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8
9 **BEFORE THE**
10 **BOARD OF PHARMACY**
11 **DEPARTMENT OF CONSUMER AFFAIRS**
12 **STATE OF CALIFORNIA**

13 In the Matter of the Accusation Against:

Case No. 5425

14 **AMERICARE PLUS PHARMACY SERVICES,**
15 **DBA AMERICARE PLUS PHARMACY;**
16 **CHAU H. LUU, OWNER**
17 **14211 Euclid Street, Unit A**
18 **Garden Grove, CA 92843**

FIRST AMENDED
ACCUSATION

19 **Pharmacy Permit No. PHY 41692**

20 **CHAU H. LUU;**
21 **AKA CHAU HUYEN LUU**
22 **14211 Euclid Street, Unit A**
23 **Garden Grove, CA 92843**

24 **Pharmacist License No. RPH 42505**

25 Respondents.

26 Complainant alleges:

27 **PARTIES**

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

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

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
26 Government Code, and the board shall have all the powers granted therein. The
27 action shall be final, except that the propriety of the action is subject to review by
28 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.

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11. Section 4160, subsection (a) states:

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

12. Section 4169(a)(3)

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

...

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

....

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

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

...

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

....

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

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

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.

6 COSTS

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

11 DRUGS

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

14 FACTS

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

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

27 24. During the October 16, 2013 inspection, while reviewing invoices from Respondent
28 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


25 VIRGINIA HEROLD
26 Executive Officer
27 Board of Pharmacy
28 Department of Consumer Affairs
State of California
Complainant

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8
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

A C C U S A T I O N

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.
21

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
sink with hot and cold running water for pharmaceutical purposes.

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

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

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

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

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

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

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

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

22 (1) Financial and shipping records (such as invoices and packing slips but
23 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
24 has notified the Administration of his intention to keep central records. Written
notification must be submitted by registered or certified mail, return receipt
25 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
26 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
27 notification by the Special Agent in Charge. All notifications must include the
following:

28 ///

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
6 readable, form.

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

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

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

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

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

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

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

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

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

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 Devises 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.

27 ///

28 ///

1 **FIFTH CAUSE FOR DISCIPLINE**

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

3 **Daily Controlled Substance Refill Data)**

4 37. 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 generate daily printouts of controlled substance refill data, and did not have
7 the pharmacist sign them or have an alternate system to document refills of controlled substances
8 as required by Federal Code of Regulations, title 21, section 1306.22, subsection (f), as set forth
9 in paragraphs 23 to 32 above, which are incorporated here by this reference.

10 **SIXTH CAUSE FOR DISCIPLINE**

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

12 **Identification Data for Dispensing Pharmacists)**

13 38. 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 in a readily retrievable format the name or initials of the
16 dispensing pharmacist for each prescription in an electronic or paper format in violation of Code
17 section 4040 and California Code of Regulations, section 1717, subsection (b), as set forth in
18 paragraphs 23 to 32 above, which are incorporated here by this reference.

19 **SEVENTH CAUSE FOR DISCIPLINE**

20 **(Unprofessional Conduct – Purchasing, Trading, Selling**

21 **or Transferring Misbranded Dangerous Drugs)**

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

28 ///

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;

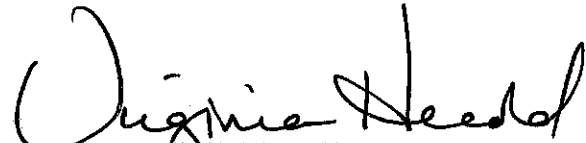
1 3. Prohibiting Respondent Luu from serving as a manager, administrator, owner,
2 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
3 Number PHY 41692 issued to Respondent Americare is placed on probation or until Pharmacy
4 Permit Number PHY 41692 is reinstated,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