BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

I.MC16, INC. dba R & X COMPOUNDING PHARMACY,
YOUNG SOOK CHOI, OWNER

Pharmacy Permit No. PHY 50776, and

YOUNG SOOK CHOI,

Pharmacist License No. RPH 41950,

Respondents

Agency Case No. 5922

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 29, 2020.

It is so ORDERED on June 29, 2020.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Greg Lippe
Board President

XAVIER BECERRA
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General
NANCY A. KAISER
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **I.MC16, INC. DBA R & X COMPOUNDING PHARMACY, YOUNG SOOK CHOI, OWNER** **3680 Wilshire Blvd, #106** **Los Angeles, CA 90010** **Permit No. PHY 50776,** **and** **YOUNG SOOK CHOI** **500 S. Lake St. #301** **Los Angeles, CA 90057** **Pharmacist License No. RPH 41950** Respondents.	Case No. 5922 OAH No. 2019120823 **STIPULATED SURRENDER OF LICENSE AND ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Nancy A. Kaiser, Deputy Attorney General.

2. I.MC16, Inc. dba R & X Compounding Pharmacy and Young Sook Choi (Respondents) are represented in this proceeding by attorney Herbert L. Weinberg, whose address is: Fenton Law Group, LLP, 1990 S Bundy Drive, Suite 777, Los Angeles, CA 90025.

3. On or about July 19, 2012, the Board issued Permit No. PHY 50776 to I.MC16, Inc. dba R & X Compounding Pharmacy, Young Sook Choi, Owner (Respondent Pharmacy). The Pharmacy Permit expired on July 1, 2016, and has not been renewed.

4. On or about August 5, 1988, the Board issued Original Pharmacist License Number RPH 41950 to Young Sook Choi (Respondent Choi). The license was in full force and effect at all times relating to charges brought herein and will expire on December 31, 2021, unless renewed.

JURISDICTION

5. Accusation No. 5922 was filed before the Board and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on May 17, 2019. Respondent timely filed their Notice of Defense contesting the Accusation. A copy of Accusation No. 5922 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation No. 5922. Respondents also have carefully read, fully discussed with counsel, and understand the effects of this Stipulated Surrender of License and Order.

7. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

9. Respondents admit the truth of each and every charge and allegation in Accusation No. 5922, agree that cause exists for discipline, and hereby surrender their Pharmacy Permit and Pharmacist License for the Board's formal acceptance.

10. Respondents understand that by signing this stipulation they enable the Board to issue an order accepting the surrender of their Pharmacy Permit and Pharmacist License without further process.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 50776, issued to Respondent I.MC16, Inc. dba R & X Compounding Pharmacy, Young Sook Choi, Owner, and Pharmacist License No. RPH 41950, issued to Young Sook Choi, are surrendered and accepted by the Board of Pharmacy (Board).

1. The surrender of Respondents' Pharmacy Permit and Pharmacist License and the acceptance of the surrendered permit and license by the Board shall constitute the imposition of discipline against Respondents. This stipulation constitutes a record of the discipline and shall become a part of Respondents' license history with the Board.

2. Respondent I.MC16, Inc. dba R & X Compounding Pharmacy shall lose all rights and privileges as a pharmacy in California as of the effective date of the Board's Decision and Order.

3. Respondent Young Sook Choi shall lose all rights and privileges as a pharmacist in California as of the effective date of the Board's Decision and Order.

4. Respondents shall cause to be delivered to the Board their respective pocket licenses and their wall certificates on or before the effective date of the Decision and Order.

5. If Respondents ever file an application for licensure or a petition for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondents stipulate that should they apply for any license from the Board on or after the effective date of this decision, all allegations set forth in the Accusation shall be deemed to be true, correct and admitted by Respondents when the Board determines whether to grant or deny the application. Respondents shall satisfy all requirements applicable to that license as of the date the application is submitted to the Board, including, but not limited to taking and passing the California Pharmacist Licensure Examination prior to the issuance of a new license. Respondents are required to report this surrender as disciplinary action. Respondents may not apply for any license, permit, or registration from the board for three years from the effective date of this decision.

6. Respondents shall pay the agency its costs of investigation and enforcement in the amount of $55,572.75 prior to issuance of a new or reinstated license.

7. If Respondents should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation No. 5922 shall be deemed to be true, correct, and admitted by Respondents for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Herbert Weinberg. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED:

_____

By: Young Sook Choi
Its: _____
I.MC16, INC. DBA R & X COMPOUNDING PHARMACY
Respondents

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED:

_____

YOUNG SOOK CHOI
Respondents

6. Respondents shall pay the agency its costs of investigation and enforcement in the amount of $55,572.75 prior to issuance of a new or reinstated license.

7. If Respondents should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation No. 5922 shall be deemed to be true, correct, and admitted by Respondents for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Herbert Weinberg. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

By: Young Sook Choi
Its: _____
I.MC16, INC. DBA R & X COMPOUNDING PHARMACY
Respondents

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

YOUNG SOOK CHOI
Respondents

I have read and fully discussed with Respondents I.MC16, Inc. dba R & X Compounding Pharmacy and Young Sook Choi the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: _____

HERBERT L. WEINBERG
Attorney for Respondents

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General

NANCY A. KAISER
Deputy Attorney General
Attorneys for Complainant

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I have read and fully discussed with Respondents I.MC16, Inc. dba R & X Compounding Pharmacy and Young Sook Choi the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 5/8/2020

HERBERT L. WEINBERG
Attorney for Respondents

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 5/8/2020

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General

Nancy Kaiser

NANCY A. KAISER
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5922

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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **I.MC16, INC. DBA R & X COMPOUNDING PHARMACY, YOUNG SOOK CHOI, OWNER** **3680 Wilshire Blvd, #106** **Los Angeles, CA 90010** **Permit No. PHY 50776** **YOUNG SOOK CHOI** **3680 Wilshire Blvd, #106** **Los Angeles, CA 90010** **Pharmacist License No. RPH 41950** Respondents.	Case No. 5922 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Interim Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about July 19, 2012, the Board of Pharmacy (Board) issued Permit Number PHY 50776 to I.MC16, Inc. dba R & X Compounding Pharmacy (Respondent R & X

Compounding Pharmacy), Young Sook Choi (Respondent Choi) (Respondents, collectively). The Permit expired on July 1, 2016, and has not been renewed.

3. On or about August 5, 1988, the Board issued Original Pharmacist License Number RPH 41950 to Young Sook Choi. The license was in full force and effect at all times relating to charges brought herein and will expire on December 31, 2019, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy, Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 118 grants the Board jurisdiction to initiate and proceed with discipline against a suspended or expired license during the period when the license can be renewed or reinstated.

6. Section 4300 of the Code authorizes the Board to discipline its license holders:

"(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

. . .

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of

the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

7. Section 4307 of the Code states in pertinent part:

"(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee."

STATUTORY PROVISIONS

8. Section 4301 of the Code authorizes discipline for unprofessional conduct:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

…

(f) The commission of an act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

…

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs."

…

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

…

(q) Engaging in conduct that subverts or attempts to subvert an investigation of the Board.

9. Section 4306.5 states:

"Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to

the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function."

10. Section 4059 of the Code states:

"(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7."

11. Section 4060 of the Code states, in pertinent part:

"A person shall not possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to Section 4052.1, 4052.2, or 4052.6. This section does not apply to the possession of any controlled substance by a manufacturer, wholesaler, third-party logistics provider, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, if in stock in containers correctly labeled with the name and address of the supplier or producer."

12. Section 4076 of the Code states:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1)Except where the prescriber . . . or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2)The directions for the use of the drug.

(3)The name of the patient or patients.

(4) The name of the prescriber or, if applicable, . . . or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10)The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules . . . ."

13. Section 4077 of the Code states, in pertinent part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

14. Section 4081 of the Code states in relevant part:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices."

15. Section 4169 of the Code states, in pertinent part:

"(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

…

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

16. Section 4402 subdivision (e) states that "[a]ny other license issued by the board may be canceled by the board if the license is not renewed within 60 days after its expiration. Any license canceled under this subdivision may not be reissued. Instead, a new application will be required."

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REGULATORY PROVISIONS

17. Cal. Code of Regs., title 16, section 1707.1 states:

"(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

3. The date on which a drug was dispensed or refilled;

4. The prescription number for each prescription; and

5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

…

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled."

18. Cal. Code of Regs., title 16, section 1707.3 states that "[p] Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

19. Cal. Code of Regs., title 16, section 1707.5 states:

"(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist,

(i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and

(ii) The manufacturer's name may be listed outside of the patient-centered area.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information

appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the

evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.”

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20. Cal. Code of Regs., title 16, section 1714 states in pertinent part:

"(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

…

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist."

21. Cal. Code of Regs., title 16, section 1715(a) states that "[t]he pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

22. Cal. Code of Regs., title 16 section 1717(b)(3) states:

"(b) In addition to the requirements of the Business and Professions Code Section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

…

(3)If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the name of the dispensing pharmacist."

23. Cal. Code of Regs., title 16, section 1761 states:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

24. Cal. Code of Regs., title 16, section 1708.2 states that "[a]ny permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and shall follow official instructions given by the board applicable to the transaction."

FEDERAL REGULATIONS

25. Code of Fed. Regs., Title 21, section 1304.04, subdivision (h) states:

"Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1-inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of

original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived."

26. Code of Federal Regulations, Title 21, section 1304.11 subsections (b), (c) and (d) state in pertinent part:

…

"(b) *Initial inventory date*. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date*. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) *Inventory date for newly controlled substances*. On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section."

27. Code of Fed. Regs., Title 21, section 1305.13, subdivision (e) states, in pertinent part, that the procedures for filling DEA Forms 222 required that "[t]he purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser."

28. Code of Fed. Regs., Title 21, section 1306.21, subdivision (a) states:

"(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Sec. 1306.05, except for the signature of the practitioner."

29. Code of Fed. Regs., Title 21, section 1306.22 states, in pertinent part:

"…

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document or electronic prescription record. If entered on another document, such as a medication record, or electronic prescription record, the document or record must be uniformly maintained and readily retrievable.

(c) The following information must be retrievable by the prescription number:

(1) The name and dosage form of the controlled substance.

(2) The date filled or refilled.

(3) The quantity dispensed.

(4) The initials of the dispensing pharmacist for each refill.

(5) The total number of refills for that prescription.

…

(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA

registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized application must also provide online retrieval (via computer monitor or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized application within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized application shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized application employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its application by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized application experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data are retained for online data entry as soon as the computer system is available for use again."

HEALTH AND SAFETY CODES SECTIONS

30. Health and Safety Code section 11150 states:

"No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code . . . shall write or issue a prescription."

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31. Health and Safety Code section 11153 subdivision (a) requires pharmacists to exercise corresponding responsibility with the physician for proper prescribing and dispensing of controlled substances as follows:

"(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

32. Health and Safe Code section 11162.1 states in pertinent part:

"(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

…

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted.

…

(13) An identifying number assigned to the approved security printer by the Department of Justice."

33. Health and Safe Code section 11164 states in pertinent part:

"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal

registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription."

34. Health and Safe Code section 11165, subdivision (d), states in pertinent part:

…

"(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription."

35. Health and Safe Code section 11166 states in pertinent part that, "[n]o person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance …"

36. Health and Safe Code section 11171 states that "[n]o person shall prescribe, administer, or furnish a controlled substance except under the conditions and in the manner provided by this division."

37. Health and Safe Code section 111430 states that "[a] drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States."

38. Health and Safe Code section 111435 states that "[a]ny drug is misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700."

39. Health and Safe Code section 111440 states that "[i]t is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

40. Health and Safe Code section 111445 states that "[i]t is unlawful for any person to misbrand any drug or device.

41. Health and Safe Code section 111450 states that "[i]t is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device."

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CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

42. Oxycodone is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(M), and is a dangerous drug pursuant to Business and Professions Code section 4022.

43. Hydrocodone (an ingredient in "Norco") is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(I), and is a dangerous drug pursuant to Business and Professions Code section 4022.

44. Promethazine with codeine is a Schedule V controlled substance as designated by Health and Safety Code section 11058, subdivision (c)(1), and is a dangerous drug pursuant to Business and Professions Code section 4022.

45. Alprazolam, the generic name for Xanax, is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(1), and is a dangerous drug pursuant to Business and Professions Code section 4022.

REASONABLE COSTS

46. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

BACKGROUND FACTS

47. On or about April 1, 2014, a Regional Compliance Manager with H.D. Smith, a pharmaceutical wholesaler, notified the Board of potential fraudulent prescriptions dispensed by Respondent R & X Compounding Pharmacy. H.D. Smith stated it had ceased taking orders from Respondent R & X Compounding Pharmacy for controlled substances. H.D. Smith advised the Board that Respondent R & X Compounding Pharmacy's orders consisted of 91% controlled substances and only 9% non-controlled substances. Additionally, 98% of Respondents' patients paid for controlled substances in cash.

48. After a site inspection of Respondent R & X Compounding Pharmacy and after educating Respondent Choi regarding her corresponding responsibility, H.D. Smith allowed Respondent to order controlled substances in limited amounts. Shortly thereafter, upon further review of Respondent R & X Compounding Pharmacy's continued problematic dispensing practices, H.D. Smith rejected all future orders from Respondent.

49. On or about July 17, 2015, the Board received Controlled Substance Utilization Review and Evaluation (CURES) data from July 1, 2012, to July 1, 2015, for Respondent R & X Compounding Pharmacy.[1]

50. Business and Professions Code section 11165 requires pharmacies to report within seven days to the California Department of Justice every schedule II, III, and IV drug prescription that is written or dispensed. The information provided establishes the CURES database, which includes information about the drug dispensed, drug quantity and strength, patient name, address, prescriber name, and prescriber authorization number, including DEA number and prescription number. The CURES database is intended to allow licensed healthcare prescribers and pharmacists the ability to access patient controlled substance history information.

51. Respondent R & X Compounding Pharmacy stopped transmitting CURES data in April 2014 despite continuing to fill and dispense prescriptions for controlled substances.

52. The CURES records revealed the top medications dispensed by Respondent R & X Compounding Pharmacy consisted entirely of medications used in the "Trinity" or "Holy Trinity."[2]

53. The most common drug dispensed by Respondent R & X Compounding Pharmacy was oxycodone 30 mg. The second most common was alprazolam 2 mg. Compared to other

[1] CURES is a system for monitoring patient controlled substance history information (See Health & Safety Code § 11165, Bus. & Professions Code § 209; see also In the Matter of the Accusation Against Pacifica Pharmacy; Thang Tran (August 9, 2013) Board of Pharmacy Case No. 3802, Precedential Decision No. 2013-01, p. 6, n. 1, available at http://www.pharmacy.ca.gov/enforcement/precendential.shtml.)

[2] On or around March 4, 2013, the DEA presented "DEA Update & Perspectives on Prescription Drug Trafficking & Abuse Trends." The DEA noted that combining carisprodol (a hydrocodone product) and benzodiazepine (typically alprazolam) is called the "Trinity." The "Holy Trinity" occurs when oxycodone replaces hydrocodone. The combination may also be called a "cocktail." These combinations are sought by drug abusers for producing a euphoric high.

local pharmacies, Respondent R & X Compounding Pharmacy sold a significantly greater percentage of controlled substances and had a higher percentage of cash sales.

54. Of the medications dispensed by Respondent R & X Compounding Pharmacy, 99.86% of the prescriptions were paid for in cash and did not go through insurance.

55. Multiple prescriptions were sent to Respondent R & X Compounding Pharmacy from as far away as Riverside (59 miles away) and San Diego (124 miles away).

First Inspection

56. On or about July 21, 2015, a Board inspector conducted an inspection of Respondent R & X Compounding Pharmacy, which included an interview of Respondent Choi.

57. When asked for pharmacy policies and procedures, self-assessment and DEA Biennial Inventory, Respondent provided a self-assessment from 2012 but had not completed self assessments for July 2013 and July 2015. Respondent had not completed a DEA Biennial Inventory.

58. When asked for invoices documenting the purchase of medication, Respondent Choi produced co-mingled invoices for controlled and non-controlled substances. Further, it was evidenced Respondent Choi was not endorsing the documents with the date and number of bottles received of each product.

59. Respondent Choi was instructed to separate invoices for controlled substances.

60. During the inspection, Respondent Choi informed the inspector that due to lack of funds, she was not paying for and did not have access to a prescription processing computer system. As a result, Respondent Choi admitted Respondent R & X Compounding Pharmacy did not have a daily log of medications filled, Respondent R & X Compounding Pharmacy had not reported controlled substances to CURES, Respondent Choi hand-wrote prescription labels, Respondent Choi did not have patient profiles maintained on each patient, and Respondent R & X Compounding Pharmacy did not have a facsimile line.

61. The inspector reviewed numerous copies of prescriptions documents. The prescriptions were not written on California Security Prescription Pads.

62. As required by Health and Safety Code section 11162.1, California Controlled Substance Prescription documents have a watermark on the back and the word "VOID" will appear when the prescription is photocopied or scanned. They also contain an identifying number of the security printer where it is printed.

63. The prescriptions filled by Respondent R & X Compounding Pharmacy were for high strength, high quantity, controlled substances with unusual directions. For example, prescriptions for alprazolam were routinely for 2 mg, while typically a patient is started on a lesser dose of 0.25 or 0.5 mg.

64. Respondent Choi admitted an individual claiming to be from a prescribing doctor's office would come to the pharmacy and fill prescriptions for two to five patients at a time. Respondent Choi had no information related to this individual other than possibly his first name.

65. Respondent sold over-the-counter Korean medications, including acyclovir, which requires a prescription in the United States. Some of these medications were not approved for use in the United States and were accordingly placed in quarantine.

66. On or about July 29, 2015, Respondent Choi was instructed to dispose of these quarantined medications via a licensed reverse distributor and provide confirmation of same. Respondent refused to timely dispose of the quarantined medications and they were subsequently seized by the Health Authority Law Enforcement Task Force.

Second Inspection

67. On or around August 13, 2015, Board inspectors conducted a second inspection of Respondent R & X Compounding Pharmacy with Respondent Choi present. The quarantined Korean medications were still present and had not been disposed of as ordered.

68. During the course of the inspection, the inspectors found multiple bottles of unknown supplement, labeled "Male Menopause," "Multi-Nano Calcium," and "Pain Relief." The labels were printed with Respondent R & X Compounding Pharmacy's information on them, making it appear as though they were manufactured by Respondent R & X Compounding Pharmacy. Respondent Choi admitted she had repacked the supplements from the manufacturer into her own bottles.

69. Respondent Choi was required to appear in court, so the inspection was terminated before completion. Respondent Choi was again instructed to dispose of the quarantined medication within 72 hours.

Third Inspection

70. On or around August 19, 2015, a Board inspector returned for a third inspection, this time accompanied by Health Authority Law Enforcement Task Force members. The quarantined medication was still present and had not been disposed of as required.

71. The quarantined Korean Medications were consequently seized. Receipts identified on the premise were written in Korean and were confirmed as pertaining to the quarantined medications.

72. When questioned, Respondent Choi admitted she had filled prescriptions and Respondent R & X Compounding Pharmacy dispensed alprazolam without a prescription. Respondent claimed she did it for patients who previously had prescriptions and promised her they had new prescriptions which they would bring at a later date, but never did. Respondent Choi admitted she provided alprazolam 2 mg in quantities of 60, 90, or 120 tablets to individuals without a prescription. Respondent Choi was unable to produce records memorializing what patients had received and how much. Thus, neither Respondents nor any other pharmacists or physicians would be able to view the patient's prescription history.

Fourth Inspection

73. On or about August 27, 2015, Pharmacy Board inspectors returned to conduct a fourth inspection. Respondent Choi again admitted to dispensing alprazolam without a prescription, estimating she dispensed around 4,000 tablets a month for four to five months without a prescription. By Respondent's own estimate, she dispensed 16,000 to 20,000 tablets of the high dosage 2 mg alprazolam, a controlled substance, without a prescription.

74. The bulk of the suspicious prescriptions came from six doctors. Two of the doctors were Board Certified Emergency Medicine doctors, who typically do not write prescriptions for long-term use or large quantities. Many prescriptions were for 120 tablets with instructions that they be taken three times per day, resulting in 40-day supply. Generally, prescriptions, especially

for controlled substances, are not written for an excess of 30 days. Thus, the directions and quantities seen here were unusual.

75. All prescriptions from three of the doctors lacked the required "California Security Prescription" watermark and security printer number. Further, all prescriptions from these three doctors appear to be from the same source, as they are similar appearance and all include the same fax number. Many prescriptions contained similar errors (e.g., prescriptions said "Norcos" instead of the correct "Norco"). Additionally, all prescriptions used one of two sets of instructions, whether for Norco, oxycodone, or alprazolam. Some prescriptions for alprazolam contained instructions indicating it was to be used for pain management, a use for which it is not indicated. The Board inspector confirmed with two of the doctors that the prescriptions were fraudulent.

76. Of the 185 pages of photocopied prescriptions with patient identification obtained during the fourth inspection, 39 pages contained patient IDs that appeared on their face to be fraudulent. Driver's Licenses included typographical and spelling errors (e.g., Victorville spelled as "Victor_ville"), some did not include a city while others failed to list a zip code, and one contained two cities listed (i.e., "Los Angeles, CA, Temecula, CA 92592"). Many identifications were for addresses that did not exist. Yet, in each instance, Respondents dispensed the medication.

77. Respondents could not account for significant amounts of controlled substances. Specifically, Respondent R & X Compounding Pharmacy and Respondent Choi could not account for approximately 35,544 tablets of alprazolam 2 mg, 6,635 tablets of oxycodone 30 mg, 4,431 tablets of Norco 10/325 mg, and 1,200 ml's of promethazine with codeine.

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FIRST CAUSE FOR DISCIPLINE

(Failure to Exercise Corresponding Responsibility)

78. Respondents are subject to disciplinary action under Code section 4301, subdivisions (d), (j) and (o), section 4306.5, subdivisions (a) – (d) in conjunction with Health and Safety Code sections 11153, subdivision (a) and Cal. Code of Regs., title 16, section 1761, subdivision (a) and (b), on the grounds of unprofessional conduct in that they violated their corresponding responsibility.

79. Specifically, Respondents had a corresponding responsibility to only dispense controlled substances for a legitimate medical purpose. However, Respondents dispensed controlled substances without a prescription, dispensed fraudulent prescriptions for controlled substances, dispensed controlled substances to patients with fake identification, and dispensed prescriptions for controlled substances lacking a legitimate medical purpose. Respondents also failed to account for multiple indicia that prescriptions for controlled substances should not be filled, including but not limited to:

- Irregularities on the face of the prescription itself;
- Age and or presentation of the patient;
- Cash payments;
- Prescriptions for large quantities of medications;
- Prescriptions for duplicative drugs;
- The same combinations of drugs prescribed for multiple patients;
- Initial prescriptions written for strong doses;
- Long distances traveled between the patient's home and the prescriber's office and/or pharmacy;
- Irregularities in the prescriber's qualifications in relation to the medication prescribed.

80. Respondents further failed to evaluate the identification provided to them by patients filling prescriptions for controlled substances. Specifically, Respondents dispensed prescriptions to individuals with identifications that contained significant errors, including but not limited to

misspellings, missing or erroneous zip codes, missing cities, or other apparent mistakes. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Act Constituting Dishonesty, Fraud, Deceit)

81. Respondents are subject to disciplinary action under Code section 4301, subdivision (f), in that Respondents committed acts constituting dishonesty, fraud, deceit or corruption. Specifically, Respondent Choi continued to violate her corresponding responsibility after being educated and having ordering cut by pharmaceutical supplier, HD Smith, failed to maintain and review patient profiles prior to dispensing medications, dispensed controlled substances pursuant to fraudulent prescriptions, dispensed controlled substances to patients who provided clearly false identification, dispensed controlled substances without a prescription, purchased and sold misbranded medications despite an opening inspection which documented not selling medications not approved for sale in the United States, failed to report controlled substance dispensing to CURES, failed to dispose of misbranded medications by the required time frame by Board Inspectors. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Making a False Certificate)

82. Respondent Choi is subject to disciplinary action under Code section 4301, subdivision (g), in that Respondent knowingly made or signed a certificate falsely representing the existence or nonexistence of a state of facts. Specifically, on an application to open an account with Bonita Pharmaceuticals dated 8/26/14, Respondent Choi provided numerous false responses, including:

a. Question #11: Respondent Choi responded that the percentage of Controlled Substances filled at Respondents business was 10% CII, 10-20% CIII-CV, and 80-90% non-controlled substances, however review of prescription documents indicated the vast majority of R&X's business was controlled substances.

b. Question #14: Respondent Choi responded that 40% of Respondents business was controlled substances, 20% was weight loss, 30% was regular customers, and 10% was "other", however this response conflicts with her response to Question #11 wherein Respondent stated that 10% of business was CII, 10-20% was CIII-CV.

c. Question #15: Respondent Choi listed Dr. Peter Lee, Dr. Johnathon Shifran, Dr. John Huh, Dr. Andrew Kim and Dr. Yong Tai as her top 5 prescribers of controlled substances. However, Dr. Lee only filled 8 total prescriptions, amounting to .55% of Respondent's total controlled substances when reporting to CURES. In addition, Dr. Takeuchi, Dr. Chumley, Dr. Tzao, Dr. Streams, Dr. Eidelman, and Dr. Kaye were not listed on the application.

d. Question #23: Respondent Choi indicated her pharmacy had never been inspected by the Board, however, Inspector De'Bora White performed an opening inspection on 7/18/12.

e. Question #24: Respondent Choi indicated that 90% of her patients would be paying via insurance and 10% cash, however over 99% of prescriptions reported to CURES were paid for via cash.

FOURTH CAUSE FOR DISCIPLINE

(Filling Incomplete, Invalid, Fraudulent Prescriptions)

83. Respondents are subject to disciplinary action under Code section 4060 in conjunction with Health and Safety Code sections 11150, 11162.1, 11164 and 11166 and 11171 and Code of Fed. Regs., Title 21, section 1306.21 in that Respondent filled incomplete, invalid and fraudulent prescriptions. Specifically, Respondents filled and dispensed prescriptions which did not conform to the requirements of law, filled and dispensed knowingly fraudulent prescriptions, filled controlled substances without a prescription, and filled prescriptions which were clearly altered in violation of pharmacy law. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

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FIFTH CAUSE FOR DISCIPLINE

(Failure to Separately Maintain Controlled Prescriptions and Invoices)

84. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in conjunction with Code of Fed. Regs., Title 21, section 1304.04, subdivision (h)(1) – (4) in that Respondents failed to separately maintain controlled substance prescriptions and invoices from non-controlled medication prescription and invoices. Further, controlled substance prescriptions were not stored in a separate file and stamped with a red "C" or identified in a computer system as required by federal regulations.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Complete DEA Inventory)

85. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in conjunction with Code of Fed. Regs., Title 21, section 1304.11, subdivisions (a) – (d) in that Respondents failed to complete a Drug Enforcement Agency (DEA) Inventory of their controlled substances. Prior to dispensing controlled substances, Respondents were required to complete an inventory of their controlled substances. Additionally, Respondents were required to complete a Biennial DEA Inventory every two years after issuance of their DEA license. During the inspection on July 21, 2015, it was discovered that Respondents had not completed a DEA Inventory at any point since opening in 2012. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Execute DEA Form 222)

86. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in conjunction with Code of Fed. Regs., Title 21, section 1305.13, subdivision (e) in that Respondents did not complete the DEA Form 222 as required. Specifically, Respondents failed to record the number of commercial or bulk containers furnished on each item and the dates

on which the containers are received by the purchaser. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Daily Printout)

87. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o) in conjunction with Cal. Code of Regs., title 16, section 1717 subdivision (b)(3) and Code of Fed. Regs., Title 21, section 1306.22, subdivisions (b), (c) and (f) in that during an inspection on or around July 21, 2015, Respondents failed to have a computer system or maintain a list of controlled substances filled daily. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

NINTH CAUSE FOR DISCIPLINE

(Failure to Maintain Patient Files)

88. Respondents are subject to disciplinary action under Cal. Code of Regs., title 16, section 1707.1 in that Respondents failed to properly maintain patient files prior to dispensing prescriptions. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

TENTH CAUSE FOR DISCIPLINE

(Incorrect Labeling)

89. Respondents are subject to disciplinary action under Code sections 4076 and 4077 in conjunction with Cal. Code of Regs., title 16 section 1707.5, subdivision (a) in that Respondents dispensed medication in containers that failed to comply with state and federal law in that they were incorrectly labeled. Specifically, Respondents improperly labeled prescriptions with pre-printed and handwritten labels which failed to contain all required information. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security and Records for Dangerous Drugs)

90. Respondents are subject to disciplinary action under Code sections 4081, subdivision (a) and 4169, subdivision (a)(5) in conjunction with Cal. Code of Regs., title 16, section 1714, subdivisions (b) and (d) in that Respondents failed to effectively control against theft or diversion of dangerous drugs and failed to maintain records of the acquisition or disposition of dangerous drugs. Specifically, Respondents could not account for the loss or sale of approximately 35,544 tablets of alprazolam 2 mg, 6,635 tablets of oxycodone 30 mg, 4,431 tablets of hydrocodone/acetaminophen 10/325 mg, and 1,200 milliliters of promethazine with codeine. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

TWELFTH CAUSE FOR DISCIPLINE

(Purchasing Dangerous Drugs from an Unlicensed Entity)

91. Respondents are subject to disciplinary action under Code sections 4169(a)(1) in that Respondents purchased dangerous drugs at wholesale with an entity not licensed with the Board as a wholesaler, third-party logistics provider, or pharmacy and sold dangerous drugs that Respondents knew or reasonably should have known were misbranded. Specifically, Respondents purchased, held, and sold misbranded Korean medications not labeled in English. The medications were purchased from an unlicensed, unknown entity and then sold to the public. Additionally, Respondents sold over-the-counter supplements that had been removed from the manufacturer's container and repacked by Respondents without a license to do so. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

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THIRTEENTH CAUSE FOR DISCIPLINE

(Holding and Selling Misbranded Medication)

92. Respondents are subject to disciplinary action under Code sections 4169(a)(3) in conjunction with Health and Safety Code sections 111430, 111435, 111440, 111445 and 111450 in that Respondents sold dangerous drugs that Respondents knew or reasonably should have known were misbranded. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Review and Maintain Patient Files Prior to Dispensing Prescriptions)

93. Respondents are subject to disciplinary action under Cal. Code of Regs., title 16, section 1707.3, in that Respondents failed to review patient drug therapy and medication records before delivering prescription drugs. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Complete Self-Assessment)

94. Respondents are subject to disciplinary action under Cal. Code of Regs. section 1715, subdivision (a), in that Respondents failed to complete a self-assessment of the Respondent R & X Compounding Pharmacy's compliance with state and federal law by July 1 in every odd-numbered year. The only self-assessment Respondent Choi was able to produce during the July 21, 2015, inspection was from 2012. Respondents did not complete a self-assessment by July 1, 2015.

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SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Transmit CURES Data)

95. Respondents are subject to disciplinary action under Health and Safety Code section 11165, subdivision (d), in that Respondents failed to transmit relevant CURES data to the Department of Justice from April 14, 2014, to July 1, 2015.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Misuse of Education)

96. Respondent Choi is subject to disciplinary action under Code section 4306.5, subdivisions (a) – (d) in conjunction with Cal. Code of Regs., title 16, section 1761, subdivision (a) and (b), on the grounds of unprofessional conduct in that Respondent committed acts or omissions that involved the appropriate exercise of her education, training or experience as a pharmacist and failed to exercise her best professional judgment with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices. Specifically, Respondent committed repeated errors in dispensing medications even after documenting the errors. Complainant incorporates paragraphs 47 – 77 by reference, as if fully set forth herein.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

97. Respondents are subject to disciplinary action under section 4301 in that Respondent engaged in acts constituting unprofessional conduct. Complainant incorporates paragraphs 47 – 96 by reference, as if fully set forth herein.

NINTEENTH CAUSE FOR DISCIPLINE

(Failure to File Discontinuation of Business)

98. Respondents are subject to disciplinary action under Cal. Code of Regs. title 16 section 1708.2 in that Respondents failed to submit a discontinuance of business form and follow Board instructions prior to discontinuing business.

99. The underlying circumstances are that on or around July 1, 2016, Respondent R & X Compounding Pharmacy's Original Permit Number PHY 50776 expired.

100. On or around February 27, 2016, Board Inspectors travelled to Respondents' facility located at 3680 Wilshire Blvd., Los Angeles, CA 90010 where they observed that the facility was closed "with material covering the glass."

101. On or around March 29, 2018, Board Inspectors sent a letter to Respondent Choi's home address of recording requesting that she completes a discontinuance of business form for Respondent R & X Compounding Pharmacy. Respondent Choi has failed to submit one in violation of the Board's instruction.

OTHER MATTERS

102. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50776, issued to I.MC16, Inc. dba R & X Compounding Pharmacy, I.MC16, Inc. dba R & X Compounding Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of a licensee for five years if Pharmacy Permit Number PHY 50776 is placed on probation or until Pharmacy Permit Number PHY 50776 is reinstated if it is revoked.

103. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50776, issued to I.MC16, Inc. dba R & X Compounding Pharmacy while Young Sook Choi served as officer and owner and had knowledge of, or knowingly participated in any conduct for which the licensee was disciplined, Young Sook Choi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of a licensee for five years if Pharmacy Permit Number PHY 50776 is placed on probation or until Pharmacy Permit Number PHY 50776 is reinstated if it is revoked.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Permit Number PHY 50776, issued to I.MC16, Inc. dba R & X Compounding Pharmacy, Young Sook Choi;

2. Revoking or suspending Original Pharmacist License Number RPH 41950 issued to Young Sook Choi;

3. Prohibiting I.MC16, Inc. dba R & X Compounding Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate or partner of a licensee for five years if Pharmacy Permit Number PHY 50776 is placed on probation or until Pharmacy Permit Number PHY 50776 is reinstated if it is revoked.

4. Prohibiting Young Sook Choi from serving as a manager, administrator, owner, member, officer, director, associate or partner of a licensee for five years if Pharmacy Permit Number PHY 50776 is placed on probation or until Pharmacy Permit Number PHY 50776 is reinstated if it is revoked.

5. Ordering R & X Compounding Pharmacy and Young Sook Choi to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

6. Taking such other and further action as deemed necessary and proper.

DATED: May 3, 2019

ANNE SODERGREN
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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