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

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

Complainant alleges:

PARTIES

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

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

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

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

JURISDICTION

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

5. Section 4300 of the Code states:

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

6. Section 4300.1 of the Code states:

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

STATUTORY AUTHORITY

7. Section 4022 of the Code states

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

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

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

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

8. Section 4040.5 states:

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

9. Section 4059.5 states:

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

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

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

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

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

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

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

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

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

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

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

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

10. Section 4081, subsection (a) states:

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

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

11. Section 4160, subsection (a) states:

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

12. Section 4169(a)(3)

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

. . .

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

. . . .

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

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

. . .

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

. . . .

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

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

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

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

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

REGULATIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COSTS

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

DRUGS

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

FACTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Maintain Clean Pharmacy)

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

SECOND CAUSE FOR DISCIPLINE

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

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

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

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Submit CURES Reports)

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

FOURTH CAUSE FOR DISCIPLINE

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

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

FIFTH CAUSE FOR DISCIPLINE

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

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

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

SIXTH CAUSE FOR DISCIPLINE

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

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

SEVENTH CAUSE FOR DISCIPLINE

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

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

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Acting as Unlicensed Reverse Distributor)

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

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

OWNERSHIP PROHIBITION

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

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

DISCIPLINE CONSIDERATIONS

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

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

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

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 41692 issued to Respondent Americare Plus Pharmacy Services, dba Americare Plus Pharmacy;

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

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

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

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

DATED: 10/7/16

Virginia Herold

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

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

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

Complainant alleges:

PARTIES

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

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

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

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

JURISDICTION

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

5. Section 4300 of the Code states:

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

6. Section 4300.1 of the Code states:

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

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

STATUTORY AUTHORITY

7. Section 4059.5 of the Code states:

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

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

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

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

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

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

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

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

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

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

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

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

8. Section 4022 of the Code states

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

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

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

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

9. Section 4040.5 states:

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

10. Section 4059.5 states:

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

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

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

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

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

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

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

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

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

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

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

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11. Section 4081, subsection (a) states:

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

12. Section 4160, subsection (a) states:

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

13. Section 4169(a)(3)

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

. . .

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

. . . .

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

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

. . .

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

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

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

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

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

(10) Date of dispensing of the prescription.

REGULATIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COSTS

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

DRUGS

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

FACTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FIRST CAUSE FOR DISCIPLINE

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

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

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

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Maintain Clean Pharmacy)

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

THIRD CAUSE FOR DISCIPLINE

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

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

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Submit CURES Reports)

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

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FIFTH CAUSE FOR DISCIPLINE

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

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

SIXTH CAUSE FOR DISCIPLINE

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

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

SEVENTH CAUSE FOR DISCIPLINE

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

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

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EIGHTH CAUSE FOR DISCIPLINE

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

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

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Acting as Unlicensed Reverse Distributor)

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

OWNERSHIP PROHIBITION

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

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

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

DISCIPLINE CONSIDERATIONS

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

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

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 41692 issued to Respondent Americare Plus Pharmacy Services, dba Americare Plus Pharmacy;

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

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

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

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

DATED: 2/24/16

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

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