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

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| In the Matter of the Accusation Against:<br><br>**AMERICARE PLUS PHARMACY SERVICES, DBA AMERICARE PLUS PHARMACY;**<br>**CHAU H. LUU, OWNER**<br>**14211 Euclid Street, Unit A**<br>**Garden Grove, CA 92843**<br><br>**Pharmacy Permit No. PHY 41692**<br><br>**CHAU H. LUU;**<br>**AKA CHAU HUYEN LUU**<br>**14211 Euclid Street, Unit A**<br>**Garden Grove, CA 92843**<br><br>**Pharmacist License No. RPH 42505**<br><br>Respondents. | Case No. 5425<br><br>**STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** |

## 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 February 22, 2017.

It is so ORDERED on January 23, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

KAMALA D. HARRIS
Attorney General of California
JAMES M. LEDAKIS
Supervising Deputy Attorney General
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*Attorneys for Complainant*

**BEFORE THE**
**BOARD OF PHARMACY**
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| In the Matter of the Accusation Against:<br><br>**AMERICARE PLUS PHARMACY SERVICES, DBA AMERICARE PLUS PHARMACY;**<br>**CHAU H. LUU, OWNER**<br>**14211 Euclid Street, Unit A**<br>**Garden Grove, CA 92843**<br><br>**Pharmacy Permit No. PHY 41692**<br><br>**CHAU H. LUU;**<br>**AKA CHAU HUYEN LUU**<br>**14211 Euclid Street, Unit A**<br>**Garden Grove, CA 92843**<br><br>**Pharmacist License No. RPH 42505**<br><br>Respondents. | Case No. 5425<br><br>**STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** |

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

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala

D. Harris, Attorney General of the State of California, by Diane De Kervor, Deputy Attorney General.

2. Chau H. Luu, also known as Chau Huyen Luu and Americare Plus Pharmacy Services, dba Americare Plus Pharmacy ("Respondents") are represented in this proceeding by attorney Herbert L. Weinberg, whose address is: 1990 S Bundy Drive Suite 777, Los Angeles, CA 90025.

3. On or about June 14, 1996, the Board issued Pharmacy Permit Number PHY 41692 to Americare Plus Pharmacy Services, dba Americare Plus Pharmacy, (Respondent Americare) located at 14211 Euclid Street, Unit A, Garden Grove, California. Chau H. Luu, aka Chau Huyen Luu, as been the individual licensed owner and Pharmacist-in-Charge of Respondent Americare since June 14, 1996. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein, and will expire on June 1, 2017, unless renewed.

4. On or about March 24, 1989, the Board issued Pharmacist License Number RPH 42505 to Chau H. Luu, also known as Chau Huyen Luu (Respondent Luu). The Pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2018, unless renewed.

JURISDICTION

5. First Amended Accusation No. 5425 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondents. The initial Accusation and all other statutorily required documents were properly served on Respondents on March 4, 2016. Respondents timely filed their Notice of Defense contesting the Accusation. The First Amended Accusation and all other statutorily required documents were properly served on Respondents on October 13, 2016.

6. A copy of First Amended Accusation No. 5425 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 5425. Respondents have also carefully

read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

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

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

CULPABILITY

10. Respondent understands and agrees that the charges and allegations in First Amended Accusation No. 5425, if proven at a hearing, constitute cause for imposing discipline upon their Licenses.

11. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation , and that Respondents hereby give up their right to contest those charges.

12. Respondents agree that Pharmacy Permit Number PHY 41692and Pharmacist License Number RPH 42505 are subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree 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 Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the

stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated 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 Pharmacy Permit No. PHY 41692 and Pharmacist License No. RPH 42505 are revoked. However, the revocation is stayed and Respondents are placed on probation for four (4) years on the following terms and conditions.

**Probation Terms for Respondent Luu**

1. **Obey All Laws**

Respondent Luu shall obey all state and federal laws and regulations.

Respondent Luu 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 contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

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

2. **Report to the Board**

Respondent Luu 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 Luu 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.

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4. **Cooperate with Board Staff**

Respondent Luu shall 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 his probation. Failure to cooperate shall be considered a violation of probation.

5. **Continuing Education**

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

6. **Notice to Employers**

During the period of probation, Respondent Luu shall notify all present and prospective employers of the decision in case number 5425 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 fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5425, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 5425 in advance of the respondent commencing work at each 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 a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 5425

and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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

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

7. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant**

During the period of probation, Respondent Luu shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Luu shall pay to the board its costs of investigation and prosecution in the amount of $7,500.00. Respondents Luu and Americare shall be jointly and severally liable for payment of these costs.

Respondents may make payments pursuant to a payment plan, if that plan is approved by the board and there shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by either respondent shall not relieve respondents Luu and Americare of their responsibility to reimburse the board its costs of investigation and prosecution.

9. **Probation Monitoring Costs**

Respondent Luu 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.

10. **Status of License**

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

If respondent's 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.

11. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent Luu cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for 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 wall license to the board within ten (10) days of notification by the board that the surrender is accepted. 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.

12. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent Luu shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new

employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

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

13. **Tolling of Probation**

Except during periods of suspension, Respondent Luu shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. **Violation of Probation**

If Respondent Luu has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and 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.

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. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, 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.

15. **Completion of Probation**

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

16. **Community Services Program**

Within sixty (60) days of the effective date of this decision, Respondent Luu shall submit to the board or its designee, for prior approval, a community service program in which Respondent Luu shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least sixty-four (64) hours for the first three years probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation. In lieu of community service, Respondent Luu may pay a fine of $10,000.

17. **Remedial Education**

Within thirty (30) days of the effective date of this decision, Respondent Luu shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to pharmacy law, pharmacy operation, and record keeping. The program of remedial

education shall consist of at least 10 additional continuing education hours per year, for the first three years of probation, which shall be completed 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.

Failure to timely submit 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, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

18. **No Ownership of Additional Licensed Premises**

Respondent Luu shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Respondent Luu currently owns or has any legal or beneficial interest in, or serves 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 Luu may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

19. **Consultant for Owner or Pharmacist-In-Charge**

During the period of probation, Respondent Luu shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the Board. Respondent may be a pharmacist-in-charge. However, if during the period of probation Respondent serves as a pharmacist-in-charge, Respondent shall retain an independent consultant at his own expense who shall be responsible

for reviewing pharmacy operations on a quarterly basis for compliance by Respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by Respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. During the period of probation, the Board or its designee, retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent Americare's operations.

Respondent Luu shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which they is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

20. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent Luu shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent Luu shall submit a certificate of completion to the board or its designee within five days after completing the course and Respondent may not use this course to satisfy continuing education requirements.

**Probation Terms for Respondent Americare**

1. **Obey All Laws**

Respondent Americare shall obey all state and federal laws and regulations.

Respondent owner 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 contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment

- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondents' Pharmacy Permit or Pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

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

2. **Report to the Board**

Respondent Americare owner 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 owner 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 Americare owner 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 Americare owner shall 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 its probation. Failure to cooperate shall be considered a violation of probation.

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5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Americare shall pay to the board its costs of investigation and prosecution in the amount of $7,500.00. Respondents Luu and Americare shall be jointly and severally liable for payment of these costs.

Respondents may make payments pursuant to a payment plan, if that plan is approved by the board and there shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondents, or by either of them, shall not relieve respondents of their responsibility to reimburse the board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondent Americare owner 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.

7. **Status of License**

Respondent Americare shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

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

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent Americare discontinue

business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for 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.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent Americare owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent

place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**

Respondent Americare shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent Americare owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If Respondent Americare has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent's license, and probation shall be

automatically 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.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, 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.

13. **Completion of Probation**

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

14. **Community Services Program**

Within sixty (60) days of the effective date of this decision, Respondent Americare owner shall submit to the board or its designee, for prior approval, a community service program in which Respondent Americare shall provide free health-care related services to a community or charitable facility or agency for the amount of $10,000 over the four years of probation.

Within thirty (30) days of board approval thereof, Respondent Americare owner shall submit documentation to the board demonstrating commencement of the community service program. Respondent owner shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation. In lieu of community service, Respondent Americare may pay a fine of $10,000.

15. **Separate File of Records**

Respondent Americare owner shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure

to maintain such file or make it available for inspection shall be considered a violation of probation.

## ACCEPTANCE

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

DATED: 11/17/16

CHAU H. LUU, OWNER and authorized representative for AMERICARE PLUS PHARMACY SERVICES, DBA AMERICARE PLUS PHARMACY, *Respondent*

I have read and fully discussed with Respondents Luu and Americare the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 11/17/2016

HERBERT L. WEINBERG
*Attorney for Respondent*

## ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 12/2/2016

Respectfully submitted,

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# Exhibit A

**First Amended Accusation No. 5425**

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

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>**AMERICARE PLUS PHARMACY SERVICES, DBA AMERICARE PLUS PHARMACY; CHAU H. LUU, OWNER**<br>**14211 Euclid Street, Unit A**<br>**Garden Grove, CA 92843**<br><br>**Pharmacy Permit No. PHY 41692**<br><br>**CHAU H. LUU;**<br>**AKA CHAU HUYEN LUU**<br>**14211 Euclid Street, Unit A**<br>**Garden Grove, CA 92843**<br><br>**Pharmacist License No. RPH 42505**<br><br>Respondents. | Case No. 5425<br><br>**FIRST AMENDED ACCUSATION** |

Complainant alleges:

PARTIES

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

2. On or about June 14, 1996, the Board issued Pharmacy Permit Number PHY 41692 to Americare Plus Pharmacy Services, dba Americare Plus Pharmacy, (Respondent Americare)

located at 14211 Euclid Street, Unit A, Garden Grove, California. Chau H. Luu, aka Chau Huyen Luu, as been the individual licensed owner and Pharmacist-in-Charge of Respondent Americare since June 14, 1996. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein, and will expire on June 1, 2016, unless renewed.

3. On or about March 24, 1989, the Board issued Pharmacist License Number RPH 42505 to Chau H. Luu, also known as Chau Huyen Luu (Respondent Luu). The Pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2016, unless renewed.

**JURISDICTION**

4. This First Amended 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 otherwise indicated.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
>
> . . .
>
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

6. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee 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.

**STATUTORY AUTHORITY**

7. Section 4022 of the Code states

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

8. Section 4040.5 states:

"Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs.

9. Section 4059.5 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, the designated representative 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 provision of 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.

10. Section 4081, subsection (a) states:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a

currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

11. Section 4160, subsection (a) states:

(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

12. Section 4169(a)(3)

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

. . .

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

. . . .

13. Section 4301 of the Code states in relevant part:

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

. . .

(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.

. . . .

14. Section 4307, subdivision (a), of the Code provides, in pertinent part, that any person who is an owner of licensee who has been revoked or is under suspension shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of a license.

Pursuant to Code section 4307, subdivision (a), in the event the license issued to Respondent Americare is revoked or placed on suspension, Respondent Luu shall be prohibited

from serving as a manager, administrator, owner, member, officer, director, associate or partner of any licensee with rights issued by the Board.

15. Health and Safety Code section 11165, subsection (d) states:

> (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
>
> (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
>
> (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
>
> (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
>
> (4) National Drug Code (NDC) number of the controlled substance dispensed.
>
> (5) Quantity of the controlled substance dispensed.
>
> (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
>
> (7) Number of refills ordered.
>
> (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
>
> (9) Date of origin of the prescription.
>
> (10) Date of dispensing of the prescription.

**REGULATIONS**

16. California Code of Regulations, title 16, section 1714, subsection (c), states:

> (c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

17. California Code of Regulations, title 16, section 1717, subsection (b), states:

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

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

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

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

18. Code of Federal Regulations, title 21, section 1304.04 states:

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

(i) The nature of the records to be kept centrally.

(ii) The exact location where the records will be kept.

(iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(iv) Whether central records will be maintained in a manual, or computer readable, form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records

required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(3) A collector that is authorized to maintain a collection receptacle at a long-term care facility shall keep all records required by this part relating to those collection receptacles at the registered location, or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to the ARCOS Unit. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

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

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

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

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

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

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

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

19. Code of Federal Regulations, title 21, section 1306.22, subsection (f), states:

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

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

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

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

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

so by the Agent or Investigator, verify the printout transmittal capability of its application by documentation (e.g., postmark).

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

**COSTS**

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

**DRUGS**

21. Insulin isophane, also known by the brand name Novolin N, is a dangerous drug under Business and Professions Code section 4022. It is used for the control of diabetes.

**FACTS**

22. On January 7, 2013, the Board received an online complaint alleging that Respondent Americare was dispensing medications with prescription vial labels which did not have the description of the medication on them.

23. On October 16, 2013, the Board conducted a routine inspection and complaint investigation at Respondent Americare. Two pharmacists, Kaitlynn T. and Tam T. were initially present during the inspection, and Respondent Luu came in later and assisted as well. During the routine inspection, the Board inspectors noted the refrigerator located by the door leading from the patient waiting area into the pharmacy had dead ant carcasses in the door shelves. Pharmacist Tam T. told the inspectors that the refrigerator was used to store overstock of dangerous drugs, and the freezer above was used to stock Zostavax vaccine. There were open packages of Novolin N., a labeled prescription amber vial, and a bottle of pediatric electrolyte solution in the refrigerator.

24. During the October 16, 2013 inspection, while reviewing invoices from Respondent Americare's primary wholesalers HD Smith and Cardinal Health, the inspector questioned

Pharmacist Tam T. about the procedure followed when receiving controlled substance orders into inventory. Pharmacist Tam T. showed the inspector an area in the stockroom where invoices of all drugs ordered by the pharmacy were kept in boxes. Pharmacist Tam T. told the inspector that Respondent Americare did not separate invoices for controlled substances in Schedules III-V and the pharmacist did not sign the invoices for the controlled substances. The inspector reviewed the boxes of invoices and collected Invoice 4959665 from HD Smith, dated August 29, 2013 and Invoice NO. 7929288 from Cardinal Health, dated September 20, 2013 to illustrate this behavior.

25. During the October 16, 2013 inspection, the Board's inspector reviewed the two computer systems used for processing prescriptions at Respondent Americare. The old computer system had Pharmacy Program Version 5.1, and the new system had Digital Rx. When questioned about weekly transmission of CURES data, Pharmacist Kaitlynn T. told the Board's inspector that Digital Rx transmitted CURES data from the new system weekly and the pharmacist on duty transmitted CURES data from the old computer system "from time to time." Neither Pharmacist Kaitlynn T. nor Pharmacist Tam T. was able to provide the inspector any proof of submission of CURES data from the old system. The inspector requested a run report of all controlled substance prescriptions filled and dispensed from the old computer between April 25, 2013 and October 16, 2013, and to provide proof of their transmission.

26. During the October 16, 2013 inspection, the inspector also asked Pharmacists Kaitlynn T. and Tam T. how Respondent Americare documented refills of prescriptions. Pharmacist Tam T. showed the inspector the log in screen of the Digital Rx system on the new computer which recorded the name of the pharmacist on duty and the inputting employee. The inspector requested the report from October 15, 2013. Pharmacist Tam T. told the inspector that Respondent Americare did not print daily dispensing reports or reports for controlled substances dispensed. The inspector requested that a report be printed for October 15, 2013. Once printed, the inspector reviewed the report with Pharmacist Tam T. The inspector explained the necessity of recording the identity of the dispensing pharmacist for each controlled substance dispenses, and asked to look at the refill strip log book. The log book was not current. Pharmacist Tam T. told the inspector the strip labels were deposited in a box and the pharmacy staff stuck them in the

log book whenever time permitted. The inspector reviewed the strip label log book and noted that the labels were not initialed, and the log book was not current.

27. During the October 16, 2013 inspection, the inspector found some prepacked lovastatin 20mg labeled as manufactured by Actavis, and with NDC#45963-634-04.[1] Some of the prepacked amber vials contained pink tablets and were marked 634, and other vials contained green tablets and were marked LU G02. The pink tablets were manufactured by Actavis.

28. Also during the October 16, 2013 inspection, Pharmacist Tam T. told the inspector that the office in the back of the pharmacy contained paperwork and business related documents. The inspector found boxes and plastic bags filled with samples of prescription drugs. Pharmacist Tam T. told the inspectors that the bags contained expired drugs waiting to be sent out for destruction. Respondent told the inspectors that some of the samples were given to her by her physician for her personal use, and some had been given to her for disposition after a deceased neighborhood physician's office had closed down. Respondent was unable to answer why she kept all the samples for personal use at work rather than at home. Respondent was unable to provide any records showing the acquisition of the drugs from the deceased physician's office. One of the Board inspectors asked Pharmacist Tam T. to inventory all the samples and the misbranded drugs for destruction. The Board inspector also asked Respondent to provide a statement about where the samples came from.

29. At the beginning of the October 16, 2013 inspection, one of the Board inspectors observed Pharmacist Tam T. take some bags of medications from under a table on which the old computer was located, and move them to a cabinet under the sink. The Board inspector retrieved the bags from the cabinet under the sink, and asked Pharmacist Tam T. what the medications

[1] The NDC, or National Drug Code, is a unique 10-digit, 3-segment number. It is a universal product identifier for human drugs in the United States. The code is present on all nonprescription (OTC) and prescription medication packages and inserts in the US. The 3 segments of the NDC identify the labeler, the product, and the commercial package size. The first set of numbers in the NDC identifies the labeler (manufacturer, repackager, or distributer). The second set of numbers is the product code, which identifies the specific strength, dosage form (i.e, capsule, tablet, liquid) and formulation of a drug for a specific manufacturer. Finally, the third set is the package code, which identifies package sizes and types. The labeler code is assigned by the FDA, while the product and package code are assigned by the labeler.

were. Pharmacist Tam T. told the inspector that the bags contained unused medications returned by customers awaiting destruction. A review of the contents of the bags showed medications with patient specific labels; some had labels of Respondent Pharmacy, and others had Alpha Drugs labels on them. The medications from Alpha Drugs were for two different patients for Abilify 30mg and Abilify 15mg tablets.

30. Following the inspection, the Board's inspectors confirmed with Respondent Luu's treating physician that he did provide Respondent Luu with samples of medications, including: ActoplusMet, Kombiglyze XR, Vesicare, Toviaz, and Tricor, and statin for treatment of ongoing medical issues.

31. Following the inspection, the Board's inspector reviewed CURES data transmitted by Respondent Pharmacy between April 25, 2013 and August 23, 2013 and obtained by the inspector during the inspection, and compared it to the report of controlled substances printed from Respondents' old computer for the same date range. None of the prescription numbers processed on the old computer system, and showed up on the CURES database.

**FIRST CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Maintain Clean Pharmacy)**

32. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondent Pharmacy had dead ants in the refrigerator inside the pharmacy which was used to store dangerous drugs, in violation of California Code of Regulations, title 16, section 1714, subsection (c), as set forth in paragraphs 22 to 31 above, which are incorporated here by this reference.

**SECOND CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Properly Maintain Records of Acquisition of Schedule III, IV and V Controlled Substances)**

33. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to maintain records of acquisition of Schedule III, IV and V controlled

substances separately or in a readily retrievable manner from ordinary invoices in violation of Federal Code of Regulations, title 21, section 1304.04, as set forth in paragraphs 22 to 31 above, which are incorporated here by this reference.

**THIRD CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Submit CURES Reports)**

34. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to submit CURES reports for 54 controlled substances processed via the old Pharmacy Program Version 5.1 processing computer and filled between April 26, 2013 and August 23, 2013, as set forth in paragraphs 22 to 31 above, which are incorporated here by this reference.

**FOURTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Properly Document Daily Controlled Substance Refill Data)**

35. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to generate daily printouts of controlled substance refill data, and did not have the pharmacist sign them or have an alternate system to document refills of controlled substances as required by Federal Code of Regulations, title 21, section 1306.22, subsection (f), as set forth in paragraphs 22 to 31 above, which are incorporated here by this reference.

**FIFTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Properly Maintain Identification Data for Dispensing Pharmacists)**

36. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to maintain in a readily retrievable format the name or initials of the dispensing pharmacist for each prescription in an electronic or paper format in violation of Code

section 4040 and California Code of Regulations, section 1717, subsection (b), as set forth in paragraphs 22 to 31 above, which are incorporated here by this reference.

**SIXTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Purchasing, Trading, Selling or Transferring Misbranded Dangerous Drugs)**

37. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents maintained on the pharmacy shelves pre-packed vials with some containing pink tablets and some containing green tablets both labeled as lovastatin 20mg, manufacturer Actavis, NDC#45963-634-04, in violation of Code section 4169, subsection (a)(3), as set forth in paragraphs 22 to 31 above, which are incorporated here by this reference.

**SEVENTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Maintain Records of Acquisition for Dangerous Drugs)**

38. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to maintain records of the acquisition of professional samples of dangerous drugs, without records of acquisition in violation of Code section 4081, subsection (a) and 4059, subsection (a), as set forth in paragraphs 22 to 31 above, which are incorporated here by this reference.

**EIGHTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Acting as Unlicensed Reverse Distributor)**

39. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents acted as a reverse distributor as defined by Code section 4043, subsection (a), by receiving prescription medications from customers and professional samples of dangerous drugs, as defined by Code section 4022, from doctor's offices without first being licensed as a reverse

distributor in violation of Code sections 4040.5, as set forth in paragraphs 22 to 31 above, which are incorporated here by this reference.

**OWNERSHIP PROHIBITION**

40. Business and Professions Code section 4307, subdivision (a), provides in pertinent part that any person whose license had been revoked or is under suspension shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of a license.

Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 41692 issued to Respondent Americare, and Respondent Luu, while acting as the manager, administrator, owner, member, officer, director, associate, or partner of Respondent Americare, had knowledge of, or knowingly participated in any conduct for which Pharmacy Permit Number PHY 41692 was revoked, suspended or placed on probation, Respondent Luu shall be prohibited from serving as manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy permit Number PHY 41692 issued to Respondent Americare is placed on probation, or until Pharmacy Permit Number PHY 41692 issued to Respondent Americare is reinstated, if Pharmacy Permit Number PHY 41692 is revoked.

**DISCIPLINE CONSIDERATIONS**

41. To determine the degree of discipline, if any, to be imposed on Respondent Americare, Complainant alleges that on or about January 16, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2011 49127, that found Respondent Americare violated Code section 4076, subsection (a)(11)(A), filling prescriptions on June 3, 2013 in containers with no physical description of the dispensed medication on the label, and section 4342 and 4169, subsection (a)(3), maintaining misbranded pre-packaged medications, and ordered Respondent Americare to pay fines totaling $5,000. That Citation is now final and is incorporated by reference as if fully set forth.

42. To determine the degree of discipline, if any, to be imposed on Respondent Luu, Complainant alleges that on or about January 16, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 59220, that found Respondent Luu violated Code section 4076,

subsection (a)(11)(A), filling prescriptions on June 3, 2013 in containers with no physical description of the dispensed medication on the label, and section 4342 and 4169, subsection (a)(3), maintaining misbranded pre-packaged medications, and ordered Respondent Luu to pay fines totaling $5,000. That Citation is now final and is incorporated by reference as if fully set forth.

**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 Pharmacy Permit Number PHY 41692 issued to Respondent Americare Plus Pharmacy Services, dba Americare Plus Pharmacy;

2. Revoking or suspending Pharmacist License No. RPH 42505 issued to Respondent Luu;

3. Prohibiting Respondent Luu from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 41692 issued to Respondent Americare is placed on probation or until Pharmacy Permit Number PHY 41692 is reinstated, if Pharmacy Permit Number PHY 41692 issued to Respondent Americare is revoked;

4. Ordering Respondent Americare Plus Pharmacy Services, dba Americare Plus Pharmacy with Respondent Luu as owner and Respondent Luu 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: 10/7/16

Virginia Herold

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
*Complainant*

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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:<br><br>**AMERICARE PLUS PHARMACY SERVICES, DBA AMERICARE PLUS PHARMACY; CHAU H. LUU, OWNER**<br>**14211 Euclid Street, Unit A**<br>**Garden Grove, CA 92843**<br><br>**Pharmacy Permit No. PHY 41692**<br><br>**CHAU H. LUU;**<br>**AKA CHAU HUYEN LUU**<br>**14211 Euclid Street, Unit A**<br>**Garden Grove, CA 92843**<br><br>**Pharmacist License No. RPH 42505**<br><br>Respondents. | Case No. 5425<br><br>**ACCUSATION** |

Complainant alleges:

PARTIES

1. Virginia Herold (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 June 14, 1996, the Board issued Pharmacy Permit Number PHY 41692 to Americare Plus Pharmacy Services, dba Americare Plus Pharmacy, (Respondent Americare) located at 14211 Euclid Street, Unit A, Garden Grove, California. Chau H. Luu, aka Chau Huyen

Luu, as been the individual licensed owner and Pharmacist-in-Charge of Respondent Americare since June 14, 1996. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein, and will expire on June 1, 2016, unless renewed.

3. On or about March 24, 1989, the Board issued Pharmacist License Number RPH 42505 to Chau H. Luu, also known as Chau Huyen Luu (Respondent Luu). The Pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2016, unless renewed.

**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 otherwise indicated.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.
>
> . . .
>
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

6. Section 4300.1 of the Code states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a

license by a licensee 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.

## STATUTORY AUTHORITY

7. 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, the designated representative 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 provision of 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.

8. Section 4022 of the Code states

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

9. Section 4040.5 states:

"Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs.

10. Section 4059.5 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, the designated representative 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 provision of 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.

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11. Section 4081, subsection (a) states:

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

12. Section 4160, subsection (a) states:

(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

13. Section 4169(a)(3)

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

. . .

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

. . . .

14. Section 4301 of the Code states in relevant part:

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

. . .

(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.

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15. Section 4307, subdivision (a), of the Code provides, in pertinent part, that any person who is an owner of licensee who has been revoked or is under suspension shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of a license.

Pursuant to Code section 4307, subdivision (a), in the event the license issued to Respondent Americare is revoked or placed on suspension, Respondent Luu shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of any licensee with rights issued by the Board.

16. Health and Safety Code section 11165, subsection (d) states:

> (d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
>
> (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
>
> (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
>
> (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
>
> (4) National Drug Code (NDC) number of the controlled substance dispensed.
>
> (5) Quantity of the controlled substance dispensed.
>
> (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
>
> (7) Number of refills ordered.
>
> (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
>
> (9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

**REGULATIONS**

17. California Code of Regulations, title 16, section 1714, subsection (c), states:

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

18. California Code of Regulations, title 16, section 1717, subsection (b), states:

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

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

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

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

19. Code of Federal Regulations, title 21, section 1304.04 states:

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

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(i) The nature of the records to be kept centrally.

(ii) The exact location where the records will be kept.

(iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.

(iv) Whether central records will be maintained in a manual, or computer readable, form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(3) A collector that is authorized to maintain a collection receptacle at a long-term care facility shall keep all records required by this part relating to those collection receptacles at the registered location, or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to the ARCOS Unit. See

the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

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

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

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

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

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

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

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The

electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

20. Code of Federal Regulations, title 21, section 1306.22, subsection (f), states:

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

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

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

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

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

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

**COSTS**

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

**DRUGS**

22. Insulin isophane, also known by the brand name Novolin N, is a dangerous drug under Business and Professions Code section 4022. It is used for the control of diabetes.

**FACTS**

23. On January 7, 2013, the Board received an online complaint alleging that Respondent Americare was dispensing medications with prescription vial labels which did not have the description of the medication on them.

24. On October 16, 2013, the Board conducted a routine inspection and complaint investigation at Respondent Americare. Two pharmacists, Kaitlynn T. and Tam T. were initially present during the inspection, and Respondent Luu came in later and assisted as well. During the routine inspection, the Board inspectors noted the refrigerator located by the door leading from

the patient waiting area into the pharmacy had dead ant carcasses in the door shelves. Pharmacist Tam T. told the inspectors that the refrigerator was used to store overstock of dangerous drugs, and the freezer above was used to stock Zostavax vaccine. There were open packages of Novolin N., a labeled prescription amber vial, and a bottle of pediatric electrolyte solution in the refrigerator.

25. During the October 16, 2013 inspection, while reviewing invoices from Respondent Americare's primary wholesalers HD Smith and Cardinal Health, the inspector questioned Pharmacist Tam T. about the procedure followed when receiving controlled substance orders into inventory. Pharmacist Tam T. showed the inspector an area in the stockroom where invoices of all drugs ordered by the pharmacy were kept in boxes. Pharmacist Tam T. told the inspector that Respondent Americare did not separate invoices for controlled substances in Schedules III-V and the pharmacist did not sign the invoices for the controlled substances. The inspector reviewed the boxes of invoices and collected Invoice 4959665 from HD Smith, dated August 29, 2013 and Invoice NO. 7929288 from Cardinal Health, dated September 20, 2013 to illustrate this behavior.

26. During the October 16, 2013 inspection, the Board's inspector reviewed the two computer systems used for processing prescriptions at Respondent Americare. The old computer system had Pharmacy Program Version 5.1, and the new system had Digital Rx. When questioned about weekly transmission of CURES data, Pharmacist Kaitlynn T. told the Board's inspector that Digital Rx transmitted CURES data from the new system weekly and the pharmacist on duty transmitted CURES data from the old computer system "from time to time." Neither Pharmacist Kaitlynn T. nor Pharmacist Tam T. was able to provide the inspector any proof of submission of CURES data from the old system. The inspector requested a run report of all controlled substance prescriptions filled and dispensed from the old computer between April 25, 2013 and October 16, 2013, and to provide proof of their transmission.

27. During the October 16, 2013 inspection, the inspector also asked Pharmacists Kaitlynn T. and Tam T. how Respondent Americare documented refills of prescriptions. Pharmacist Tam T. showed the inspector the log in screen of the Digital Rx system on the new computer which recorded the name of the pharmacist on duty and the inputting employee. The

inspector requested the report from October 15, 2013. Pharmacist Tam T. told the inspector that Respondent Americare did not print daily dispensing reports or reports for controlled substances dispensed. The inspector requested that a report be printed for October 15, 2013. Once printed, the inspector reviewed the report with Pharmacist Tam T. The inspector explained the necessity of recording the identity of the dispensing pharmacist for each controlled substance dispenses, and asked to look at the refill strip log book. The log book was not current. Pharmacist Tam T. told the inspector the strip labels were deposited in a box and the pharmacy staff stuck them in the log book whenever time permitted. The inspector reviewed the strip label log book and noted that the labels were not initialed, and the log book was not current.

28. During the October 16, 2013 inspection, the inspector found some prepacked lovastatin 20mg labeled as manufactured by Actavis, and with NDC#45963-634-04.[1] Some of the prepacked amber vials contained pink tablets and were marked 634, and other vials contained green tablets and were marked LU G02. The pink tablets were manufactured by Actavis.

29. Also during the October 16, 2013 inspection, Pharmacist Tam T. told the inspector that the office in the back of the pharmacy contained paperwork and business related documents. The inspector found boxes and plastic bags filled with samples of prescription drugs. Pharmacist Tam T. told the inspectors that the bags contained expired drugs waiting to be sent out for destruction. Respondent told the inspectors that some of the samples were given to her by her physician for her personal use, and some had been given to her for disposition after a deceased neighborhood physician's office had closed down. Respondent was unable to answer why she kept all the samples for personal use at work rather than at home. Respondent was unable to provide any records showing the acquisition of the drugs from the deceased physician's office.

[1] The NDC, or National Drug Code, is a unique 10-digit, 3-segment number. It is a universal product identifier for human drugs in the United States. The code is present on all nonprescription (OTC) and prescription medication packages and inserts in the US. The 3 segments of the NDC identify the labeler, the product, and the commercial package size. The first set of numbers in the NDC identifies the labeler (manufacturer, repackager, or distributer). The second set of numbers is the product code, which identifies the specific strength, dosage form (i.e, capsule, tablet, liquid) and formulation of a drug for a specific manufacturer. Finally, the third set is the package code, which identifies package sizes and types. The labeler code is assigned by the FDA, while the product and package code are assigned by the labeler.

One of the Board inspectors asked Pharmacist Tam T. to inventory all the samples and the misbranded drugs for destruction. The Board inspector also asked Respondent to provide a statement about where the samples came from.

30. At the beginning of the October 16, 2013 inspection, one of the Board inspectors observed Pharmacist Tam T. take some bags of medications from under a table on which the old computer was located, and move them to a cabinet under the sink. The Board inspector retrieved the bags from the cabinet under the sink, and asked Pharmacist Tam T. what the medications were. Pharmacist Tam T. told the inspector that the bags contained unused medications returned by customers awaiting destruction. A review of the contents of the bags showed medications with patient specific labels; some had labels of Respondent Pharmacy, and others had Alpha Drugs labels on them. The medications from Alpha Drugs were for two different patients for Abilify 30mg and Abilify 15mg tablets.

31. Following the inspection, the Board's inspectors confirmed with Respondent Luu's treating physician that he did provide Respondent Luu with samples of medications, including: ActoplusMet, Kombiglyze XR, Vesicare, Toviaz, and Tricor, and statin for treatment of ongoing medical issues.

32. Following the inspection, the Board's inspector reviewed CURES data transmitted by Respondent Pharmacy between April 25, 2013 and August 23, 2013 and obtained by the inspector during the inspection, and compared it to the report of controlled substances printed from Respondents' old computer for the same date range. None of the prescription numbers processed on the old computer system, and showed up on the CURES database.

**FIRST CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Have Dangerous Drugs or Devises Ordered by Pharmacist)**

33. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents did not have invoices for controlled substances delivered from H D. Smith and

Cardinal Health signed by a pharmacist in violation of Code section 4059.5, subsection (a), as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

**SECOND CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Maintain Clean Pharmacy)**

34. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondent Pharmacy had dead ants in the refrigerator inside the pharmacy which was used to store dangerous drugs, in violation of California Code of Regulations, title 16, section 1714, subsection (c), as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

**THIRD CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Properly Maintain Records of Acquisition of Schedule III, IV and V Controlled Substances)**

35. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to maintain records of acquisition of Schedule III, IV and V controlled substances separately or in a readily retrievable manner from ordinary invoices in violation of Federal Code of Regulations, title 21, section 1304.04, as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

**FOURTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Submit CURES Reports)**

36. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to submit CURES reports for 54 controlled substances processed via the old Pharmacy Program Version 5.1 processing computer and filled between April 26, 2013 and August 23, 2013, as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

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**FIFTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Properly Document Daily Controlled Substance Refill Data)**

37. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to generate daily printouts of controlled substance refill data, and did not have the pharmacist sign them or have an alternate system to document refills of controlled substances as required by Federal Code of Regulations, title 21, section 1306.22, subsection (f), as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

**SIXTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Properly Maintain Identification Data for Dispensing Pharmacists)**

38. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to maintain in a readily retrievable format the name or initials of the dispensing pharmacist for each prescription in an electronic or paper format in violation of Code section 4040 and California Code of Regulations, section 1717, subsection (b), as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

**SEVENTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Purchasing, Trading, Selling or Transferring Misbranded Dangerous Drugs)**

39. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents maintained on the pharmacy shelves pre-packed vials with some containing pink tablets and some containing green tablets both labeled as lovastatin 20mg, manufacturer Actavis, NDC#45963-634-04, in violation of Code section 4169, subsection (a)(3), as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

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**EIGHTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Failure to Maintain Records of Acquisition for Dangerous Drugs)**

40. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents failed to maintain records of the acquisition of professional samples of dangerous drugs, without records of acquisition in violation of Code section 4081, subsection (a) and 4059, subsection (a), as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

**NINTH CAUSE FOR DISCIPLINE**

**(Unprofessional Conduct – Acting as Unlicensed Reverse Distributor)**

41. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that during the Board inspection on October 16, 2013, Respondents acted as a reverse distributor as defined by Code section 4043, subsection (a), by receiving prescription medications from customers and professional samples of dangerous drugs, as defined by Code section 4022, from doctor's offices without first being licensed as a reverse distributor in violation of Code sections 4040.5, as set forth in paragraphs 23 to 32 above, which are incorporated here by this reference.

**OWNERSHIP PROHIBITION**

42. Business and Professions Code section 4307, subdivision (a), provides in pertinent part that any person whose license had been revoked or is under suspension shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of a license.

Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 41692 issued to Respondent Americare, and Respondent Luu, while acting as the manager, administrator, owner, member, officer, director, associate, or partner of Respondent Americare, had knowledge of, or knowingly participated in any conduct for which Pharmacy Permit Number PHY 41692 was revoked, suspended or placed on probation, Respondent Luu shall be prohibited

from serving as manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy permit Number PHY 41692 issued to Respondent Americare is placed on probation, or until Pharmacy Permit Number PHY 41692 issued to Respondent Americare is reinstated, if Pharmacy Permit Number PHY 41692 is revoked.

**DISCIPLINE CONSIDERATIONS**

43. To determine the degree of discipline, if any, to be imposed on Respondent Americare, Complainant alleges that on or about January 16, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2011 49127, that found Respondent Americare violated Code section 4076, subsection (a)(11)(A), filling prescriptions on June 3, 2013 in containers with no physical description of the dispensed medication on the label, and section 4342 and 4169, subsection (a)(3), maintaining misbranded pre-packaged medications, and ordered Respondent Americare to pay fines totaling $5,000. That Citation is now final and is incorporated by reference as if fully set forth.

44. To determine the degree of discipline, if any, to be imposed on Respondent Luu, Complainant alleges that on or about January 16, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 59220, that found Respondent Luu violated Code section 4076, subsection (a)(11)(A), filling prescriptions on June 3, 2013 in containers with no physical description of the dispensed medication on the label, and section 4342 and 4169, subsection (a)(3), maintaining misbranded pre-packaged medications, and ordered Respondent Luu to pay fines totaling $5,000. That Citation is now final and is incorporated by reference as if fully set forth.

**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 Pharmacy Permit Number PHY 41692 issued to Respondent Americare Plus Pharmacy Services, dba Americare Plus Pharmacy;

2. Revoking or suspending Pharmacist License No. RPH 42505 issued to Respondent Luu;

3. Prohibiting Respondent Luu from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 41692 issued to Respondent Americare is placed on probation or until Pharmacy Permit Number PHY 41692 is reinstated, if Pharmacy Permit Number PHY 41692 issued to Respondent Americare is revoked;

4. Ordering Respondent Americare Plus Pharmacy Services, dba Americare Plus Pharmacy with Respondent Luu as owner and Respondent Luu 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: 2/24/16

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
*Complainant*

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