# 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 Settlement and Disciplinary 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

Ву

Seung W. Oh, Pharm.D. Board President

1	ROB BONTA		
2	Attorney General of California JOSHUA A. ROOM		
3	Supervising Deputy Attorney General		
	CHRISTOPHER M. YOUNG Deputy Attorney General		
4	State Bar No. 238532 455 Golden Gate Avenue, Suite 11000		
5	San Francisco, CA 94102-7004 Telephone: (415) 510-3554		
6	Facsimile: (415) 703-5480 Attorneys for Complainant		
7			
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CO	ONSUMER AFFAIRS	
10	STATE OF CA	ALIFORNIA	
11			
12	In the Matter of the Accusation Against:	Case No. 6958	
13	ONERXPRESS INC. DBA IRON HORSE		
14	SPECIALTY PHARMACY; VINH HIEP HUU NGUYEN, CHIEF EXECUTIVE	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO	
15	OFFICER 1479 Ygnacio Valley Rd. Ste. 101	RESPONDENT VINH HIEP HUU	
16	Walnut Creek, CA 94598	NGUYEN ONLY	
17	Original Pharmacy Permit No. PHY 51096		
18	VINH HIEP HUU NGUYEN		
19	945 Chesterfield Ln. Danville, CA 94506		
20	Original Pharmacist License No. RPH 59777		
21	Respondents.		
22			
23	In the interest of a prompt and speedy settle	ment of this matter, consistent with the public	
24	interest and the responsibility of the Board of Pha	rmacy of the Department of Consumer Affairs,	
25	the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will		
26	be submitted to the Board for approval and adopti	on as the final disposition of the Accusation	
27	solely with respect to Vinh Hiep Juu Nguyen.		
28			

# **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. Respondent Vinh Hiep Juu Nguyen, RPh (Respondent) 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 July 12, 2007, the Board issued Original Pharmacist License No. RPH 59777 to Respondent Vinh Hiep Juu Nguyen. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 6958, and will expire on January 31, 2023, unless 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 his Notice of Defense contesting the Accusation.
- 5. A copy of Accusation No. 6958 is attached as exhibit A and incorporated herein by reference.

# ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6958. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent is fully aware of his 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 him; the right to present evidence and to testify on his 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. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

## **CULPABILITY**

- 9. Respondent understands and agrees that the charges and allegations in Accusation No. 6958, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License.
- 10. 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 Respondent hereby gives up his right to contest those charges.
- 11. Respondent agrees that his Original Pharmacist License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

# **RESERVATION**

12. 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**

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his 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 Settlement 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.

- 14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 15. This Stipulated Settlement and Disciplinary 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 Settlement and Disciplinary 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.
- 16. 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 Disciplinary Order:

# **DISCIPLINARY ORDER**

IT IS HEREBY ORDERED that Original Pharmacist License No. RPH 59777 issued to Respondent Vinh Hiep Juu Nguyen is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions:

#### 1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

an arrest or issuance of a criminal complaint for violation of any provision of the

Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws

a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment

a conviction of any crime
the filing of a disciplinary pleading, issuance of a citation, or initiation of
another
administrative action filed by any state or federal agency which involves
respondent's license or which is related to the practice of pharmacy or the
manufacturing, obtaining, handling, distributing, billing, or charging for any drug,

Failure to timely report such occurrence shall be considered a violation of probation.

# 2. Report to the Board

device or controlled substance.

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

#### 3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

#### 4. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of Respondent's probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any

term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

#### 5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

# 6. Reporting of Employment and Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 6958 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of each of Respondent's employer(s), and the name(s) and telephone number(s) of all of Respondent's direct supervisor(s), as well as any pharmacist(s)-incharge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) Respondent's direct supervisor, (b) Respondent's pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of Respondent's employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6958, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the

acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 6958, and the terms and conditions imposed thereby.

If respondent works for or is employed by or through an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 6958, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a Pharmacist, or any position for which a Pharmacist is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

#### 7. Notification of Change(s) in Name, Address(es), or Phone Number(s)

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

# 8. Restrictions on Supervision and Oversight of Licensed Facilities

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

#### 9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$15,000.00. Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

# 10. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

#### 11. Status of License

Respondent shall, at all times while on probation, maintain an active, current Original Pharmacist License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Original Pharmacist License shall be considered a violation of probation.

If respondent's Original Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

#### 12. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may relinquish his license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided.

Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

#### 13. Practice Requirement – Extension of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a Pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the board or its designee.

If respondent does not practice as a Pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10)

days following the next calendar month during which respondent practices as a Pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

#### 14. **Violation of Probation**

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in Accusation No. 6958 shall be deemed true and correct.

#### 15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

#### 16. Remedial Education

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to

compounding (USP 797) and/or pharmacy operational standards and security of dangerous drugs. The program of remedial education shall consist of at least 6 hours each year of probation, having 50% in-person training or live webinar online classes, at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

#### 17. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered a violation of probation.

#### 18. No Ownership or Management of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90)

1	days following the effective date of this decision and shall immediately thereafter provide written		
2	proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide		
3	documentation thereof shall be considered a violation of probation.		
4	<u>ACCEPTANCE</u>		
5	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully		
6	discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will		
7	have on my Original Pharmacist License. I enter into this Stipulated Settlement and Disciplinary		
8	Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order		
9	of the Board of Pharmacy.		
10			
11	DATED:		
12	VINH HIEP JUU NGUYEN, RPH Respondent		
13	I have read and fully discussed with Respondent Vinh Hiep Juu Nguyen the terms and		
14	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.		
15	I approve its form and content.		
16	DATED:		
17	NATALIA MAZINA Attorney for Respondent		
18			
19	<u>ENDORSEMENT</u>		
20	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully		
21	submitted for consideration by the Board of Pharmacy.		
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1	days following the effective date of this decision and shall immediately thereafter provide written		
2	proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide		
3	documentation thereof shall be considered a violation of probation.		
4	ACCEPTANCE		
5	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully		
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7	have on my Original Pharmacist License. I enter into this Stipulated Settlement and Disciplinary		
8	Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order		
9	of the Board of Pharmacy.		
10	Dist.		
11	DATED: 6/21/2021 Constituents		
12	Respondent VINH HIEP JUU NGUYEN, RPH		
13	I have read and fully discussed with Respondent Vinh Hiep Juu Nguyen the terms and		
14	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order		
15	I approve its form and content.		
16	DATED: 6/25/21		
17	NATALIA MAZINA Attorney for Respondent		
18			
19	ENDORSEMENT		
20	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully		
21	submitted for consideration by the Board of Pharmacy.		
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1	DATED:	7/28/2/	Respectfully submitted,
2			ROB BONTA Attorney General of California JOSHUA A. ROOM
3			JOSHUA A. ROOM Supervising Deputy Attorney General
4			
5			CHRISTOPHER M. YOUNG
6			Deputy Attorney General  Attorneys for Complainant
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# Exhibit A

Accusation No. 6958

1	XAVIER BECERRA		
2	Attorney General of California JOSHUA A. ROOM Supervising Deputy Attorney General		
3	Supervising Deputy Attorney General CHRISTOPHER M. YOUNG Deputy Attorney General		
4	State Bar No. 238532 455 Golden Gate Avenue, Suite 11000		
5	San Francisco, CA 94102-7004 Telephone: (415) 510-3554		
6	Facsimile: (415) 703-5480 Attorneys for Complainant		
7	Thiomeys for Complainant		
8	BEFOR ROARD OF P		
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF CA	ALIFORNIA	
11			
12	In the Matter of the Accusation Against:	Case No. 6958	
13	ONERXPRESS INC. DBA IRON HORSE SPECIALTY PHARMACY; VINH HIEP		
14	HUU NGUYEN, CHIEF EXECUTIVE OFFICER	ACCUSATION	
15	1479 Ygnacio Valley Rd. Ste. 101 Walnut Creek, CA 94598		
16	Original Pharmacy Permit No. PHY 51096		
17	VINH HIEP HUU NGUYEN 945 Chesterfield Ln.		
18	Danville, CA 94506		
19 20	Original Pharmacist License No. RPH 59777		
20   21	Respondents.		
22			
23	<u>PARTIES</u>		
24	1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity		
25	as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.		
26	2. On or about November 26, 2012, the Board of Pharmacy issued Original Pharmacy		
27	Permit Number PHY 51096 to OneExpress Inc., o	lba Iron Horse Specialty Pharmacy; Vinh Hiep	
28			
		1	

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

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2	(j) The violation of any of the statutes of this state, or of the United States regulating controlled substances and dangerous drugs.			
3				
4	(o) Violating or attempting to violate, directly or indirectly, or assisting in or			
5	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			
6				
7	13. Health and Safety Code section 11164 states, in pertinent part:			
8	(b)			
9	(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any			
10	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			
11	person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted			
12	prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.			
13	14. Health and Safety Code section 11209 states:			
14				
15	(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			
16	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			
17	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.			
18	(b) The delivery receipt and any record of discrepancy shall be maintained by			
19	the wholesaler or manufacturer for a period of three years.			
20	(c) A violation of this section is a misdemeanor.			
21	(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.			
22				
23	15. Health and Safety Code Section 111440 states it is unlawful for any person to			
24	manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.			
25	REGULATORY PROVISIONS			
26	16. California Code of Regulations, title 16, section 1714, subdivisions (d) and (e), state			
27	(d) Each pharmacist while on duty shall be responsible for the security of the			
28	prescription department, including provisions for effective control against theft or			

#### **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	Quantity	Overbilled
	Purchased	Billed	
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

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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.

# 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.