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

In the Matter of the Accusation Against: **SERV-RITE PHARMACY;** **ROBERT M. LANE**, Owner 9420 E. Slauson Pico Rivera, CA 90660 Pharmacy Permit No. PHY 34009 and **ROBERT M. LANE,** Pharmacist-in-Charge 9420 E. Slauson Pico Rivera, CA 90660 Pharmacist License No. RPH 23877 Respondents.	Case No. 4571 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about December 23, 1986, the Board of Pharmacy issued Permit Number PHY 34009 to Serv-Rite Pharmacy, with Robert M. Lane as an individual licensed owner and

pharmacist in charge (Respondent Serv-Rite). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2014, unless renewed.

3. On or about February 18, 1965, the Board of Pharmacy issued Pharmacist License Number RPH 23877 to Robert M. Lane (Respondent Lane). Respondent Lane was an individual licensed owner and pharmacist-in-charge of Respondent Serv-Rite between December 23, 1986 and the present. Respondent Lane's Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2015, unless renewed.

JURISDICTION

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

5. Section **118**, subdivision (b), of the Code provides that the suspension/expiration/surrender/cancellation of a license shall not deprive the Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

6. 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."

7. Section **4070** of the Code states at Subdivision "a":

"(a) Except as provided in section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of section 4040(c) shall soon as practicable

be reduced to writing by the pharmacist and shall be filled, by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy."

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8. Section **4081** of the Code states:

"(a) All records of manufacture and of sale, acquisition, 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, 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.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

"(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."

9. Section **4104** of the Code states:

"(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physical impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

"(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

"(c) Every pharmacy shall report and provide to the board within 14 days of the receipt of development thereof, the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental or physical impairment affect his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

"(d) The report required in subdivision (c) shall include sufficient detail to inform the board of the facts upon which the report is based, including an estimate of the type of quantity of all dangerous drugs involved, the timeframe over which the losses are suspected, and the date of the last controlled substances inventory. Upon request of the board, the pharmacy shall prepare and submit an audit involving the dangerous drugs suspected to be missing.

"(e) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report."

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10. Section **4116** of the Code states:

"(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted to that area, place, or premises described in the license issued by the board wherein controlled, substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacy or performing clerical inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

"(b)(1) The board may, by regulation, establish reasonable security measures consistent with this section in order to prevent unauthorized persons from gaining access to the area, place, or premises or to the controlled substances or dangerous drugs or dangerous devices therein.

"(2) The board shall, by regulation, establish conditions for the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing authorizing personnel from the pharmacy. These conditions shall ensure the security of the pharmacy and its operations during the temporary absence of the pharmacist and shall allow at the discretion of the pharmacist, nonpharmacist personnel to remain and perform any lawful activities during the pharmacist's temporary absence."

11. Section **4125** of the Code states:

"(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

"(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer reviews documents and not subject to

discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

"(c) This section shall become operative on January 1, 2002."

12. Section **4163** of the Code states at subdivision "a":

"(a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person."

13. 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.

"(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure

. . .

14. Section **4301** of the Code states:

"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:

. . .

"(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

. . .

"(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.

15. 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."

16. Health and Safety Code section **11165** provides in pertinent part:

"(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

. . .

"(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, Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice.

(2) The prescriber's category of licensure and license number; 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, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispenses.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

STATE REGULATIONS

17. California Code of Regulations, title 16, section **1707.5** (Patient-Centered Labels for Prescription Drug Containers; Requirements) states in pertinent part as follows:

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

"(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

"(A) Name of the patient

"(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

"(C) The directions for the use of the drug.

"(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

"(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

"(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

. . .

"(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

18. California Code of Regulations, title 16, section **1714** (Operational Standards and Security) states:

(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(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.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

(f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

(g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

19. California Code of Regulations, title 16, section **1715**. (Self-Assessment of a Pharmacy by the Pharmacist-in-Charge) states:

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) The components of this assessment shall be on Form 17M-13 (Rev. 01/11) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 (Rev. 01/11) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

20. California Code of Regulations, title 16, section **1717**, states:

"(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

"Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, store in a cool, dry place.

"(b) In addition to the requirements of Section 4040, Business and Professions Code, 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.

"(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself.

"All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

"Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

"(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.

"(e) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.26.

" Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

(3) Original date and last dispensing date;

(4) Number of refills and date originally authorized;

(5) Number of refills remaining but not dispensed;

(6) Number of refills transferred.

"(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years."

21. California Code of Regulations, title 16, section **1793.1** provides in pertinent part:

"Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may: (a) Receive a new prescription order orally from a prescriber or other person authorized by law.

. . .

FEDERAL REGULATIONS

22. Code of Federal Regulations, Title 21, section **1304.04** (Maintenance of Records and Inventories) provided at subdivision "f":

(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 Schedule 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 Schedule III, IV and V shall be maintained either separately from all other records of the registrant.

23. Code of Federal Regulations Title 21, section **1304.11** provides in pertinent part:

"(b) Initial Inventory date Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances....

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take an inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date."

24. Code of Federal Regulations, Title 21, section **1305.13** (Procedure for filing DEA Form 222) provides:

(a) A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

(b) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60

days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

(c) The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the DEA Form 222, except as specified in paragraph (f) of this section.

(d) The supplier must retain Copy 1 of the DEA Form 222 for his or her files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the fiscal shipment is made or the 60-day validity period expires.

(e) The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

(f) DEA Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

25. Code of Federal Regulations, Title 21, section **1306.22** provides at subdivision "f":

(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 prescriptions in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hardcopy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This staff include, but 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 dispended 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 hardcopy 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 hat the data indicated are correct and then sign the 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 the 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.

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COST RECOVERY

26. Section **125.3** of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

27. The following allegations are common to all causes for discipline in this matter:

a. At all times relevant herein, Respondent Richard Lane was owner and pharmacist-in-charge of Serv-Rite Pharmacy, located in Pico Rivera, CA.

Board Inspection – March 22, 2012

b. On or about March 22, 2012 a representative of the Board inspected Respondent Serv-Rite Pharmacy. Respondent Lane and licensed pharmacy technician B. Gonzales (an employee of the pharmacy) were present during the inspection.

c. During the inspection, the Inspector noticed that the pharmacy's shelves were dusty and dirty; and that a sink on the premises was "filthy," in violation of statutory requirements. (Title 16, California Code of Regulations section 1714 at subsection (c)).

d. Pursuant to his inquiry, the Inspector observed that that both Respondent Lane and employee B. Gonzalez both had pharmacy keys on their own separate key chains, in violation of statutory requirements.(Title 16, California Code of Regulations section 1714, subdivisions (d) and (e) which limit individuals who may legally possess an unsecured key to a pharmacy.)

e. In reviewing a bundle of prescription orders received by the pharmacy, the Inspector observed that employee B. Gonzalez was receiving and transcribing telephone prescription orders from doctor's offices, in violation of statutory requirements.(Title 16, California Code of Regulations section 1714, subdivision (c); Business and Profession Code section 4070).

f. Respondent Lane produced a partially completed self-assessment form, which was not prepared in compliance with all statutory requirements. (Title 16, California Code of

Regulation section 1715). Further, based on the inspection and interviews of pharmacy staff, at least 11 entries on the partially completed form were false and inaccurate.

g. Pursuant to questioning by the Inspector, Respondent Lane admitted that he had not submitted CURES data on a weekly basis as required by statute.(Health and Safety Code section 11165, subdivision (d).)

h. Pursuant to questioning by the Inspector, Respondent Lane admitted that he did not have the Quality Assurance Program, nor the written policy and procedures or review forms required by statute (Business and Professions Code section 4125).

i. Pursuant to questioning by the Inspector, Respondent Lane admitted that he did not have any policy and procedures for an impaired employee as required by statute (Business and Profession Code section 4104).

j. Pursuant to questioning by the Inspector, Respondent Lane admitted that he did not have any policy and procedures in place to assist patients with limited English proficiency understand information on the prescription label or otherwise provide interpretive services, as required by statute (Title 16 California Code of Regulations section 1707.5 subdivision (d)).

k. In reviewing prescription labels prepared for patients of the pharmacy, the Inspector observed that the labels generated by computers in use at Respondent Serve-Rite Pharmacy no longer complied with current statutory labeling requirements.(Title 16 California Code of Regulations section 1707.5 subsection (d).)

l. Pursuant to questioning by the Inspector, Respondent Lane admitted that he did not have documentation or make daily print-outs of controlled substance refills dispensed by the pharmacy, and had no refill records printed or signed by the pharmacist, as required by statute (Code of Federal Regulations section 1306.22; Business and Professions Code section 4081).

Federal Record Keeping Requirements

m. The Inspector observed that the pharmacy's DEA inventory was incomplete, not signed, and did not otherwise comply with statutory requirements, (Code of Federal Regulations section 1304.11, sub-division (c).)

n. The Inspector found the pharmacy's DEA 222 Copy 3 records were piled in a drawer and not endorsed as required with information regarding the quantity and date received.(Code of Federal Regulations section 1305.09.)

o. The Inspector reviewed the pharmacy's invoices on site, and discovered that all of the invoices were co-mingled and not maintained separately by type (e.g. Schedule II controlled substance records maintained separately from Schedule III-V) as required by statute (Code of Federal Regulations section 1304.04 subdivision (f).)

p. As noted above, Respondent Lane admitted that he did not have documentation or make daily print-outs of controlled substance refills dispensed by the pharmacy, and had no refill records printed or signed by the pharmacist in violation of state and federal statutes. (Code of Federal Regulations section 1306.22(f) (3), which describes a required protocol for refills of computerized prescriptions for controlled substances, that includes printing the order, and having the dispensing pharmacist sign and date the printout; Business and Professions Code section 4081.)

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards)

28. Respondents LANE and SERV-RITE are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with section Title 16, California Code of Regulations section 1714 subdivision (c) (which requires that the pharmacy, fixtures and equipment shall be maintained in a clean and orderly condition) in that during the Board inspection n March 22, 2012, the Inspector noted that the pharmacy's shelves were dusty and dirty; and that a sink on the premises was "filthy."

SECOND CAUSE FOR DISCIPLINE

(Failure to Secure Pharmacy: Unauthorized Employee Provided With Pharmacy Key)

29. Respondents LANE and SERV-RITE are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Code section 4116 , subdivision (b) and Title 16, California Code of

Regulations section 1714, subdivisions (d) and (e) (which limit individuals who may legally possess a key to a pharmacy) in that during the Board inspection on March 22, 2012, the Inspector observed that an unauthorized individual (B. Gonzalez) had been issued and had unsecured access to a pharmacy key.

THIRD CAUSE FOR DISCIPLINE

(Failure to Comply with Requirements for Transcription of Oral Prescriptions)

30. Respondents LANE ad SERV-RITE are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o) in conjunction with Code section 4070 (a) and Title 16, California Code of Regulations sections 1717 subdivision (c) (all orally transmitted prescriptions must be promptly reduced to writing and initialed by a pharmacist) **and** 1793.1 subdivision (a) (only a pharmacist can receive a *new* prescription order orally), in that on or about March 22, 2012, and on a routine basis, Respondents allowed non–pharmacist employee B. Gonzalez to receive and transcribe telephonic prescriptions.

FOURTH CAUSE FOR DISCIPLINE

(Failed to Comply With Self Assessment Form Requirements)

31. Respondents LANE and SERV-RITE are subject to subject to disciplinary action under Code section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Title 16, California Code of Regulations section 1715, subdivision (a) (which requires that a pharmacy must complete a new self-assessment form before July 1 or ever odd numbered year) in that during a Board inspection on or about March 22, 2012, Respondents were unable to locate or produce a current, properly completed self assessment form.

FIFTH CAUSE FOR DISCIPLINE

(Failed to Maintain Records of Dangerous Drugs Open For Inspection)

32. Respondents LANE and SERV-RITE are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Code section 4081 (which requires that all pharmacy records of

acquisition and disposition of dangerous drugs shall be open to inspection at al times during business hours and preserved for a 3 year period), in that during the Board inspection on March 22, 2012, pursuant to questioning by the Inspector, Respondents did not have and were unable to show documentation or daily print-outs of controlled substance refills dispensed by the pharmacy, and had no refill records printed or signed by the pharmacist.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Submit CURES Data on a Weekly Basis)

33. Respondents LANE and SERV-RITE are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Health and Safety Code section 11165(d) , in that in our about March of 2012 Respondents admitted they had never complied, and/ or had routinely failed to comply with state law requirements for submission of CURES data on a weekly basis.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Implement Quality Assurance Program)

34. Respondents LANE and SERV-RITE are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Code section 4125 , in that in our about March of 2012 Respondents admitted they had never implemented and/ or had routinely failed to comply with state law Quality Assurance Program requirements, nor did Respondents have the written policy and procedures or review forms required by statute.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Comply With Operational Requirements –Impaired Employee Policy)

35. Respondents LANE and SERV-RITE are subject to subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with Code section 4104 , in that at the time of the Board's inspection in March of 2012 Respondents admitted they had never implemented and/ or had routinely failed to comply with state law requiring that Resents establish policy and procedures for an impaired employee.

NINTH CAUSE FOR DISCIPLINE

(Failure to Comply with Patient-Centered Labeling Requirements)

36. Respondents LANE and SERV-RITE are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1707.5, subdivisions (a) and (d) in that based on the Board's March 2012 inspection, Respondents failed to comply or were unable to comply with patient-centered prescription labeling requirements as follows:

a. **Title 16 California Code of Regulations section 1707.5 subdivision (a)** – The labels generated by computers in use at Respondent Serve-Rite Pharmacy no longer complied with current statutory labeling requirements.

b. **Title 16 California Code of Regulations section 1707.5 subdivision (d)).** – Respondents failed to have any policy and procedures in place to assist patients with limited English proficiency understand information on the prescription label or otherwise provide interpretive services.

TENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Record Keeping Requirements – Federal Regulations)

37. Respondents LANE and SERV-RITE are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with multiple federal regulations pertaining to pharmacy record keeping requirements as specified below, due to their failure to manage and operate Serv-Rite pharmacy in accord with current state and federal law:

a. **Code of Federal Regulations section 1304.11 (c)**- The pharmacy's DEA inventory was incomplete, not signed, and did not otherwise comply with statutory requirements.

b. **Code of Federal Regulations section 1305.09** - The pharmacy's DEA 222 Copy 3 records were piled in a drawer and not endorsed as required with information regarding the quantity and date received.

c. **Code of Federal Regulations section 1304.04(f)** - The pharmacy's invoices were co-mingled and not maintained separately by type as required by statute.

d. **Code of Federal Regulations section 1306.22 (f) (3)** (and Business and Professions Code section 4081) - Failure to maintain daily print-outs of controlled substance refills dispensed by the pharmacy.

DISCIPLINARY CONSIDERATIONS

38. To determine the degree of penalty to be imposed on Respondent(s), if any, Complainant makes the following additional allegations:

Prior Citation – Respondent Serv-Rite Pharmacy

a. On or about July 21 and 22, 2008, a representative of the Board inspected and investigated Respondent Serv-Rite Pharmacy. Pursuant to that inspection, on December 18, 2008, Administrative Citation/Assessment of Fine No. **CI 2007 36009** was issued to Respondent Serv Rite for violating Codes and Regulations as set forth below, resulting in the issuance of a $2,750.00 fine, which Respondent paid in full. The citation is now final.

Code/Regulation(s) Violated	Description
1. California Code of Regulations (CCR), title 16, § 1793.7	Requirements for pharmacies employing pharmacy technicians
2. CCR, title 16, § 1715.5	Implementation of electronic monitoring of Schedule II prescriptions
3. Code of Federal Regulations (CFR), title 21.§ 1304.	Inventory Requirements
4. CCR, title 16, § 1714.1	Pharmacy Operations during the temporary absence of a pharmacist

Prior Citation – Respondent Lane

a. On or about July 21 and 22, 2008, a representative of the Board inspected and investigated Respondent Serv-Rite Pharmacy. Pursuant to that inspection, on December 18, 2008, Administrative Citation/Assessment of Fine No. **CI 200838036** was issued to Respondent Lane for violating Codes and Regulations as set forth below, resulting in the issuance of a

$2,750.00 fine, which Respondent paid in full. The citation is now final.

Code/Regulation(s) Violated	Description
1. CCR, title 16, § 1793.7	Requirements for pharmacies employing pharmacy technicians
2. CCR, title 16, § 1715.5	Implementation of electronic monitoring of Schedule II prescriptions
3. CFR, title 21, § 1304.11	Inventory Requirements
4. CCR, title 21, § 1714.1	Pharmacy Operations during the temporary absence of a pharmacist

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 Permit Number PHY 34009 to Serv-Rite Pharmacy;

2. Ordering Serv-Rite Pharmacy 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;

3. Revoking or suspending Pharmacist License Number RPH 23877, issued to Robert M. Lane;

4. Ordering Robert M. Lane 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;

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

DATED: 3/27/14

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

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