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

In the Matter of the Accusation Against:

ONERXPRESS INC. dba IRON HORSE SPECIALTY PHARMACY;
VINH HIEP HUU NGUYEN, CHIEF EXECUTIVE OFFICER,
Original Pharmacy Permit No. PHY 51096;

and

VINH HIEP HUU NGUYEN,
Original Pharmacist License No. RPH 59777,

Respondents.

Agency Case No. 6958

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 October 7, 2021.

It is so ORDERED on September 7, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
CHRISTOPHER M. YOUNG
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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**:** **ONERXPRESS INC. DBA IRON HORSE SPECIALTY PHARMACY; VINH HIEP HUU NGUYEN, CHIEF EXECUTIVE OFFICER** **1479 Ygnacio Valley Rd. Ste. 101** **Walnut Creek, CA 94598** **Original Pharmacy Permit No. PHY 51096** **VINH HIEP HUU NGUYEN** **945 Chesterfield Ln.** **Danville, CA 94506** **Original Pharmacist License No. RPH 59777** Respondents.	Case No. 6958 **STIPULATED SURRENDER OF LICENSE AND ORDER AS TO RESPONDENT ONERXPRESS INC. DBA IRON HORSE SPECIALTY PHARMACY ONLY**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs, the parties hereby agree to the following Stipulated Surrender and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the Accusation solely with respect to Respondent OneRxPress Inc. dba Iron Horse Specialty Pharmacy.

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 Rob Bonta, Attorney General of the State of California, by Christopher M. Young, Deputy Attorney General.

2. OneRxPress Inc., dba Iron Horse Specialty Pharmacy is represented in this proceeding by attorney Natalia Mazina, whose address is: Mazina Law, 100 Pine Street, Suite 1250, San Francisco, CA, 94111.

3. On or about November 26, 2012, the Board issued Original Pharmacy Permit No. PHY 51096 to OneRxPress Inc., dba Iron Horse Specialty Pharmacy; Vinh Hiep Juu Nguyen, Chief Executive Officer (Respondent). The Original Permit expired on May 3, 2017, and has not been renewed.

JURISDICTION

4. Accusation No. 6958 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on December 18, 2020. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 6958 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6958. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

6. Respondent is fully aware of its 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 it; the right to present evidence and to testify on its 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.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent understands that the charges and allegations in Accusation No. 6958, if proven at a hearing, constitute cause for imposing discipline upon its Original Pharmacy Permit.

9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation and that those charges constitute cause for discipline. Respondent hereby gives up its right to contest that cause for discipline exists based on those charges.

10. Respondent understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of its Original Pharmacy Permit without further process.

RESERVATION

11. The admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board. Respondent understands and agrees 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 Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its 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.

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

14. 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.

15. 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 Original Pharmacy Permit No. PHY 51096 issued to Respondent OneRxPress Inc., dba Iron Horse Specialty Pharmacy, is surrendered and accepted by the Board. Respondent may not reapply or petition the Board for reinstatement of its surrendered license for three years from the effective date of this decision.

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

2. Respondent 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 shall cause to be delivered to the Board its pocket license and, if one was issued, its wall certificates on or before the effective date of the Decision and Order.

4. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply

with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 6958 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

5. If Respondent 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. 6958 shall be deemed to be true, correct, and admitted by Respondent 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. I understand the stipulation and the effect it will have on my Original 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: _____

_____
ONERXPRESS INC., DBA IRON HORSE SPECIALTY PHARMACY; VINH HIEP JUU NGUYEN, CHIEF EXECUTIVE OFFICER AND PHARMACIST-IN-CHARGE
Respondent

I have read and fully discussed with Respondent OneRxPress Inc., dba Iron Horse Specialty Pharmacy; Vinh Hiep Juu Nguyen, Chief Executive Officer and Pharmacist-in-Charge, the terms

with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 6958 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

5. If Respondent 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. 6958 shall be deemed to be true, correct, and admitted by Respondent 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. I understand the stipulation and the effect it will have on my Original 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: 6/21/2021

ONERXPRESS INC., DBA IRON HORSE SPECIALTY PHARMACY; VINH HIEP JUU NGUYEN, CHIEF EXECUTIVE OFFICER AND PHARMACIST-IN-CHARGE
Respondent

I have read and fully discussed with Respondent OneRxPress Inc., dba Iron Horse Specialty Pharmacy; Vinh Hiep Juu Nguyen, Chief Executive Officer and Pharmacist-in-Charge, the terms

and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: July 28, 2021

NATALIA MAZINA
Attorney for Respondent

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,

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

CHRISTOPHER M. YOUNG
Deputy Attorney General
Attorneys for Complainant

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and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: _____

NATALIA MAZINA
Attorney for Respondent

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: 7/28/21

Respectfully submitted,

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

Christopher M. Young

CHRISTOPHER M. YOUNG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6958

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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
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In the Matter of the Accusation Against**:** **ONERXPRESS INC. DBA IRON HORSE SPECIALTY PHARMACY; VINH HIEP HUU NGUYEN, CHIEF EXECUTIVE OFFICER** **1479 Ygnacio Valley Rd. Ste. 101** **Walnut Creek, CA 94598** **Original Pharmacy Permit No. PHY 51096** **VINH HIEP HUU NGUYEN** **945 Chesterfield Ln.** **Danville, CA 94506** **Original Pharmacist License No. RPH 59777** Respondents.	Case No. 6958 **ACCUSATION**

PARTIES

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

2. On or about November 26, 2012, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 51096 to OneExpress Inc., dba Iron Horse Specialty Pharmacy; Vinh Hiep

Juu Nguyen, Chief Executive Officer (Respondent Pharmacy). The Original Pharmacy Permit expired on May 3, 2017, and has not been renewed.

3. On or about July 12, 2007, the Board of Pharmacy issued Original Pharmacist License Number RPH 59777 to Vinh Hiep Huu Nguyen (Respondent Nguyen). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2021, unless renewed. Board records reflect that Respondent Nguyen served as Pharmacist in Charge (PIC) for Respondent Pharmacy at all times relevant to the charges brought herein, until the expiration of the pharmacy license in 2017.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless indicated.

5. Code section 4011 provides that the Board shall administer and enforce the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.].

6. Code section 4300, subdivision (a), provides that every license issued by the Board may be suspended or revoked.

7. Code section 4300.1 provides that the expiration, cancellation, forfeiture, suspension, or voluntary surrender of a license "shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

8. Code section 4307, subdivision (a), states:

> (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.

STATUTORY PROVISIONS

9. Section 4059.5 of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user"s agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been

entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

10. 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 certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, 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, the name of certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1., the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, 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, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, 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,

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(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his or her scope of practice.

11. Section 4116 of the Code states:

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

(b)

(1) The board may, by regulation, establish reasonable security measures consistent with this section in order to prevent unauthorized persons from gaining access to the area, place, or premises or to the controlled substances or dangerous drugs or dangerous devices therein.

(2) The board shall, by regulation, establish conditions for the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing authorized personnel from the pharmacy. These conditions shall ensure the security of the pharmacy and its operations during the temporary absence of the pharmacist and shall allow, at the discretion of the pharmacist, nonpharmacist personnel to remain and perform any lawful activities during the pharmacist's temporary absence.

12. Section 4301 of the Code states, in pertinent part:

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 includes, but is not limited to, any of the following:

. . .

(f) The commission of any 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 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.

13. Health and Safety Code section 11164 states, in pertinent part:

(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.

14. Health and Safety Code section 11209 states:

(a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy.

(b) The delivery receipt and any record of discrepancy shall be maintained by the wholesaler or manufacturer for a period of three years.

(c) A violation of this section is a misdemeanor.

(d) Nothing in this section shall require a common carrier to label a package containing controlled substances in a manner contrary to federal law or regulation.

15. Health and Safety Code Section 111440 states it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

REGULATORY PROVISIONS

16. California Code of Regulations, title 16, section 1714, subdivisions (d) and (e), state:

(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.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

17. California Code of Regulations, title 16, section 1716, states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. [¶] Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

18. California Code of Regulations, title 16, section 1735.2, states in pertinent part:

(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

. . .

(c) "A reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(5) With regard to any individual prescriber to whom the pharmacy furnishes,

and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

. . .

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

19. California Code of Regulations, title 16, section 1735.3, states:

(a) For each compounded drug preparation, pharmacy records shall include:

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia -- National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard

date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA- registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

20. California Code of Regulations, title 16, section 1735.5, states:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the

staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

21. California Code of Regulations, title 16, section 1735.6, states:

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3)

(A) For sterile compounding, each BSC or CACI shall be externally exhausted.

(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted. For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

22. California Code of Regulations, title 16, section 1735.7, states:

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

23. California Code of Regulations, title 16, section 1735.8, states:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

24. California Code of Regulations, title 16, section 1793.7, subdivision (b), states:

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

25. 21 C.F.R. §1304.11(c) states, in pertinent part:

(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.

26. 21 C.F.R. §1306.21(a) states, in pertinent part:

(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 FederalFood, 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 § 1306.05, except for the signature of the practitioner.

COST RECOVERY

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

FACTUAL ALLEGATIONS

28. Respondent Pharmacy, located in Walnut Creek, California, and Respondent Nguyen, the Pharmacist-in-Charge and Owner of Respondent Pharmacy, engaged in billing fraud when they over-billed Humana, a health-insurance company, for doses of nine different medications, as summarized in the following chart:

Drug Name	Quantity Purchased	Quantity Billed	Overbilled
BACLOFEN TAB 10 MG	14,100	94,550	80,450
BETHANECHOL 25 MG TABLET	600	810	210
BUDESONIDE EC 3 MG CAPSULE	100	230	130
CLONIDINE HCL TAB 0.2 MG	2,100	5,400	3,300
CYCLOBENZAPRINE HCL TAB 10 MG	16,200	18,080	1,880
DICLOFENAC POTASSIUM TAB 50 MG	2,900	6,240	3,340
DICLOFENAC SOD. DR 50 MG	0	1,440	1,440
KETOPROFEN CAP 50 MG	800	22,800	22,000
KETOPROFEN CAP SR 24HR 200 MG	0	22,325	22,325
LIDOCAINE OINT 5%	0	23,525.5	23,525.5

The total doses of these nine medications that were billed to Humana, but that were not actually purchased or maintained in Respondent Pharmacy's inventory, amounted to 158,601 doses of medications. Respondent Nguyen conceded that the amount of the drugs purchased did not match the amount of drugs billed, because Respondents used the national drug code (NDC) for tablets, capsules, and ointments in their billing to Humana, when Respondents actually used

powders of those drugs for the purpose of compounding, thus resulting in large sales versus purchase variances identified by Humana in its audit and complaint. Respondents' use of incorrect NDCs for billing Humana resulted in fraudulent billing.

29. On or about May 4, 2017, Board of Pharmacy inspectors conducted an on-site inspection of Respondent Pharmacy. Upon arrival, inspectors discovered that Respondent Nguyen was not present at the pharmacy, but that pharmacy technician employees were present and working in the pharmacy unsupervised by a licensed pharmacist. Inspectors learned that pharmacy technician Sevilla signed for and received schedule II-IV controlled substances on May 4, 2017, when no pharmacist was present. The pharmacy technician also conceded that she was conducting a controlled substances inventory, even though no supervising pharmacist was present, and that she had her own key to the pharmacy. A second pharmacy technician arrived to work unsupervised while inspectors were at the pharmacy. The inspectors closed Respondent Pharmacy, asked the pharmacy technician to leave the pharmacy key inside, then set the alarm and exit the pharmacy. Inspectors sealed the door with evidence tape until Respondent Nguyen could meet them the next day.

30. On or about May 5, 2017, a Board inspector met Respondent Nguyen at Respondent Pharmacy. The inspector requested that Respondent Nguyen provide the pharmacy's compounding self-assessment document. Respondent Nguyen was interviewed regarding his compounding business which involved compounding creams for rheumatoid arthritis and neuropathic pain. Respondents' records established that the transdermal creams were the primary business for Respondent Pharmacy. Respondent Nguyen indicated that Respondent Pharmacy prepared numerous "sample" prescriptions for distribution to various doctors' offices, but did not maintain compounding records for "samples." Respondent Pharmacy did not have order requests for compounded samples from prescribers for office use, as required, prior to dispensing "samples."

31. Syringes labeled enrofloxacine 1%, ketoconazole 1%, dexamethasone 0.1% otic ointment, as well as Methimazole 5mg/0.1ml Transdermal were found in the refrigerator. Respondent Nguyen was unable to provide compounding logs and/or a master formula for these

drugs, even though the compounding self-assessment completed by Respondent Nguyen acknowledged that he needed to retain records related to these compounds.

32. Respondent Nguyen provided Respondent Pharmacy's operating procedure manuals. The operating procedures were generic policies purchased by Respondent Pharmacy to meet regulatory compliance, but the policies were not modified as required to reflect the business practices of Respondent Pharmacy. Respondent Nguyen could not produce any evidence that the policies and procedures were reviewed annually as required. In the compounding self-assessment document, Respondent Nguyen indicated he had reviewed and updated policies and procedures, although he was unable to substantiate this with actual documentation. Moreover, Respondents did not maintain a detailed Quality Assurance Policy, even though several products sent by Respondent Nguyen for testing and analysis had results outside the acceptable ranges for potency in Certificates of Analysis (COAs). There was no quality assurance plan for recall or procedures in place regarding the actions to be taken when products were out of acceptable ranges for potency, and there were no policies for contacting potentially impacted patients.

33. Respondent Nguyen provided marketing materials for the compounded creams used to solicit prescriptions from providers, including a fax prescription form with check boxes next to controlled substances, including ketamine products and a tramadol product. A form of this type for controlled substances, transmitted via fax, is required to be reduced to a writing and validated for authenticity by the pharmacy prior to dispensing. A review of Respondent Pharmacy's records substantiated that on at least fifteen separate occasions, Respondents neglected to authenticate prescriptions for controlled substances, including for ketamine. Other marketing materials indicated that Respondent Nguyen and his staff visited prescribers' offices all over the Bay Area, including prescribers well outside of Respondent Pharmacy's normal service area.

34. Respondent Nguyen provided training records for his compounding staff, which included a written competency for two staff and a training/education log. There was no evidence provided that any compounding staff received on-going evaluations of their work, only that they had received initial compounding training. Respondent Nguyen engaged in compounding, but did not have any on-going training records for himself. The compounding self-assessment

completed by Respondent Nguyen indicated that Respondents were in compliance with compounding training and record-keeping, when they were not.

35. Inspectors requested that Respondent Nguyen provide DEA biennial inventory documents, but Respondent Nguyen was only able to provide one document dated June 2016, with no date of when the inventory was conducted. Respondent Pharmacy was operational from January 2, 2013, and no initial inventory was provided.

36. During the inspection, an unlabeled cup containing powder was located near the compounding powder hood. Respondent Nguyen was unable to identify what the substance was. Respondent Pharmacy had one powder hood for compounding/weighing powders used in making the creams. The hood was required to be vented externally due to the hazardous drugs in Respondent Pharmacy's compounding area. Respondent Nguyen conceded that the powder hood was not externally vented. Inspectors verified that Respondent Pharmacy compounded capsules using hazardous drugs (progesterone capsules along with products containing progesterone and estrogen) on or about February 3, 2017, March 2, 2017, and March 3, 2017.

37. Inspectors requested and received compounding prescription documents of products made by Respondent Pharmacy and sold to patients. Board regulations require a master formula document along with a compounding log for each compounded drug preparation. Respondent Pharmacy's documents were a "hybrid" of regulatory requirements, as they provided the master formula document as a compounding/dispensing record for the batches that Respondent Pharmacy compounded. The actual, measured quantity of the ingredients was not indicated on Respondent Pharmacy's compounding log. Also, there was no record of calibration or certification of the equipment used in compounding. Numerous errors were identified in reviewing these compounding documents, including but not limited to: (1) the failure to record the actual weight of each ingredient, (2) recording inaccurate "beyond use dates" (BUDs), where some ingredients in the compound expired before the expiration date assigned to the final product, (3) no sign-off indicating who prepared and/or verified the compounded materials, (4) no sign-off indicating the review of quality assurance steps relating to the preparation, and (5) no records showing equipment used or calibration/certification of equipment. Respondents'

numerous compounding record-keeping deficiencies were consistently repeated for multiple different compounds prepared by Respondent Pharmacy.

38. Inspectors reviewed prescription documents, and found several deviations between the directions provided by a prescriber compared to the directions printed on the label by the pharmacy. For example, in one instance the prescriber directed one gram of a cream to be applied 3-4 times a day, but Respondent Pharmacy's directions were to apply one or two grams (2-4 pumps) of the cream 3-4 times a day.

39. While reviewing the inventory, inspectors found several bubble packed prescriptions for RX#13221 dated July 22, 2016 and August 16, 2016, which were returned to Respondent Pharmacy's current inventory. Respondent Nguyen conceded they were returned from the Board and Care home. Respondent Nguyen was unable to show records that the claims were reversed; instead, Respondent Pharmacy's records indicated the prescriptions in the current inventory had already been delivered. Respondent Pharmacy is not a reverse distributor, that is, it is not allowed to return medication to the inventory unless certain criteria are met. Instead, the returned prescriptions should have been sent for destruction, and the claims reversed.

FIRST CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Billing Fraud)

40. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301, subdivisions (f) and/or (o), for unprofessional conduct. Respondents substantially over-billed a health insurer by using the wrong billing codes as described above in paragraph 29.

SECOND CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Recordkeeping of Compounded Drug Preparations)

41. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1735.3(d), which requires that compounding records be maintained in a readily retrievable form for at least three years from the date the record was last in effect. As described above in paragraphs 30 and 31, Respondents failed to produce compounding records for various samples, failed to keep records of disposition

showing which prescribers received the samples, and did not keep master formula records or compounding logs for various compounds discovered in the pharmacy refrigerator.

THIRD CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Recordkeeping of Compounded Drug Preparations)

42. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1735.3(a)(2)(E) and (F), which requires that compounding records be maintained including a master formula document, a compounding log identifying the quantity of each ingredient used in compounding, and the manufacturer, expiration date, and lot number of each component. As described above in paragraphs 30, 31, and 37, Respondents failed to maintain proper compounding records, and failed to record the actual, measured quantity of the ingredients and failed to include lot numbers and expiration dates for the products used in the compounding.

FOURTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Compounding Policies and Procedures)

43. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1735.5, subdivisions (a) and (b), which require that any pharmacy engaged in compounding maintain written policies and procedures for compounding that establish procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation and other standard operating procedures, and that such policies and procedures be reviewed and updated on an annual basis. As described above in paragraph 32, Respondents failed to produce policies and procedures during an inspection on May 5, 2017, other than generic policies not specifically tailored to Respondent Pharmacy, with no documented annual review(s).

FIFTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Compounding Limitations and Requirements)

44. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1735.2, subdivision (c)(1), which requires that when furnishing a "reasonable quantity" for office use, the prescriber must

transmit a purchase order prior to furnishing. As described above in paragraph 30, Respondents failed to have order requests for compounded samples provided to physicians for office use.

SIXTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Training of Compounding Staff)

45. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1735.7, subdivisions (a) and (b), which requires that a pharmacy engaged in compounding maintain documentation demonstrating that personnel involved in compounding have the requisite skills and training, and that all aspects of the pharmacy policies and procedures are covered in the training. As described above in paragraph 34, Respondents failed to maintain records showing on-going competency evaluations for staff, and failed to have any on-going training records for Respondent Nguyen.

SEVENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Compounding Quality Assurance)

46. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1735.8, subdivisions (a) and (d), which requires that compounding records include a written quality assurance plan to monitor and ensure the potency, quality, integrity, and labeled strength of compounded drug preparations, as well as a written procedure for scheduled action in the event any compounded drug preparation is discovered to be outside minimum standards. As described above in paragraph 32, Respondents failed to maintain a written quality assurance policy and procedure.

EIGHTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Receiving Dangerous Drugs or Devices)

47. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and 4059.5, subdivision (a), which requires that only a pharmacist may receive dangerous drugs or devices. As described above in paragraph 29, an unsupervised pharmacy technician received and signed for dangerous drugs on or about May 4, 2017.

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NINTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Misbranded Drugs)

48. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and Health and Safety Code section 111440, which prohibits a pharmacy from holding or selling misbranded drugs or devices. As described above in paragraph 39, Respondents maintained two bubble cards returned from a Board and Care facility in the current inventory instead of quarantining them for destruction and reversing the prescriptions in the computer system, resulting in false records showing patients received the prescriptions.

TENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Security; Pharmacist Responsibility)

49. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and 4116, subdivision (a), which requires that a pharmacist supervise a pharmacy technician in an area containing controlled substances, dangerous drugs, or dangerous devices. As described above in paragraph 29, a pharmacy technician was found working in Respondent Pharmacy unsupervised, in possession of a pharmacy key, and received a delivery.

ELEVENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Compounding Facilities and Equipment)

50. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1735.6, subdivision (e), which requires that hazardous drug compounding be performed in an externally vented room with specific requirements for adequate safety and ventilation. As described above in paragraph 36, Respondents did not have an externally vented powder hood even though Respondent Pharmacy was engaged in compounding hazardous drugs.

TWELFTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Requirements for Pharmacies Employing Pharmacy Techs)

51. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1793.7, subdivision (b), which requires that pharmacy technicians work under the direct supervision of a pharmacist. As

described above in paragraph 29, a pharmacy technician worked in the pharmacy unsupervised, and another pharmacy technician was seen arriving to the pharmacy to also work unsupervised.

THIRTEENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Inventory Requirements; Biennial Inventory)

52. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and 21 C.F.R. § 1304.11(c), which requires an initial and biennial inventories of all stocks of controlled substances. As described above in paragraph 35, Respondents failed to conduct a biennial inventory on a fixed date and didn't include information relevant to the inventory of when it was conducted (open or close of business). There was no initial inventory or inventory conducted within 2 years of Respondent Pharmacy's opening.

FOURTEENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Dishonesty/False Statements)

53. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(f) and/or (g), which include as unprofessional conduct the commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, or the knowing making or signing a document that falsely represents the existence or nonexistence of a state of facts. As described above in paragraph 39, Respondents failed to reverse billed prescriptions that were not received by the patient when it took back prescriptions and returned them to the current inventory, creating a false record of dispensing.

FIFTEENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Operational Standards and Security)

54. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1714, subdivisions (d) and (e), which require that only a pharmacist may possess access to controlled substances, unless in the case of an emergency. As described above in paragraph 29, Respondents allowed a pharmacy technician to possess a key to the pharmacy, including to areas of Respondent Pharmacy containing controlled substances, and a pharmacy technician took delivery of same.

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SIXTEENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Variation from Prescriptions)

55. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and California Code of Regulations, section 1716, which requires that a drug labeled by a pharmacy not deviate from the requirements or instructions of the prescriber without prior authorization. As described above in paragraph 38, Respondents made errors in the directions for use on prescription labels, deviating from the directions provided by the prescriber.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Requirement of Prescription)

56. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), 21 C.F.R. § 1306.21(a), and Health and Safety Code section 11164, subdivision (b)(1), which requires that prescriptions for controlled substances received by fax must be reduced to writing and authenticated. As described above in paragraph 33, on 15 separate occasions controlled substance prescriptions were received that were not reduced to a writing and authenticated with the prescriber.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Nguyen: Receiving Requirements for Controlled Substances)

57. Respondents Pharmacy and Nguyen are subject to disciplinary action under Code section 4301(j) and/or (o), and Health and Safety Code section 11209, which requires that controlled substance deliveries may only be received by a pharmacist. As described above in paragraph 29, Respondents allowed an unsupervised pharmacy technician to receive and sign for controlled substances on or about May 4, 2017.

OTHER MATTERS

58. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy License Number PHY 51096, Respondent Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Respondent Pharmacy License Number PHY 51096 is placed on probation, or until reinstatement if Respondent Pharmacy License Number PHY 51096 is revoked.

59. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy License Number PHY 51096 issued to Respondent Pharmacy while Respondent Nguyen was the pharmacist-in-charge, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Respondent Nguyen shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Respondent Pharmacy License Number PHY 51096 is placed on probation, or until reinstatement if Respondent Pharmacy License Number PHY 51096 is revoked.

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 Original Pharmacy Permit Number PHY 51096, issued to OneExpress Inc., dba Iron Horse Specialty Pharmacy; Vinh Hiep Juu Nguyen, Chief Executive Officer and Pharmacist-in-Charge (Respondent Pharmacy);

2. Revoking or suspending Original Pharmacist License Number RPH 59777, issued to Vinh Hiep Juu Nguyen (Respondent Nguyen);

3. Prohibiting Respondent Pharmacy or Respondent Nguyen from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number PHY 51096 is placed on probation, or until reinstatement if Original Pharmacy Permit Number PHY 51096 is revoked;

4. Ordering Respondent Pharmacy and Respondent Nguyen, jointly and severally, 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,

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

DATED: 12/7/2020

Signature on File

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

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