

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

In the Matter of the Accusation Against:

**AMERICARE PLUS PHARMACY
SERVICES, DBA AMERICARE PLUS
PHARMACY;
CHAU H. LUU, OWNER
14211 Euclid Street, Unit A
Garden Grove, CA 92843**

Pharmacy Permit No. PHY 41692

**CHAU H. LUU;
AKA CHAU HUYEN LUU
14211 Euclid Street, Unit A
Garden Grove, CA 92843**

Pharmacist License No. RPH 42505

Respondents.

Case No. 5425

**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

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

11 In the Matter of the Accusation Against:

Case No. 5425

12 **AMERICARE PLUS PHARMACY**
13 **SERVICES, DBA AMERICARE PLUS**
14 **PHARMACY;**

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

15 **CHAU H. LUU, OWNER**
14211 Euclid Street, Unit A
Garden Grove, CA 92843

16 **Pharmacy Permit No. PHY 41692**

17 **CHAU H. LUU;**
18 **AKA CHAU HUYEN LUU**
14211 Euclid Street, Unit A
19 **Garden Grove, CA 92843**

20 **Pharmacist License No. RPH 42505**

21 Respondents.

22
23 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
24 entitled proceedings that the following matters are true:

25 PARTIES

26 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.
27 She brought this action solely in her official capacity and is represented in this matter by Kamala
28

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

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

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

13 4. On or about March 24, 1989, the Board issued Pharmacist License Number RPH
14 42505 to Chau H. Luu, also known as Chau Huyen Luu (Respondent Luu). The Pharmacist
15 license was in full force and effect at all times relevant to the charges brought herein and will
16 expire on October 31, 2018, unless renewed.

17 JURISDICTION

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

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

26 ADVISEMENT AND WAIVERS

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

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

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

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

12 CULPABILITY

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

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

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

23 CONTINGENCY

24 13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
25 understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may
26 communicate directly with the Board regarding this stipulation and settlement, without notice to
27 or participation by Respondents or their counsel. By signing the stipulation, Respondents
28 understand and agree that they may not withdraw their agreement or seek to rescind the

1 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this
2 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of
3 no force or effect, except for this paragraph, it shall be inadmissible in any legal action between
4 the parties, and the Board shall not be disqualified from further action by having considered this
5 matter.

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

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

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

18 **DISCIPLINARY ORDER**

19 IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 41692 and Pharmacist License
20 No. RPH 42505 are revoked. However, the revocation is stayed and Respondents are placed on
21 probation for four (4) years on the following terms and conditions.

22 **Probation Terms for Respondent Luu**

23 1. **Obey All Laws**

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

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

27

28

- 1 • an arrest or issuance of a criminal complaint for violation of any provision of the
- 2 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
- 3 substances laws
- 4 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
- 5 criminal complaint, information or indictment
- 6 • a conviction of any crime
- 7 • discipline, citation, or other administrative action filed by any state or federal agency
- 8 which involves respondent's Pharmacist license or which is related to the practice of
- 9 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
- 10 for any drug, device or controlled substance.

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

12 **2. Report to the Board**

13 Respondent Luu shall report to the board quarterly, on a schedule as directed by the board
14 or its designee. The report shall be made either in person or in writing, as directed. Among other
15 requirements, respondent shall state in each report under penalty of perjury whether there has
16 been compliance with all the terms and conditions of probation. Failure to submit timely reports
17 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency
18 in submission of reports as directed may be added to the total period of probation. Moreover, if
19 the final probation report is not made as directed, probation shall be automatically extended until
20 such time as the final report is made and accepted by the board.

21 **3. Interview with the Board**

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

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1 **4. Cooperate with Board Staff**

2 Respondent Luu shall cooperate with the board's inspection program and with the board's
3 monitoring and investigation of respondent's compliance with the terms and conditions of his
4 probation. Failure to cooperate shall be considered a violation of probation.

5 **5. Continuing Education**

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

8 **6. Notice to Employers**

9 During the period of probation, Respondent Luu shall notify all present and prospective
10 employers of the decision in case number 5425 and the terms, conditions and restrictions imposed
11 on respondent by the decision, as follows:

12 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
13 respondent undertaking any new employment, respondent shall cause his direct supervisor,
14 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
15 tenure of employment) and owner to report to the board in writing acknowledging that the listed
16 individual(s) has/have read the decision in case number 5425, and terms and conditions imposed
17 thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s)
18 submit timely acknowledgment(s) to the board.

19 If respondent works for or is employed by or through a pharmacy employment service,
20 respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity
21 licensed by the board of the terms and conditions of the decision in case number 5425 in advance
22 of the respondent commencing work at each licensed entity. A record of this notification must be
23 provided to the board upon request.

24 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
25 (15) days of respondent undertaking any new employment by or through a pharmacy employment
26 service, respondent shall cause his direct supervisor with the pharmacy employment service to
27 report to the board in writing acknowledging that he has read the decision in case number 5425
28

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

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

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

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

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

16 **8. Reimbursement of Board Costs**

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

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

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

26 **9. Probation Monitoring Costs**

27 Respondent Luu shall pay any costs associated with probation monitoring as determined by
28 the board each and every year of probation. Such costs shall be payable to the board on a

1 schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as
2 directed shall be considered a violation of probation.

3 **10. Status of License**

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

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

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

12 Following the effective date of this decision, should Respondent Luu cease practice due to
13 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
14 respondent may tender his license to the board for surrender. The board or its designee shall have
15 the discretion whether to grant the request for surrender or take any other action it deems
16 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
17 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
18 record of discipline and shall become a part of the respondent's license history with the board.

19 Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to
20 the board within ten (10) days of notification by the board that the surrender is accepted.

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

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

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

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

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

6 13. Tolling of Probation

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

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

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

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

26 14. Violation of Probation

27 If Respondent Luu has not complied with any term or condition of probation, the board
28 shall have continuing jurisdiction over respondent, and probation shall automatically be extended,

1 until all terms and conditions have been satisfied or the board has taken other action as deemed
2 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
3 to impose the penalty that was stayed.

4 If respondent violates probation in any respect, the board, after giving respondent notice
5 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
6 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a
7 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If
8 a petition to revoke probation or an accusation is filed against respondent during probation, the
9 board shall have continuing jurisdiction and the period of probation shall be automatically
10 extended until the petition to revoke probation or accusation is heard and decided.

11 **15. Completion of Probation**

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

14 **16. Community Services Program**

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

25 **17. Remedial Education**

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

1 education shall consist of at least 10 additional continuing education hours per year, for the first
2 three years of probation, which shall be completed at respondent's own expense. All remedial
3 education shall be in addition to, and shall not be credited toward, continuing education (CE)
4 courses used for license renewal purposes.

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

9 Following the completion of each course, the board or its designee may require the
10 respondent, at his own expense, to take an approved examination to test the respondent's
11 knowledge of the course. If the respondent does not achieve a passing score on the examination,
12 this failure shall be considered a violation of probation. Any such examination failure shall
13 require respondent to take another course approved by the board in the same subject area.

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

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

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

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

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

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

11 **20. Ethics Course**

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

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

19 **Probation Terms for Respondent Americare**

20 **1. Obey All Laws**

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

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

- 24 • an arrest or issuance of a criminal complaint for violation of any provision of the
25 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
26 substances laws
- 27 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
28 criminal complaint, information or indictment

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

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

7 **2. Report to the Board**

8 Respondent Americare owner shall report to the board quarterly, on a schedule as directed
9 by the board or its designee. The report shall be made either in person or in writing, as directed.
10 Among other requirements, respondent owner shall state in each report under penalty of perjury
11 whether there has been compliance with all the terms and conditions of probation. Failure to
12 submit timely reports in a form as directed shall be considered a violation of probation. Any
13 period(s) of delinquency in submission of reports as directed may be added to the total period of
14 probation. Moreover, if the final probation report is not made as directed, probation shall be
15 automatically extended until such time as the final report is made and accepted by the board.

16 **3. Interview with the Board**

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

23 **4. Cooperate with Board Staff**

24 Respondent Americare owner shall cooperate with the board's inspection program and with
25 the board's monitoring and investigation of respondent's compliance with the terms and
26 conditions of its probation. Failure to cooperate shall be considered a violation of probation.

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1 **5. Reimbursement of Board Costs**

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

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

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

11 **6. Probation Monitoring Costs**

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

16 **7. Status of License**

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

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

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

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

1 business, respondent owner may tender the premises license to the board for surrender. The
2 board or its designee shall have the discretion whether to grant the request for surrender or take
3 any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of
4 the license, respondent will no longer be subject to the terms and conditions of probation.

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

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

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

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

24 9. **Notice to Employees**

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

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

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

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

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

17 **11. Posted Notice of Probation**

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

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

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

26 **12. Violation of Probation**

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

1 automatically extended until all terms and conditions have been satisfied or the board has taken
2 other action as deemed appropriate to treat the failure to comply as a violation of probation, to
3 terminate probation, and to impose the penalty that was stayed.

4 If respondent owner violates probation in any respect, the board, after giving respondent
5 owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary
6 order that was stayed. Notice and opportunity to be heard are not required for those provisions
7 stating that a violation thereof may lead to automatic termination of the stay and/or revocation of
8 the license. If a petition to revoke probation or an accusation is filed against respondent during
9 probation, the board shall have continuing jurisdiction and the period of probation shall be
10 automatically extended until the petition to revoke probation or accusation is heard and decided.

11 13. **Completion of Probation**

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

14 14. **Community Services Program**

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

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

23 Failure to timely submit, commence, or comply with the program shall be considered a
24 violation of probation. In lieu of community service, Respondent Americare may pay a fine of
25 \$10,000.

26 15. **Separate File of Records**

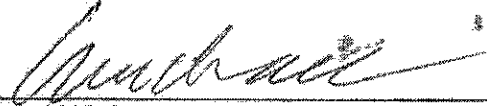
27 Respondent Americare owner shall maintain and make available for inspection a separate
28 file of all records pertaining to the acquisition or disposition of all controlled substances. Failure

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

3 ACCEPTANCE

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

9 DATED: 11/17/16


10 CHAU H. LUU, OWNER and authorized
11 representative for AMERICARE PLUS PHARMACY
12 SERVICES, DBA AMERICARE PLUS PHARMACY,
13 Respondent

14 I have read and fully discussed with Respondents Luu and Americare the terms and
15 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.

16 I approve its form and content.

17 DATED: 11/17/2016


18 HERBERT L. WEINBERG
19 Attorney for Respondent

20 ENDORSEMENT

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

23 Dated: 12/2/2016

24 Respectfully submitted,

25 KAMALA D. HARRIS
26 Attorney General of California
27 JAMES M. LEDAKIS
28 Supervising Deputy Attorney General

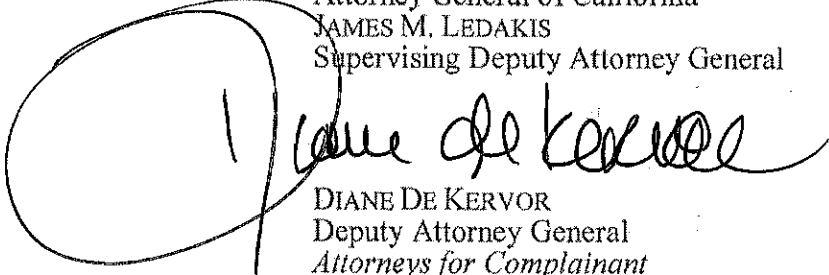

DIANE DE KERVOR
Deputy Attorney General
Attorneys for Complainant

Exhibit A

First Amended Accusation No. 5425

1 KAMALA D. HARRIS
Attorney General of California
2 JAMES LEDAKIS
Supervising Deputy Attorney General
3 DIANE DE KERVOR
Deputy Attorney General
4 State Bar No. 174721
600 West Broadway, Suite 1800
5 San Diego, CA 92101
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6 San Diego, CA 92186-5266
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7 Facsimile: (619) 645-2061
Attorneys for Complainant
8

9
10 **BEFORE THE**
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 5425

13 **AMERICARE PLUS PHARMACY SERVICES,**
14 **DBA AMERICARE PLUS PHARMACY;**
CHAU H. LUU, OWNER
14211 Euclid Street, Unit A
15 Garden Grove, CA 92843

FIRST AMENDED
ACCUSATION

16 **Pharmacy Permit No. PHY 41692**

17 **CHAU H. LUU;**
AKA CHAU HUYEN LUU
18 14211 Euclid Street, Unit A
19 Garden Grove, CA 92843

20 **Pharmacist License No. RPH 42505**

21 Respondents.

22 Complainant alleges:

23 **PARTIES**

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

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

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

5 3. On or about March 24, 1989, the Board issued Pharmacist License Number RPH
6 42505 to Chau H. Luu, also known as Chau Huyen Luu (Respondent Luu). The Pharmacist
7 license was in full force and effect at all times relevant to the charges brought herein and will
8 expire on October 31, 2016, unless renewed.

9 JURISDICTION

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

13 5. Section 4300 of the Code states:

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

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

17 (1) Suspending judgment.

18 (2) Placing him or her upon probation.

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

21 (4) Revoking his or her license.

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

23 ...

24 (e) The proceedings under this article shall be conducted in accordance with
25 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
26 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.

1 6. Section 4300.1 of the Code states:

2 The expiration, cancellation, forfeiture, or suspension of a board-issued
3 license by operation of law or by order or decision of the board or a court of law,
4 the placement of a license on a retired status, or the voluntary surrender of a
5 license by a licensee shall not deprive the board of jurisdiction to commence or
6 proceed with any investigation of, or action or disciplinary proceeding against, the
7 licensee or to render a decision suspending or revoking the license.

8 STATUTORY AUTHORITY

9 7. Section 4022 of the Code states

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

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

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

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

20 8. Section 4040.5 states:

21 "Reverse distributor" means every person who acts as an agent for
22 pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and

23 other entities by receiving, inventorying, warehousing, and managing the
24 disposition of outdated or nonsaleable dangerous drugs.

25 9. Section 4059.5 states:

26 (a) Except as otherwise provided in this chapter, dangerous drugs or
27 dangerous devices may only be ordered by an entity licensed by the board and
28 shall be delivered to the licensed premises and signed for and received by a
29 pharmacist. Where a licensee is permitted to operate through a designated
30 representative, the designated representative shall sign for and receive the delivery.

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

35 (c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital
36 pharmacy may be made to a central receiving location within the hospital.
37 However, the dangerous drugs or dangerous devices shall be delivered to the

1 licensed pharmacy premises within one working day following receipt by the
2 hospital, and the pharmacist on duty at that time shall immediately inventory the
3 dangerous drugs or dangerous devices.

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

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

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

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

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

28 (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

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

6
7 11. Section 4160, subsection (a) states:

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

11 12. Section 4169(a)(3)

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

13 ...

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

17

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

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

23 ...

24 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
25 abetting the violation of or conspiring to violate any provision or term of this
26 chapter or of the applicable federal and state laws and regulations governing
27 pharmacy, including regulations established by the board or by any other state or
28 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

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

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

4 (d) For each prescription for a Schedule II, Schedule III, or Schedule IV
5 controlled substance, as defined in the controlled substances schedules in federal
6 law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14,
7 respectively, of Title 21 of the Code of Federal Regulations, the dispensing
8 pharmacy, clinic, or other dispenser shall report the following information to the

9 Department of Justice as soon as reasonably possible, but not more than seven
10 days after the date a controlled substance is dispensed, in a format specified by the
11 Department of Justice:

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

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

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

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

24 (5) Quantity of the controlled substance dispensed.

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

27 (7) Number of refills ordered.

28 (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.

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

2 (b) In addition to the requirements of Business and Professions Code section
3 4040, the following information shall be maintained for each prescription on file
4 and shall be readily retrievable:

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

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

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

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

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

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

23 (1) Financial and shipping records (such as invoices and packing slips but
24 not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may
25 be kept at a central location, rather than at the registered location, if the registrant
26 has notified the Administration of his intention to keep central records. Written
27 notification must be submitted by registered or certified mail, return receipt
28 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

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

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

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

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

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

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

23 (4) In the event that a registrant fails to comply with these conditions, the
24 Special Agent in Charge may cancel such central recordkeeping authorization, and
25 all other central recordkeeping authorizations held by the registrant without a
26 hearing or other procedures. In the event of a cancellation of central recordkeeping
27 authorizations under this paragraph the registrant shall, within the time specified
28 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

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

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

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

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

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

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

18 (4) Paper prescriptions for Schedules III, IV, and V controlled substances
19 shall be maintained at the registered location either in a separate prescription file
20 for Schedules III, IV, and V controlled substances only or in such form that they
21 are readily retrievable from the other prescription records of the pharmacy.
22 Prescriptions will be deemed readily retrievable if, at the time they are initially
23 filed, the face of the prescription is stamped in red ink in the lower right corner
24 with the letter "C" no less than 1 inch high and filed either in the prescription file
25 for controlled substances listed in Schedules I and II or in the usual consecutively
26 numbered prescription file for noncontrolled substances. However, if a pharmacy
27 employs a computer application for prescriptions that permits identification by
28 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 (1) Any such proposed computerized application must provide online
2 retrieval (via computer monitor or hard-copy printout) of original prescription
3 order information for those prescription orders that are currently authorized for
4 refilling. This shall include, but is not limited to, data such as the original
5 prescription number; date of issuance of the original prescription order by the
6 practitioner; full name and address of the patient; name, address, and DEA
7 registration number of the practitioner; and the name, strength, dosage form,
8 quantity of the controlled substance prescribed (and quantity dispensed if different
9 from the quantity prescribed), and the total number of refills authorized by the
10 prescribing practitioner.

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

19 (3) Documentation of the fact that the refill information entered into the
20 computer each time a pharmacist refills an original paper, fax, or oral prescription
21 order for a Schedule III or IV controlled substance is correct must be provided by
22 the individual pharmacist who makes use of such an application. If such an
23 application provides a hard-copy printout of each day's controlled substance
24 prescription order refill data, that printout shall be verified, dated, and signed by
25 the individual pharmacist who refilled such a prescription order. The individual
26 pharmacist must verify that the data indicated are correct and then sign this
27 document in the same manner as he would sign a check or legal document (e.g.,
28 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

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

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

10 COSTS

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

15 DRUGS

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

18 FACTS

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

22 23. On October 16, 2013, the Board conducted a routine inspection and complaint
23 investigation at Respondent Americare. Two pharmacists, Kaitlynn T. and Tam T. were initially
24 present during the inspection, and Respondent Luu came in later and assisted as well. During the
25 routine inspection, the Board inspectors noted the refrigerator located by the door leading from
26 the patient waiting area into the pharmacy had dead ant carcasses in the door shelves. Pharmacist
27 Tam T. told the inspectors that the refrigerator was used to store overstock of dangerous drugs,
28 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.

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

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

8 25. During the October 16, 2013 inspection, the Board's inspector reviewed the two
9 computer systems used for processing prescriptions at Respondent Americare. The old computer
10 system had Pharmacy Program Version 5.1, and the new system had Digital Rx. When
11 questioned about weekly transmission of CURES data, Pharmacist Kaitlynn T. told the Board's
12 inspector that Digital Rx transmitted CURES data from the new system weekly and the
13 pharmacist on duty transmitted CURES data from the old computer system "from time to time."
14 Neither Pharmacist Kaitlynn T. nor Pharmacist Tam T. was able to provide the inspector any
15 proof of submission of CURES data from the old system. The inspector requested a run report of
16 all controlled substance prescriptions filled and dispensed from the old computer between April
17 25, 2013 and October 16, 2013, and to provide proof of their transmission.

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

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

3 27. During the October 16, 2013 inspection, the inspector found some prepacked
4 lovastatin 20mg labeled as manufactured by Actavis, and with NDC#45963-634-04.¹ Some of
5 the prepacked amber vials contained pink tablets and were marked 634, and other vials contained
6 green tablets and were marked LU G02. The pink tablets were manufactured by Actavis.

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

19 29. At the beginning of the October 16, 2013 inspection, one of the Board inspectors
20 observed Pharmacist Tam T. take some bags of medications from under a table on which the old
21 computer was located, and move them to a cabinet under the sink. The Board inspector retrieved
22 the bags from the cabinet under the sink, and asked Pharmacist Tam T. what the medications
23

24 ¹ The NDC, or National Drug Code, is a unique 10-digit, 3-segment number. It is a
25 universal product identifier for human drugs in the United States. The code is present on all
26 nonprescription (OTC) and prescription medication packages and inserts in the US. The 3
27 segments of the NDC identify the labeler, the product, and the commercial package size. The first
28 set of numbers in the NDC identifies the labeler (manufacturer, repackager, or distributor). 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.

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

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

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

15 FIRST CAUSE FOR DISCIPLINE

16 (Unprofessional Conduct – Failure to Maintain Clean Pharmacy)

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

23 SECOND CAUSE FOR DISCIPLINE

24 (Unprofessional Conduct – Failure to Properly Maintain Records 25 of Acquisition of Schedule III, IV and V Controlled Substances)

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

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

4 **THIRD CAUSE FOR DISCIPLINE**

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

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

12 **FOURTH CAUSE FOR DISCIPLINE**

13 **(Unprofessional Conduct – Failure to Properly Document**

14 **Daily Controlled Substance Refill Data)**

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

21 **FIFTH CAUSE FOR DISCIPLINE**

22 **(Unprofessional Conduct – Failure to Properly Maintain**

23 **Identification Data for Dispensing Pharmacists)**

24 36. Respondents are subject to disciplinary action for unprofessional conduct under Code
25 section 4301, subsection (o), in that during the Board inspection on October 16, 2013,
26 Respondents failed to maintain in a readily retrievable format the name or initials of the
27 dispensing pharmacist for each prescription in an electronic or paper format in violation of Code
28

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

3 **SIXTH CAUSE FOR DISCIPLINE**

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

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

12 **SEVENTH CAUSE FOR DISCIPLINE**

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

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

21 **EIGHTH CAUSE FOR DISCIPLINE**

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

23 39. Respondents are subject to disciplinary action for unprofessional conduct under Code
24 section 4301, subsection (o), in that during the Board inspection on October 16, 2013,
25 Respondents acted as a reverse distributor as defined by Code section 4043, subsection (a), by
26 receiving prescription medications from customers and professional samples of dangerous drugs,
27 as defined by Code section 4022, from doctor's offices without first being licensed as a reverse
28

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

3 **OWNERSHIP PROHIBITION**

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

8 Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY
9 41692 issued to Respondent Americare, and Respondent Luu, while acting as the manager,
10 administrator, owner, member, officer, director, associate, or partner of Respondent Americare,
11 had knowledge of, or knowingly participated in any conduct for which Pharmacy Permit Number
12 PHY 41692 was revoked, suspended or placed on probation, Respondent Luu shall be prohibited
13 from serving as manager, administrator, owner, member, officer, director, associate, or partner of
14 a licensee for five years if Pharmacy permit Number PHY 41692 issued to Respondent Americare
15 is placed on probation, or until Pharmacy Permit Number PHY 41692 issued to Respondent
16 Americare is reinstated, if Pharmacy Permit Number PHY 41692 is revoked.

17 **DISCIPLINE CONSIDERATIONS**

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

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

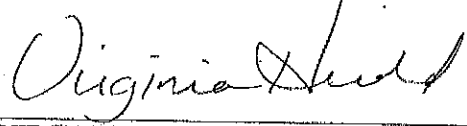
1 subsection (a)(11)(A), filling prescriptions on June 3, 2013 in containers with no physical
2 description of the dispensed medication on the label, and section 4342 and 4169, subsection
3 (a)(3), maintaining misbranded pre-packaged medications, and ordered Respondent Luu to pay
4 fines totaling \$5,000.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

6 **PRAYER**

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

- 9 1. Revoking or suspending Pharmacy Permit Number PHY 41692 issued to Respondent
10 Americare Plus Pharmacy Services, dba Americare Plus Pharmacy;
- 11 2. Revoking or suspending Pharmacist License No. RPH 42505 issued to Respondent
12 Luu;
- 13 3. Prohibiting Respondent Luu from serving as a manager, administrator, owner,
14 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
15 Number PHY 41692 issued to Respondent Americare is placed on probation or until Pharmacy
16 Permit Number PHY 41692 is reinstated, if Pharmacy Permit Number PHY 41692 issued to
17 Respondent Americare is revoked;
- 18 4. Ordering Respondent Americare Plus Pharmacy Services, dba Americare Plus
19 Pharmacy with Respondent Luu as owner and Respondent Luu to pay the Board of Pharmacy the
20 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
21 Professions Code section 125.3; and
- 22 5. Taking such other and further action as deemed necessary and proper.

23
24 DATED: 10/7/16



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

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Attorneys for Complainant

9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 5425

13 **AMERICARE PLUS PHARMACY SERVICES,**
14 **DBA AMERICARE PLUS PHARMACY;**
15 **CHAU H. LUU, OWNER**
14211 Euclid Street, Unit A
Garden Grove, CA 92843

ACCUSATION

16 Pharmacy Permit No. PHY 41692

17 **CHAU H. LUU;**
18 **AKA CHAU HUYEN LUU**
14211 Euclid Street, Unit A
Garden Grove, CA 92843

19 Pharmacist License No. RPH 42505

20 Respondents.

22 Complainant alleges:

23 **PARTIES**

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

26 2. On or about June 14, 1996, the Board issued Pharmacy Permit Number PHY 41692 to
27 Americare Plus Pharmacy Services, dba Americare Plus Pharmacy, (Respondent Americare)
28 located at 14211 Euclid Street, Unit A, Garden Grove, California. Chau H. Luu, aka Chau Huyen

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

4 3. On or about March 24, 1989, the Board issued Pharmacist License Number RPH
5 42505 to Chau H. Luu, also known as Chau Huyen Luu (Respondent Luu). The Pharmacist
6 license was in full force and effect at all times relevant to the charges brought herein and will
7 expire on October 31, 2016, unless renewed.

8 JURISDICTION

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

12 5. Section 4300 of the Code states:

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

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

16 (1) Suspending judgment.

17 (2) Placing him or her upon probation.

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

20 (4) Revoking his or her license.

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

22 ...

23 (e) The proceedings under this article shall be conducted in accordance with
24 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the
25 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.

26 6. Section 4300.1 of the Code states:

27 The expiration, cancellation, forfeiture, or suspension of a board-issued
28 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

1 license by a licensee shall not deprive the board of jurisdiction to commence or
2 proceed with any investigation of, or action or disciplinary proceeding against, the
licensee or to render a decision suspending or revoking the license.

3 STATUTORY AUTHORITY

4 7. Section 4059.5 of the Code states:

5 (a) Except as otherwise provided in this chapter, dangerous drugs or
6 dangerous devices may only be ordered by an entity licensed by the board and shall
7 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.

8 (b) A dangerous drug or dangerous device transferred, sold, or delivered to a
9 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
10 user's agent.

11 (c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital
12 pharmacy may be made to a central receiving location within the hospital.
However, the dangerous drugs or dangerous devices shall be delivered to the
13 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.

14 (d) Notwithstanding any other provision of law, a dangerous drug or
15 dangerous device may be ordered by and provided to a manufacturer, physician,
dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to
16 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
17 dangerous device, or a duly authorized representative of the person or entity, shall
sign for the receipt of the dangerous drug or dangerous device.

18 (e) A dangerous drug or dangerous device shall not be transferred, sold, or
19 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
20 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
21 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
22 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.

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

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

26 (2) Only the pharmacist-in-charge or a pharmacist designated by the
27 pharmacist-in-charge has access to the secure storage facility after dangerous drugs
or dangerous devices have been delivered.
28

1 (3) The secure storage facility has a means of indicating whether it has been
2 entered after dangerous drugs or dangerous devices have been delivered.

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

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

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

12 8. Section 4022 of the Code states

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

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

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

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

23 9. Section 4040.5 states:

24 "Reverse distributor" means every person who acts as an agent for
25 pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and

26 other entities by receiving, inventorying, warehousing, and managing the
27 disposition of outdated or nonsaleable dangerous drugs.

28 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.

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

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

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

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

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

28 (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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1 15. Section 4307, subdivision (a), of the Code provides, in pertinent part, that any person
2 who is an owner of licensee who has been revoked or is under suspension shall be prohibited from
3 serving as a manager, administrator, owner, member, officer, director, associate or partner of a
4 license.

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

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

10 (d) For each prescription for a Schedule II, Schedule III, or Schedule IV
11 controlled substance, as defined in the controlled substances schedules in federal
12 law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14,
13 respectively, of Title 21 of the Code of Federal Regulations, the dispensing
14 pharmacy, clinic, or other dispenser shall report the following information to the

15 Department of Justice as soon as reasonably possible, but not more than seven days
16 after the date a controlled substance is dispensed, in a format specified by the
17 Department of Justice:

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

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

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

28 (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.

1 (10) Date of dispensing of the prescription.

2 **REGULATIONS**

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

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

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

9 (b) In addition to the requirements of Business and Professions Code section
10 4040, the following information shall be maintained for each prescription on file
11 and shall be readily retrievable:

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

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

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

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

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

25 (a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every
26 inventory and other records required to be kept under this part must be kept by the
27 registrant and be available, for at least 2 years from the date of such inventory or
28 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:

///

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

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

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

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

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

9 (3) A collector that is authorized to maintain a collection receptacle at a
10 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.

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

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

15 (2) If the records are kept on microfilm, computer media or in any form
16 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
17 (other than pricing information), a key to the code shall be provided to make the
records understandable.

18 (3) The registrant agrees to deliver all or any part of such records to the
19 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
20 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

27 (4) Paper prescriptions for Schedules III, IV, and V controlled substances
28 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

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

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

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

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

21 (2) Any such proposed computerized application must also provide online
22 retrieval (via computer monitor or hard-copy printout) of the current refill history
23 for Schedule III or IV controlled substance prescription orders (those authorized
24 for refill during the past six months). This refill history shall include, but is not
25 limited to, the name of the controlled substance, the date of refill, the quantity
26 dispensed, the identification code, or name or initials of the dispensing pharmacist
27 for each refill and the total number of refills dispensed to date for that prescription
28 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.

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

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

22 COSTS

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

27 DRUGS

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

26 24. On October 16, 2013, the Board conducted a routine inspection and complaint
27 investigation at Respondent Americare. Two pharmacists, Kaitlynn T. and Tam T. were initially
28 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

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

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

15 26. During the October 16, 2013 inspection, the Board's inspector reviewed the two
16 computer systems used for processing prescriptions at Respondent Americare. The old computer
17 system had Pharmacy Program Version 5.1, and the new system had Digital Rx. When
18 questioned about weekly transmission of CURES data, Pharmacist Kaitlynn T. told the Board's
19 inspector that Digital Rx transmitted CURES data from the new system weekly and the
20 pharmacist on duty transmitted CURES data from the old computer system "from time to time."
21 Neither Pharmacist Kaitlynn T. nor Pharmacist Tam T. was able to provide the inspector any
22 proof of submission of CURES data from the old system. The inspector requested a run report of
23 all controlled substance prescriptions filled and dispensed from the old computer between April
24 25, 2013 and October 16, 2013, and to provide proof of their transmission.

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

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

10 28. During the October 16, 2013 inspection, the inspector found some prepacked
11 lovastatin 20mg labeled as manufactured by Actavis, and with NDC#45963-634-04.¹ Some of the
12 prepacked amber vials contained pink tablets and were marked 634, and other vials contained
13 green tablets and were marked LU G02. The pink tablets were manufactured by Actavis.

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

23
24 ¹ The NDC, or National Drug Code, is a unique 10-digit, 3-segment number. It is a
25 universal product identifier for human drugs in the United States. The code is present on all
26 nonprescription (OTC) and prescription medication packages and inserts in the US. The 3
27 segments of the NDC identify the labeler, the product, and the commercial package size. The first
28 set of numbers in the NDC identifies the labeler (manufacturer, repackager, or distributor). 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.

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

4 30. At the beginning of the October 16, 2013 inspection, one of the Board inspectors
5 observed Pharmacist Tam T. take some bags of medications from under a table on which the old
6 computer was located, and move them to a cabinet under the sink. The Board inspector retrieved
7 the bags from the cabinet under the sink, and asked Pharmacist Tam T. what the medications
8 were. Pharmacist Tam T. told the inspector that the bags contained unused medications returned
9 by customers awaiting destruction. A review of the contents of the bags showed medications with
10 patient specific labels; some had labels of Respondent Pharmacy, and others had Alpha Drugs
11 labels on them. The medications from Alpha Drugs were for two different patients for Abilify
12 30mg and Abilify 15mg tablets.

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

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

22 **FIRST CAUSE FOR DISCIPLINE**

23 **(Unprofessional Conduct – Failure to Have Dangerous**
24 **Drugs or Devices Ordered by Pharmacist)**

25 33. Respondents are subject to disciplinary action for unprofessional conduct under Code
26 section 4301, subsection (o), in that during the Board inspection on October 16, 2013,
27 Respondents did not have invoices for controlled substances delivered from H D. Smith and
28

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

3 **SECOND CAUSE FOR DISCIPLINE**

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

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

10 **THIRD CAUSE FOR DISCIPLINE**

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

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

19 **FOURTH CAUSE FOR DISCIPLINE**

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

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

///

1 **EIGHTH CAUSE FOR DISCIPLINE**

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

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

10 **NINTH CAUSE FOR DISCIPLINE**

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

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

19 **OWNERSHIP PROHIBITION**

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

24 Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY
25 41692 issued to Respondent Americare, and Respondent Luu, while acting as the manager,
26 administrator, owner, member, officer, director, associate, or partner of Respondent Americare,
27 had knowledge of, or knowingly participated in any conduct for which Pharmacy Permit Number
28 PHY 41692 was revoked, suspended or placed on probation, Respondent Luu shall be prohibited

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

5 **DISCIPLINE CONSIDERATIONS**

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

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

22 **PRAYER**

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

- 25 1. Revoking or suspending Pharmacy Permit Number PHY 41692 issued to Respondent
26 Americare Plus Pharmacy Services, dba Americare Plus Pharmacy;
- 27 2. Revoking or suspending Pharmacist License No. RPH 42505 issued to Respondent
28 Luu;

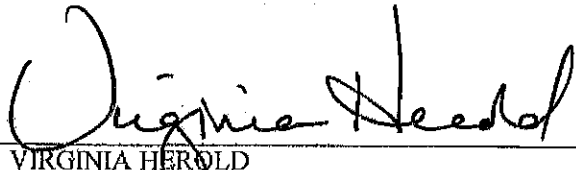
1 3. Prohibiting Respondent Luu from serving as a manager, administrator, owner,
2 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
3 Number PHY 41692 issued to Respondent Americare is placed on probation or until Pharmacy
4 Permit Number PHY 41692 is reinstated,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

6 4. Ordering Respondent Americare Plus Pharmacy Services, dba Americare Plus
7 Pharmacy with Respondent Luu as owner and Respondent Luu to pay the Board of Pharmacy the
8 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
9 Professions Code section 125.3; and

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

11
12
13 DATED:

2/24/16



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

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