), DEA investigators from the DEA Fresno Resident Office conducted an administrative audit and investigation of Medicine Chest. The accountability audit revealed that the Pharmacy: failed to complete an initial inventory when issued a DEA registration, as required by 21 C.F.R. §1304.11 (b); had inaccurate records in violation of 21 C.F.R. §§1304.21 (a), and 1304.22 (c), (a)(2)(i), (ii), (iv); had dispensed controlled substances using the wrong DEA Registration Number / prescriber's name, contrary to the requirements of 21 C.F.R. § 1304.21 (a); had failed to enter the "quantity received" and "date received" fields on DEA-222 forms as required by 21 C.F.R. § 1305.13 (e); had filled at least 1 prescription not manually signed by the prescriber, as required by 21 C.F.R. § 1306.05 (d); had filled or dispensed prescriptions that lacked information required under California Health & Safety Code § 11164 (a)(1); *see also* 21 C.F.R. § 1306.06 and 21 U.S.C. § 842 (a)(2); and had failed to document the date on which controlled substances were received on invoices for schedule III – V drugs in violation of 21 C.F.R. § 1304.21 (a) and (d).

F. As a result of DEA's investigation, the United States contends that Medicine Chest has committed multiple violations of the CSA, including a violation of 21 U.S.C. § 842(a)(1) and multiple violations of 842(a)(5).

G. At all times relevant to the activity alleged herein, the CSA authorized a civil
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penalty for each violation of § 842(a)(1) and each violation of § 842(a)(5). 21 U.S.C. § 842(c)(1)(A).

H. The United States' claims and allegations against Medicine Chest as set forth herein shall hereinafter be referred to as the "Covered Conduct," which includes the matters referenced in Paragraphs E and F above.

I. This Settlement Agreement is not an admission of liability by Medicine Chest or anyone else for civil penalties under the CSA or for the Covered Conduct.

J. However, Medicine Chest acknowledges that on some occasions during the period between January 2016 and the present, it unintentionally maintained records of controlled substances in a manner not fully consistent with Medicine Chest's compliance obligations under the CSA and its implementing regulations.

K. To avoid the delay, uncertainty, inconvenience, and expense of litigation, the Parties mutually desire to reach a full and final settlement of this matter pursuant to the Terms and Conditions set forth below.

**NOW, THEREFORE**, in consideration of the mutual promises, covenants, conditions, terms, and obligations set forth in this Settlement Agreement, the Parties agree to settle this matter as follows:

#### III. TERMS AND CONDITIONS

1. In consideration of the obligations of the Parties set forth in this Settlement Agreement, Medicine Chest agrees to pay the total sum of twenty-seven-thousand five-hundred dollars (\$27,500.00) (the "Settlement Amount") to the United States, and Owner agrees to the sale terms set forth below and to limit her ownership interest in any other pharmacy as follows: a) Payment of the full Settlement Amount shall be made to the United States within thirty (30) days of the execution of this settlement agreement;

b) Payments shall be made to the United States by electronic funds transfer, pursuant to written instructions to be provided by the United States Attorney's Office for the Eastern District of California.

c) Owner shall consummate the sale of certain pharmacy assets of the Medicine Chest, divesting herself of all ownership interest therein, to another person or entity with no prior familial or personal relationship with Owner, and/or cease operating as a pharmacy within 180 days of this agreement and promptly notify the United States Attorney for the Eastern District of California when the sale, divestiture and/or cessation of operation is complete.

d) Owner agrees that she shall not maintain an ownership interest in any pharmacy for a period of five years. For the avoidance of doubt, this paragraph is not intended to restrict Owner's ability to own common stock or other non-controlling, non-management, ownership or shares in a publicly traded corporation. In addition, nothing in this Settlement Agreement is intended to affect in any way Muller's ability to continue to work as a pharmacy technician or other non-management capacity at a pharmacy not owned by Muller.

2. Subject to the exceptions in Paragraph 3 below concerning excluded claims, in consideration of the obligations of Medicine Chest in this Settlement Agreement, and conditioned upon the full payment of the Settlement Amount, the Owner's compliance with Paragraph 1(c) as set forth herein, and full compliance with all terms and conditions of this agreement, the United States (on behalf of itself, its officers, agents, agencies, and departments) hereby fully and finally releases the Owner, and Medicine Chest and its current and former officers, directors, employees, members, contractors and consultants, divisions, affiliates, agents, Medicine Chest Settlement Agreement - Page **4** of **9** 

direct or indirect parent corporations, direct or indirect subsidiaries, direct or indirect brother or sister corporations, and the successors or assigns of any of them from any and all liability for violations of the CSA, and the regulations promulgated thereunder, known or unknown, arising out of the Covered Conduct occurring prior to the effective date of this Agreement.

3. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement as to any entity or person, including Medicine Chest and the Owner, are the following potential claims of the United States:

a) Any civil, criminal, or administrative liability arising under Title 26,
United States Code (Internal Revenue Code);

b) Any criminal liability;

c) Any claim by the United States (or its agencies) not arising out of or related to the Covered Conduct within the DEA Fresno Resident Office Area of Responsibility ("AOR")<sup>1</sup>; and

Any liability based upon such obligations as are created by this Settlement
Agreement.

4. As additional consideration for this Settlement Agreement, Medicine Chest hereby fully and finally releases the United States and its employees, servants, agents, agencies, and departments from any and all liability for any known or unknown civil claims, demands, obligations, actions, causes of action, damages, costs, losses, attorneys' fees, interest, and expenses, including any claims for compensatory or punitive damages, which Medicine Chest has or may have with respect to the Covered Conduct, including without limitation concerning

<sup>&</sup>lt;sup>1</sup> The Fresno AOR includes the counties of Calaveras, Tuolumne, Stanislaus, Merced, Mariposa, Madera, Fresno, Kings, Tulare, Inyo, and Kern.

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the United States' investigation and litigation of its claims.

5. Except as otherwise stated herein, each Party to this Settlement Agreement shall bear its own costs, attorneys' fees, and other expenses incurred in any manner in connection with the investigation, litigation, and resolution of this matter, including the preparation and performance of this Settlement Agreement.

6. Medicine Chest agrees that any and all costs it has or will incur in connection with this matter—including payment of the Settlement Amount, attorneys' fees, costs of investigation, negotiation, and remedial actions to be taken following the effective date of this Agreement—shall be unallowable costs for government contract accounting and for Medicare, Medicaid, TRICARE, and FEHBP reimbursement purposes.

7. Except as provided in paragraphs 2 and 4, this Settlement Agreement is intended to be for the sole benefit of the Parties only. The Parties do not release any claims against any other person or entity not expressly released by this Settlement Agreement.

8. Each individual signing this Settlement Agreement on behalf of Medicine Chest represents and warrants that he or she has the power, consent, and authorization of Medicine Chest to execute this Settlement Agreement.

9. The individuals signing on behalf of the United States represent that they are signing this Settlement Agreement in their official capacities and that they are authorized to execute this Settlement Agreement.

10. Each Party represents and warrants that it has not transferred any claim being released under this Settlement Agreement, and is not aware of any such transfer, and that the Party is not aware of any prohibition of any type that prevents the Party from performing the terms of this Settlement Agreement.

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

12. Each Party warrants that it has been represented by, and has sought and obtained the advice of, independent legal counsel with regard to the nature, purpose, and effect of this Settlement Agreement. The Settlement Agreement was negotiated by the Parties and their respective counsel, each of whom had the opportunity to participate in the drafting thereof. The Parties hereby declare that the terms of this Settlement Agreement have been completely read, fully understood, and voluntarily accepted following opportunity for review by legal counsel of their choice.

13. Each of the Parties warrants and represents that it freely and voluntarily enters into this Settlement Agreement without any degree of duress or compulsion whatsoever, after having been apprised of all relevant information and data by its legal counsel. Each of the Parties further warrants and represents that no other Party or its representative has made any promise, representation or warranty, express or implied, except as expressly set forth in this Settlement Agreement, and that no Party has relied on any inducements, promises, or representations made by any Party to this Settlement Agreement, or its representatives, or any other person, except as expressly set forth herein.

14. For purposes of construction, this Settlement Agreement shall be deemed to have been drafted by all Parties to this Settlement Agreement. The words of this Settlement Agreement shall not, therefore, be construed against any Party for that reason in any subsequent dispute, but shall be construed so as to effect their fair meaning, the Parties having waived the benefit of California Civil Code § 1654 and similar laws.

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15. The Parties consent to the public disclosure of this Settlement Agreement, and of information about this Settlement Agreement.

16. This Settlement Agreement constitutes the complete agreement between the Parties, and supersedes and replaces all prior negotiations and agreements, whether written or oral, regarding the resolution of the claims between the Parties with respect to the subject matter hereof.

17. This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which taken together shall constitute one valid and binding Settlement Agreement between the Parties.

18. This Settlement Agreement may not be altered, amended, or modified, except by a writing duly executed by authorized representatives of all Parties.

19. This Settlement Agreement is governed by the laws of the United States. The Parties agree that, should any judicial action be required to enforce or interpret this Settlement Agreement, or to resolve any dispute hereunder, the exclusive jurisdiction and venue for such action shall be in the United States District Court for the Eastern District of California.

20. This Settlement Agreement is effective, final, and binding as of the date of signature of the last signatory to the Settlement Agreement. Transmittal and receipt of facsimiles or PDF versions of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

21. All Parties agree to cooperate fully and to execute any and all supplementary documents and to take all additional actions that may be necessary or appropriate to give full force and effect to the terms and intent of this Settlement Agreement.

22. The statements set forth in Sections I and II of this Settlement Agreement are incorporated by reference herein as if set forth in full.

# THE UNITED STATES

Dated: 10 4 19

MCGREGOR W. SCOTT United States Attorney

By:

Geoffrey D. Wilson Assistant United States Attorney Attorneys for the United States

# MEDICINE CHEST

Dated: 10-2-19

The Medicine Chest, LLC

By: Diane Muller Its: Sole Member

#### DIANE MULLER

Dated:  $10^{2}$ 

Diane Muller In her individual capacity

# APPROVED AS TO FORM

Dated: 10-2-2019

By:

William C. Hahesy, Esq. Law Office of William C. Hahesy Attorney for The Medicine Chest, LLC

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