KAMALA D. HARRIS
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General
DANIEL D. MCGEE
Deputy Attorney General
State Bar No. 218947
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 322-6115
Facsimile: (916) 324-5567
E-mail: Daniel.McGee@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **L & S PHARMACY, INC. (dba VALLEY PHARMACY OF SACRAMENTO), LELAND KWONG MA, OWNERS** **7600 Hospital Drive, Suite A** **Sacramento, CA 95823** **Pharmacy Permit No. PHY 49845,** **LEONARD KWONG MARR** **7600 Hospital Drive, Suite A** **Sacramento, CA 95823** **Pharmacist License No. RPH 36980,** **and** **LELAND KWONG MA** **17215 Horst Avenue** **Cerritos, CA 90703** **Pharmacist License No. RPH 32234** Respondents.	Case No. 5886 **ACCUSATION**

Complainant alleges:

PARTIES

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

Consumer Affairs.

2. On or about April 1, 2009, the Board issued Pharmacy Permit Number PHY 49845 to L & S Pharmacy, Inc. to do business as Valley Pharmacy of Sacramento ("Valley Pharmacy") with Leland Kwong Ma as President and 100% shareholder and Leonard Kwong Marr designated as the Pharmacist-in-Charge (PIC) since April 1, 2009. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2017, unless renewed.

3. On or about August 18, 1982, the Board issued Original Pharmacist License Number RPH 36980 to Leonard Kwong Marr ("Marr"). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2018, unless renewed. As alleged, Marr is Valley Pharmacy's PIC.

4. On or about August 7, 1978, the Board issued Original Pharmacist License Number RPH 32234 to Leland Kwong Ma ("Ma"). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2018, unless renewed. As alleged, Ma is President and 100% shareholder of Valley Pharmacy.

JURISDICTION

5. 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.

6. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code §§ 4000, *et seq.*] and the Uniform Controlled Substances Act [Health & Safety Code §§ 11000, *et seq.*].

7. Code section 4300 states, in pertinent part:

> (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...

8. Code section 4300.1 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 PROVISIONS

9. Code section 4307(a) states:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

10. Code section 4156 provides that "[a] pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any

statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter."

11. Code Section 4301 states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct...Unprofessional conduct shall include, but is not limited to, any of the following:
>
> (b) Incompetence.
>
> (c) Gross negligence.
>
> (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
>
> ...
>
> (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.

12. Code section 4306.5 provides, in pertinent part:

> Unprofessional conduct for a pharmacist may include any of the following:
>
> (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.
>
> (b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.
>
> (c) Acts or omissions that involve, in whole or in part, the failure to consult

appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function...

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

13. Code section 4113 provides, in pertinent part, that every pharmacy shall designate a pharmacist-in-charge who shall be responsible for the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

14. Code section 4081 provides:

(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... pharmacy...[maintaining] a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy...shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section...

15. Code Section 4333 states, in pertinent part, that all prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years.

16. Code Section 4105 states, in pertinent part:

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d)(1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed

premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

....

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made....

17. Health & Safety Code section 11153, subsection (a), provides:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

18. Health and Safety Code section 11162.1, subsection (a), provides:

(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7)(A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1-24
25-49
50-74
75-100
101-150
151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14)(A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

19. Health and Safety Code section 11164, provides, in pertinent part:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink...

20. Health & Safety Code section 11165, subsection (a), addresses enactment of the Controlled Substance Utilization Review and Evaluation System (CURES), a database maintained by the Department of Justice for the electronic monitoring of, and Internet access to, information regarding the prescribing and dispensing of Schedule II-IV controlled substances. CURES is California's Prescription Drug Monitoring Program ("PDMP"). Health & Safety Code section 11165, subsection (d), mandates any dispenser of a Schedule II-IV controlled substance, including pharmacies, to report the disposition of any Schedule II-IV controlled substance as soon as possible, but not more than seven days after the date a controlled substance is dispensed.

REGULATORY PROVISIONS

21. California Code of Regulations ("CCR"), title 16, section 1707.2, subsection (b), provides, in pertinent part:

> (b)(1) ... a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
>
> (A) whenever the prescription drug has not previously been dispensed to a patient; or
>
> (B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.
>
> (2) When the patient or agent is not present...a pharmacy shall ensure that the patient receives written notice:
>
> (A) of his or her right to request consultation; and
>
> (B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record....

22. CCR, title 16, section 1707.3, provides, in pertinent part, that prior to consultation, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered.

23. CCR, title 16, section 1714.1, provides, in pertinent part:

> (b) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication...
> ...

(f) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods...The policies and procedures shall be open to inspection by the board or its designee at all times during business hours...

24. CCR, title 16, section 1714, provides, in pertinent part:

(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.
....

(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....

25. CCR, title 16, section 1711, provides, in pertinent part:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber....

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

....

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) ... A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e), shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

26. CCR, title 16, section 1735, provides, in pertinent part:

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances

...

(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices....

27. CCR, title 16, section 1735.2, subsection (d), provides:

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

28. CCR, title 16, section 1735.3, provides, in pertinent part:

(a) For each compounded drug product, the pharmacy records shall

include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component....

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

....

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

29. CCR, title 16, section 1735.4, subsection (a), provides that "[i]n addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s)."

30. CCR, title 16, section 1735.6, subsection (a), provides that "[a]ny pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment."

31. CCR, title 16, section 1735.7, subsection (a), provides that "[a]ny pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding."

32. CCR, title 16, section 1716, provides, in pertinent part, that "[p]harmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber

or to select the drug product in accordance with Section 4073 of the Business and Professions Code...."

33. CCR, title 16, section 1761, provides:

> (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
>
> (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

FEDERAL REGULATIONS

34. Code of Federal Regulations ("CFR"), title 21, section 1301.75, subsection (b), provides that "[c]ontrolled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances."

35. CFR, title 21, section 1306.04, subsection (a), provides:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

COST RECOVERY

36. 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.

DRUG CLASSIFICATIONS

37. Promethazine with Codeine is a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subsection (c)(1).

38. "Lioresal" is a brand name for baclofen, a muscle relaxant.

39. "Norco" is a brand name for hydrocodone/acetaminophen (APAP), used in the treatment of pain management. Hydrocodone/acetaminophen is a Schedule III controlled substance under Health and Safety Code section 11056, subsection (e)(5), and a Schedule II controlled substance under CFR, title 21, section 1308.12.

40. "Dolophine" is a brand name for methadone, used in the treatment of pain management. Methadone is a Schedule II controlled substance under Health and Safety Code section 11055, subsection (d)(2).

41. "MS Contin" is a brand name for morphine sulfate, used in the treatment of pain management. Morphine sulfate is a Schedule II controlled substance under Health and Safety Code section 11055, subsection (b)(1)(L).

42. "Mycostatin" is a brand name for nystatin, used in the treatment of fungal infection.

43. "Ditropan" is a brand name for oxybutynin, used in the treatment of bladder spasms.

44. "OxyContin" and "Roxicodone" are brand names for oxycodone, used in the treatment of pain management. Oxycodone is a Schedule II controlled substance under Health and Safety Code section 11055, subsection (b)(1)(M).

45. "Percocet" is a brand name for oxycodone/acetaminophen (APAP), used in the treatment of pain management. Oxycodone/acetaminophen is a Schedule II controlled substance under Health and Safety Code section 11055, subsection (b)(1)(M).

46. "Xanax" is a brand name for alprazolam, used in the treatment of anxiety. Alprazolam is a Schedule IV controlled substance under Health and Safety Code section 11057, subsection (d)(1).

47. All the aforementioned drugs are dangerous drugs under Code section 4022.

FACTUAL BACKGROUND

48. An audit of controlled substance purchases found that Valley Pharmacy had ordered

high quantities of promethazine/codeine liquid, a commonly abused Schedule V ("CV") controlled substance. The Board therefore further investigated Valley Pharmacy's practices.

49. Dispensers of controlled substances are not required to report CV controlled substances to the CURES database. Since promethazine/codeine is a CV substance, a review of Valley Pharmacy's CURES data did not show its reported usage. The Board therefore reviewed other areas of Valley Pharmacy's controlled substance practices. Based on this review, the Board found indications of possible trends of early refills of controlled substances, and of dispensing controlled substances with possible irregularities and "red flags" of abuse or misuse.

November 12, 2015 Inspection and Subsequent Investigation:

50. On November 12, 2015, Board inspector SK ("SK") went to Valley Pharmacy to conduct an onsite inspection. Upon arrival, Valley Pharmacy's PIC, Respondent Marr, was identified among other pharmacy personnel consisting of three pharmacy technicians, TCH EM, TCH SX, and TCH TK. Inspector SK proceeded to observe the workflow and work patterns of the pharmacy. SK made the following observations during the 11/12/15 inspection and subsequent investigation thereon.

Patient Consultation:

51. SK observed that the pharmacy had prescriptions bagged for delivery. When SK asked what paperwork was given to patients upon prescription delivery, TCH EM pulled a paper out of one bag and verified that it was the only information given with deliveries. PIC Marr verified these circumstances. The form did not notify patients of their right to receive a consultation as required by CCR, title 16, section 1707.2, subsection (b)(2).

52. SK also monitored new prescription consultation activities by PIC Marr and staff. In so doing, SK observed three new prescriptions (nos. 8039052-8039054) for oxycodone, oxybutynin and baclofen being dispensed to patient PB without any oral consultation. This violated CCR, title 16, section 1707.2.

Medication Record Review:

53. SK observed that PIC Marr had failed to perform any medication record review before the new prescriptions were dispensed to patient PB. Also, that PIC Marr had failed to

access the pharmacy computer to review medication records when filling other prescriptions and conducting occasional consultations. This violated CCR, title 16, section 1707.3.

Absence of Pharmacist Policy:

54. SK asked to review the pharmacy's policies and procedures regarding operations during pharmacist absence. Those policies and procedures stated that a patient could pick up new prescriptions in the absence of the pharmacist, and consultation would be provided upon the pharmacist's return. This violated CCR, title 16, section 1714.1.

Record Storage:

55. Under Code section 4333, subsection (a), Valley Pharmacy was required to maintain, onsite, at least three years' records of dangerous drug/device acquisition and disposition. At the time of the 11/12/15 inspection, Valley Pharmacy was therefore required to have records for the period of 11/12/12-11/12/15. The oldest original prescription document records available for SK's inspection were located in a box labeled January 18, 2013. PIC Marr admitted that Valley Pharmacy did not have a full three years of records onsite due to insufficient space and that he kept some of the records at his personal residence. This violated Code section 4333(a) since Valley Pharmacy did not have any waiver from the Board for such off-site storage.

Pharmacy and Controlled Substance Security:

56. SK reviewed Valley Pharmacy's storage and security of controlled substances. PIC Marr showed SK controlled substances stored on drug stock shelves generally in alphabetical order. PIC Marr also showed SK three drawers containing CII-V controlled substances in no particular order. The top drawer appeared to have a lock, but was unlocked. The bottom drawer did not have any locking devices. PIC Marr stated he did not want to lock the controlled substances in case he was robbed. This violated CFR, title 21, section 1301.75, subdivision (b).

Quality Assurance Program (Prescription Errors):

57. SK reviewed Valley Pharmacy's records related to medication errors. In so doing, PIC Marr gave SK a binder containing the pharmacy's Quality and Assurance Program policies and procedures, incident reporting form, and a copy of the quality assurance law. There were no completed reports or reviews of prescription errors.

58. When SK questioned PIC Marr regarding these circumstances, PIC Marr admitted that at least one prescription error had occurred within the last year and that he did not document the same. This violated CCR, title 16, section 1711. PIC Marr also admitted that he had never documented any medication errors during his six-year tenure as Valley Pharmacy's PIC.

Dispensing Records:

59. In issuing his inspection report on November 12, 2015, SK directed PIC Marr and Valley Pharmacy to e-mail, in excel format, and within seven days, complete records of all drugs acquired and disposed of during the period of 10/1/12-11/12/15.

60. Between 11/25/15 and 1/3/16, PIC Marr sent the requested dispensing records at least five times on 11/25/15, 12/21/15, 12/28/15, 12/30/15 and 1/4/16. None of the records so forwarded were complete or accurate since they were inconsistent with both Valley Pharmacy's stated prescription volume (300 prescriptions per day) and prescription volume as listed on the pharmacy's CURES report. PIC Marr, in turn, blamed third parties for the perceived errors.

61. On January 5, 2016, SK requested PIC Marr to arrange a conference call with the pharmacy's software vendor to try and obtain complete and accurate records. PIC Marr failed to do so.

62. On January 19, 2016, SK sent the pharmacy owner, Respondent Ma, a letter requesting complete and accurate records. Ma did not send the records and instead suggested that SK conduct a conference call with PIC Marr and the pharmacy's software vendor.

63. On February 3, 2016, SK received yet another USB drive from PIC Marr purporting to contain the complete and accurate records. These records were also incomplete and inaccurate. For example, many records were duplicates indicating that certain controlled substance prescriptions had been filled up to 17 times.

CURES Reporting:

64. SK's review of Valley Pharmacy's CURES data found gaps of time where Valley Pharmacy made no reports of dispensed controlled substance prescriptions as follows: 10/12/12-10/22/12 (10 days); 1/4/13-1/12/13 (eight days); 1/19/13-1/28/13 (nine days); 8/2/13-8/12/13 (10 days); 11/7/14-11/17/14 (10 days); and 4/24/15-5/4/15 (10 days). Since Valley Pharmacy is

closed weekends, this amounted to a potential of 45 days during which controlled substance activity went unreported. Meanwhile, although inaccurate and incomplete, the records alleged above which PIC Marr provided documented controlled substances being dispensed during the time periods in question.

Drug Audits:

65. Valley Pharmacy had past reports of controlled substances being stolen on 1/14/2014, 6/25/14 and 11/25/14, resulting in the following losses:

Total tablets/capsules	27,543
Total liquid (ml)	17,663
Total liquid 5 ml doses	3,532

66. In order to determine the effect of the improper security of controlled substances observed during the 11/12/15 inspection, and to determine if records of controlled substances were being properly maintained, SK conducted an audit of the selected controlled substances referenced in paragraph 65 below. In performing the audit, SK utilized various information received from PIC Marr (including a count of the pharmacy's stock on hand) in addition to data received directly from Valley Pharmacy's drug wholesalers.[1]

67. SK's audit indicated that Valley Pharmacy was significantly short the following controlled substances: alprazolam 2 mg (-4,774 tablets); hydrocodone/APAP 10/325 mg (-14,239 tablets); promethazine/codeine 6.5/10 mg (-260,579 ml).[2] Meanwhile, the audit showed the pharmacy was significantly over the following controlled substances: hydrocodone/APAP 5/325

[1] In conducting controlled substances inventories, an estimate of quantities in open bottles of 1,000 units or less is allowed for CIII-V controlled substances (*e.g.*, alprazolam and promethazine/codeine). Meanwhile, CII controlled substances (*e.g.*, hydrocodone, oxycontin and oxycodone) require an exact count for each inventory, each dispensing, and each instance of other occurrences which could affect the CII controlled substance inventory. While federal law defined hydrocodone as a CIII controlled substance at the start of the audit period, it was changed to a CII on 10/6/14, before the end of the audit period. Hydrocodone remains classified as a CIII controlled substance under California law.

[2] Regarding the promethazine/codeine specifically, this highly-abused CIV controlled substance is usually dosed in 5 ml increments. Its shortage amounted to over 52,000 doses of controlled substances for which Valley Pharmacy could not account. Additionally, the missing quantity of promethazine/codeine syrup was over 542 pint-sized bottles, which would total over 542 pounds of controlled substances, excluding bottle weight.

mg (+2,206 tablets); oxycodone 30 mg (+1,173 tablets); oxycodone 5 mg (+1,127 tablets); oxycontin 20 mg (+165 tablets); and oxycontin 80 mg (+51 tablets).

68. PIC Marr was unable to account for these discrepancies. Instead, each time PIC Marr provided audit responses, they included different delivered quantities for some drugs, reflecting the pattern of Valley Pharmacy's failure to maintain complete and accurate records of the acquisition and disposition of controlled substances.

Compounding:

69. During the 11/12/15 inspection, PIC Marr acknowledged that Valley Pharmacy occasionally compounded non-sterile prescriptions. When SK requested all records Valley Pharmacy had related to compounding, PIC Marr admitted the pharmacy kept no such records separate, including master formulas or compounding formulas.

70. When SK requested an example of prescriptions that Valley Pharmacy had compounded and dispensed, PIC Marr provided prescription no. 8037774. The prescription was dispensed on 11/4/15, for a combination of liquid drugs (including the dangerous drug nyastin) to be mixed by the pharmacy and used orally by the patient. There were no compounding records for prescription no. 8037774 other than the notes made on the back of the original prescription document.

71. PIC Marr confirmed that Valley Pharmacy had no other records related to the prescription, and that the documentation on this prescription was typical of the procedure used on all Valley Pharmacy compounded prescriptions. The prescription was therefore compounded without a written master formula or record on the prescription document that included each the:

- Inactive ingredients to be used;
- Process and/or procedures used to prepare the drug;
- Quality reviews required at each step in preparation of the drug;
- Post-compounding process or procedures required; and
- Expiration dating requirements.

72. Likewise, Valley Pharmacy did not maintain records of the compounded prescription preparation that included the:

- Master formula record;
- Date the drug product was compounded;
- Identity of the pharmacy personnel who compounded the drug product;
- Manufacturer, lot number, and expiration date of each component;
- Equipment used in compounding the drug product; and
- Expiration date of the final compounded drug product.

73. Valley Pharmacy had a completed compounding self-assessment on file outlining applicable laws and regulations related to prescription compounding. PIC Marr had completed and signed the document indicating Valley Pharmacy was in compliance. Contrary to PIC Marr's representation, SK determined that Valley Pharmacy compounded prescription preparations without:

- Labels setting forth the generic name(s) of the principal active ingredient(s) and the strength(s) of the products;
- Written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products; and
- Written documentation sufficient to demonstrate that pharmacy personnel had the requisite skills and training.

Corresponding Responsibility:

74. During the 11/12/15 inspection and subsequent investigation thereon, SK found that PIC Marr and Valley Pharmacy had grossly deviated from the standard of practice related to the dispensing of controlled substances by dispensing controlled substances on prescriptions in the presence of well-known "red flags" of abuse or misuse. These included at least the following prescriptions:

RF, MD Prescriptions:

75. Prescription nos. 8014018, 8014327, 8014373 and 8014481 were purportedly written by RF, MD. Each prescription was for high quantities of oxycodone (Roxicodone) in strengths varying from 10 mg to 30 mg, and dispensed to patients new to Valley Pharmacy, paying cash for the prescriptions – all red flags.

76. Further, each prescription was written on an invalid prescription form missing the following features mandated by Health and Safety Code section 11162.1:

- Six quantity check-off boxes;
- A watermark printed on the bottom of the prescription blank stating "California Security Prescription;"
- A statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted;"
- The preprinted license number of the prescribing practitioner;
- Check boxes printed on the form so that the prescriber may indicate the number of refills ordered;
- An identifying number assigned to the approved security printer by the Department of Justice; and
- The lot number printed on the form and the form sequentially numbered.

77. Another irregularity was that three of the prescriptions had a written diagnosis of "Goute, Goute arthritis." Gout is a common medical condition. Misspelling the word "gout" on a medical prescription is also a red flag. So, too, is use of oxycodone in the treatment of gout.

78. Also, noted on the back of three of the prescription documents was "Phoney 5-14-15," which was days after the prescriptions were actually dispensed. PIC Marr and Valley Pharmacy had a duty to verify authenticity of the prescriptions before dispensing the same. PIC Marr explained that some of Valley Pharmacy's patients look dangerous and that the pharmacy tries to get them out as soon as possible.

79. Moreover, prescription no. 8014327 was for 100 tablets of "**ROXICODONE 30 MG.**" The prescription was dispensed for 100 tablets of oxycodone 10 mg. This was a variation from the purported prescription (*i.e.*, a medication error) since there was no indication on the prescription document of any authorization for this change in strength.

HC, NP Prescriptions:

80. Prescription nos. 8010806, 8010807, 8011298, 8011299, 8011301, 8013443 and 8013445 were purportedly written by HC, NP, for three different patients. Each prescription was

dispensed on invalid prescription forms lacking the following mandated features:

- A watermark printed on the bottom of the prescription blank stating "California Security Prescription;"
- An identifying number assigned to the approved security printer by the Department of Justice; and
- The lot number printed on the form.

Valley Pharmacy dispensed the six prescriptions without verifying authenticity despite the red flags of non-compliant prescription forms and new patients paying cash for the prescriptions. This supplied 300 tablets of hydrocodone/APAP 10/325 mg and over 1,000 ml's of promethazine/codeine syrup pursuant to invalid prescription documents.

TM, MD Prescription:

81. Prescription no. 8002498 was purportedly written by TM, MD. The name of the prescribing doctor (which was in Valley Pharmacy's database) as preprinted on the top of the prescription form was misspelled. Also, the form did not contain the following required features:

- A watermark printed on the bottom of the prescription blank stating "California Security Prescription;"
- An identifying number assigned to the approved security printer by the Department of Justice; and
- The lot number printed on the form.

Valley Pharmacy dispensed the prescription without verifying authenticity despite the red flags of a non-compliant prescription form, the preprinted doctor's name being misspelled, and a new patient paying cash for the prescription.

DK, DDS Prescriptions:

82. Prescription nos. 7940930, 7943672, 7946251 and 7960075 were purportedly written by DK, DDS. Each prescription was for a high dose (30 mg) and high quantity (180-240 tablets) of oxycodone. Oxycodone is unusual in dental treatment, especially in such high quantities and doses. Valley Pharmacy dispensed the four prescriptions (a total of 840 tablets) despite the red flags of new patients paying cash, an unusual medication for dental treatment, high dose and high

quantity. DK, DDS has since confirmed that the prescriptions were fake and that he has never prescribed oxycodone in connection with his dental practice.

AE, MD Prescription:

83. Prescription no. 8014312 was purportedly written by AE, MD for the hydrocodone containing controlled substance Lortab. The prescription document was on a controlled substance form that appeared to meet all of the requirements, but was incomplete since there was no quantity written on the prescription document other than the box checked indicating that the quantity was for "151+" units. Since the prescription was written to be taken as needed, the total dose prescribed could not be calculated. Valley Pharmacy dispensed the prescription for one 473 ml bottle without verifying the total quantity actually prescribed and despite the red flags of a new patient paying $240 cash.

HK, MD Prescriptions:

84. Prescription nos. 8038515, 8038513, 8038577, 8038903 were purportedly written by HK, MD. Each prescription was for the CII controlled substance hydrocodone/APAP 10/325 mg. Under Health and Safety Code section 11164, an original prescription form signed and dated in ink by the prescriber is required for such prescriptions to be filled; they may not be faxed. Here, each prescription was an electronic "computer-to-fax" prescription, and therefore invalid. Notwithstanding, Valley Pharmacy filled them.

NS, MD Prescriptions:

85. Prescription nos. 8038620, 8038599, 8038778 and 8038766 were purportedly written by NS, MD, a doctor who was placed on probation following an accusation that he had prescribed controlled substances (including promethazine/codeine syrup) without proper record keeping or exams. These prescriptions – to four separate patients (each of whom were an African-American male born between 1990 and 1994) – were also for promethazine/codeine 240 ml, with directions to take two teaspoons once daily at bedtime for severe cough and headache. The non-prescription antihistamine loratadine 10 mg was also prescribed to each of the four patients. Further, each prescription was filled between 11/10/15 and 11/11/15.

86. Headache is not an indication for promethazine/codeine. Also, the presentation of

prescriptions to Valley Pharmacy of such similar prescriptions (patients, drugs, quantities, stated unapproved treatments) within such a short timeframe should have been red flags that the drugs may have been sought for abuse. Another red flag was the public record of NS, MD's probation status. Valley Pharmacy dispensed the prescriptions without verification.

Patient BB:

87. On 12/2/12, Valley Pharmacy filled two prescriptions for new patient BB, namely, prescription nos. 7924592 (for 240 tablets of oxycodone 30 mg) and 7924593 (for 480 ml of promethazine/codeine). BB paid cash for the prescriptions.

88. These prescriptions also had the following irregularities and ambiguities:

- The prescribed dose of oxycodone was a total of 240 mg per day – eight times the starting dose PIC Marr stated as being appropriate;
- The highly-abused controlled substance promethazine/codeine was prescribed in a full pint-sized bottle together with oxycodone in high dose.

89. Despite these red flags, Valley Pharmacy filled the prescriptions without verification. Meanwhile, SK's review of CURES revealed that patient BB had received 120 tablets of oxycodone 30 mg from another pharmacy just four days prior.

90. On 2/20/13, Valley Pharmacy filled two other prescriptions for BB, namely, nos. 7930983 (for 240 tablets of methadone 10 mg) and 7930984 (for 480 ml of promethazine/codeine). Valley Pharmacy dispensed these controlled substance prescriptions without verification despite the red flags of cash payment for high medication quantities.

Patient MW:

91. On 11/14/12, Valley Pharmacy dispensed to patient MW prescription nos. 7923296 (for 100 tablets of oxycodone 30 mg) and 7923295 (for 480 ml of promethazine/codeine). Valley Pharmacy did so without verification despite the red flags of oxycodone and promethazine/codeine being prescribed together in high doses and quantities to a new patient paying cash.

Patient JC:

92. On 2/8/12, Valley Pharmacy dispensed to patient JC prescription nos. 7930031 (for

240 tablets of oxycodone 30 mg) and 7930030 (for 480 ml promethazine/codeine). Valley Pharmacy did so without verification despite the red flags of oxycodone and promethazine/codeine (480 ml) being prescribed in high doses and quantities at the same time to a new patient paying cash.

Patient RM:

93. On 9/5/13, Valley Pharmacy dispensed to patient RM prescription no. 7947920, consisting of hydrocodone/APAP 10/325 mg (180 tablets). This prescription was a verbal order ostensibly taken as a transfer from an out-of-state pharmacy for a new patient paying cash – all red flags. Again, Valley Pharmacy did so without verification.

94. SK's review of patient RM's CURES record revealed that RM had obtained hydrocodone/APAP 10/325 mg at least 19 times in a 99-day period (5/23/13-8/30/13) prior to Valley Pharmacy's 9/5/13 fill. This was evidence of "doctor shopping," and supplied RM with a 332-day supply of hydrocodone/APAP.

Patient HP:

95. On 5/8/15, Valley Pharmacy dispensed to patient HP prescription nos. 8014372 (for 60 tablets of morphine sulfate ER 15 mg) and 8014374 (for 150 ml of morphine sulfate 100 mg/5 ml solution). The 100 mg/5 ml morphine oral solution was dispensed with the following directions:

- 10 ml (200 mg) every four hours for moderate pain;
- 20 ml (400 mg) every four hours for severe pain.

This dosing was unusual and irregular since it amounted to 10-20 times the recommended dosing for morphine, necessitating verification. Further, patient HP was 65 years old. Morphine prescribing information specifies that elderly patients generally should be started on low doses of morphine and observed closely.

96. Again, there was no indication on the prescriptions of any inquiry or verification by Valley Pharmacy to resolve these irregularities that could lead to patient harm. Instead, Valley Pharmacy dispensed these prescriptions notwithstanding the dosing red flags.

//

Patient RJ:

97. On 11/29/12, Valley Pharmacy dispensed to patient RJ prescription no. 7924314 for 240 tablets of methadone 10 mg. The prescription had a notation that the amount to be taken by the patient was not to exceed eight tablets per day. RJ was also a new patient paying cash for a high quantity of controlled substance. Again, Valley Pharmacy dispensed the prescription without verification despite the existence of red flags.

98. Further, SK's review of RJ's CURES report showed that a different pharmacy had filled an identical quantity of methadone 10 mg just 17 days prior, and that another pharmacy had filled a prescription for hydrocodone/APAP 10/325 mg just 14 days prior.

Early Refills:

99. In evaluating Valley Pharmacy's refilling practices, SK found that PIC Marr/Valley Pharmacy had filled 276 controlled substance prescriptions more than five days before previously dispensed supplies were exhausted. Many prescriptions were filled more than seven days early, which was the standard PIC Marr stated he used. SK determined that this, too, constituted a failure in corresponding responsibility.

FIRST CAUSE FOR DISCIPLINE

(Failure to Provide Oral Consultation to Patients)

100. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated CCR, title 16, section 1707, subdivisions(b)(1)(A) and (B)(2), as follows:

a. On November 12, 2015, Respondents dispensed to Patient PB prescriptions that were new without providing oral consultation, as set forth in paragraph 52 above.

b. On November 12, 2015, Respondents failed to provide patients who received their medications by delivery service with a written notice of their right to request an oral consultation from a pharmacist, as set forth in paragraph 51 above.

SECOND CAUSE FOR DISCIPLINE

(Failure to Perform Medication Record Review Prior to Patient Consultation)

101. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under

Code Section 4301, subdivision (o), in that Respondents violated CCR, title 16, section 1707.3, by failing to perform medication record review before dispensing prescriptions, including to patient PB, as set forth in paragraph 53 above.

THIRD CAUSE FOR DISCIPLINE

(Improper Absence of Pharmacist Policy)

102. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated CCR, title 16, section 1714.1, subdivision (b), by maintaining a policy that allowed new prescriptions requiring consultation to be dispensed to patients in the absence of a pharmacist, as set forth in paragraph 54 above.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Dangerous Drugs on Premises)

103. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated Code section 4333, subdivision(a), by failing to maintain on the premises, and make available for inspection, all records of prescriptions filled by the pharmacy for three years, as set forth in paragraph 55 above. Further, records earlier than January 8, 2013, were removed from the pharmacy, without a waiver from the Board, and stored at the residence of PIC Marr, in violation of pharmacy law.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Pharmacy, Fixtures, and Equipment so that Drugs were Safely and Properly Secured)

104. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivisions (o) and (j), and CCR, title 16, section 1714, subdivision (b), and CFR, title 21, section 1301.75, subdivision (b), in that Respondents failed to safely and properly secure controlled substances in a securely locked, substantially constructed cabinet, or otherwise by dispersing the controlled substances throughout the pharmacy's stock of non-controlled substances, as set forth in paragraph 56 above.

105. Meanwhile, drug audits of controlled substances between May 1, 2013 and November 12, 2015, found significant shortages of controlled substances, for which Respondents failed to

account, as set forth in paragraph 66 through 68 above.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Comply with Quality Assurance Program)

106. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), and CCR, title 16, section 1711, subdivisions (e) and (f), in that Respondents failed to document medication errors when at least one error had occurred within the year prior to the 11/12/15 inspection, as set forth in paragraphs 57 and 58 above. Respondents failed to engage in a Quality Assurance Program in a manner to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to medication errors to assess the cause and any contributing factor(s) such as system or process failure(s).

107. Further, Respondents did not keep all of the following records in an immediately retrievable form in the pharmacy:

- Date, location, and participants in the quality assurance review;
- Pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact;
- Findings and determinations generated by the quality assurance review; and
- Recommended changes to pharmacy policy, procedure, systems, or processes.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Report Controlled Substance Prescriptions to CURES)

108. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), and Health and Safety Code section 11165, subdivision (d), in that Respondents did not report to CURES Schedule II-IV controlled substances that were dispensed, as set forth in paragraph 64 above.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain a Current Inventory of All Dangerous Drugs)

109. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated Code sections 4081, subdivision

(a), and 4105, subdivision (d)(1). As set forth in paragraphs 65 through 68 above, Respondents failed to maintain an accurate current inventory of all dangerous drugs, and significant shortages and overages of controlled substances were discovered, as set forth in paragraph 65. Additionally, Respondents were unable to produce accurate prescription records, which they maintained electronically. Despite several attempts, Respondents were unable to produce a complete and accurate electronic copy of all records of drug acquisition and disposition, as set forth in paragraphs 59 through 63 above.

NINTH CAUSE FOR DISCIPLINE

(Compounding of Drug Products Without Master Formula Records and Other Information Required by Law)

110. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated CCR, title 16, section 1735.2, subdivision (d), as set forth in paragraphs 69 through 71 above. The extent of Respondents' compounding activity could not be determined due to a lack of compounding records.

TENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Record Requirements)

111. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated CCR, title 16, section 1735.3, subdivisions (a) and (d), as set forth in paragraph 72 above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Facilities and Equipment Requirements)

112. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated CCR, title 16, section 1735.6, subdivision (a), because Respondents dispensed compounded prescription no. 8037774 without maintaining written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products, as set forth in paragraph 73 above.

//

//

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Training Records of Pharmacy Personnel Involved in Compounding)

113. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated CCR, title 16, section 1735.7, subdivision (a), because Respondents dispensed compounded prescription no. 8037774 without maintaining written documentation sufficient to demonstrate pharmacy personnel had the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding, as set forth in paragraph 73 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Dispensing Medication in Variance from Prescription)

114. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code section 4301, subdivision (o), in that Respondents violated CCR, title 16, section 1716, when they dispensed prescription no. 8014327 for 100 tablets of oxycodone 10 mg when the purported prescription document was for oxycodone 30 mg, as set forth in paragraph 79 above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Exercise Corresponding Responsibility with Regard to the Dispensing or Furnishing of Controlled Substances)

115. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), and 4306.5, subdivisions (c), for unprofessional conduct in that Respondents dispensed controlled substances without ensuring the prescriptions were issued for a legitimate medical purpose and in the usual course of professional practice, leading to the excessive furnishing of Schedule II-V controlled substances. In so doing, Respondents violated Health and Safety Code sections 11153, subdivision (a), and 11164, subdivision (a)(1), CFR, title 21, section 1306.04, subdivision (a), and CCR, title 16, section 1761, subdivisions (a) and (b).

116. As set forth in greater detail in paragraphs 74 through 98 above, Respondents dispensed, without verification and/or adequate consultation of appropriate patient, prescription and like records, controlled substances on prescriptions with red flags of abuse or misuse,

including forged prescriptions, non-compliant controlled substance forms, and prescriptions having factors of irregularity. Such factors of irregularity included prescriptions written outside of the prescriber's scope of practice, cash payment for prescriptions by new patients, high doses and/or quantities, and prescriptions for similar patients dispensed in a short time period which did not match the drug's usual use.

117. Additionally, Respondents dispensed at least 276 controlled substance prescriptions more than five days before previous supplies were exhausted, without ensuring their use was for a legitimate medical purpose, as set forth in paragraph 99 above.

118. PIC Marr had the training, education and experience to evaluate prescriptions in order to make informed dispensing decisions. PIC Marr either failed to utilize or otherwise ignored this training, education and experience, and along with Valley Pharmacy, furnished excessive controlled substances on forged, non-compliant and irregular prescriptions, in violation of Code section 4306.5, subdivision (a). Respondents therefore also failed to exercise or implement their best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances and dangerous drugs, directly leading to patients receiving excessive controlled substances, in violation of Code section 4306.5, subdivision (b).

FIFTEENTH CAUSE FOR DISCIPLINE

(Excessive Furnishing of Controlled Substances)

119. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code Sections 4301, subdivisions (d) and (o), for unprofessional conduct in that Respondents clearly excessively furnished controlled substances in violation of Health and Safety Code sections 11153, subdivision (a), and 11164, subdivision (a)(1), CFR, title 21, section 1306.04, subdivision (a), and CCR, title 16, section 1761, subdivisions (a) and (b), as set forth in paragraphs 74 through 99 above.

SIXTEENTH CAUSE FOR DISCIPLINE

(Gross Negligence)

120. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code sections 4301, subdivision (c), for unprofessional conduct in that Respondents were grossly

negligent in dispensing controlled substances, as set forth in paragraphs 74 through 99 above.

121. Further, as alleged in greater detail throughout this accusation, Respondents were grossly negligent in that they violated several statutes and regulations governing the practice of pharmacy as follows:

- Code sections 4333, 4081 and 4104;
- Health and Safety Code sections 11165 and 11153;
- CCR, title 16, sections 1707.2, 1707.3, 1714, 1714.1, 1711, 1735.2, 1735.3, 1735.4, 1735.6, 1735.7, and 1716; and,
- CFR, title 21, sections 1301.75 and 1306.04.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Incompetence)

122. Respondents PIC Marr and Valley Pharmacy are subject to disciplinary action under Code Sections 4301, subdivision (b), for unprofessional conduct in that Respondents were incompetent in dispensing controlled substances, as set forth in paragraphs 74 through 99 above.

123. Further, as alleged in greater detail throughout this accusation, Respondents were incompetent in that they violated several statutes and regulations governing the practice of pharmacy as follows:

- Code sections 4333, 4081 and 4104;
- Health and Safety Code sections 11165 and 11153;
- CCR, title 16, sections 1707.2, 1707.3, 1714, 1714.1, 1711, 1735.2, 1735.3, 1735.4, 1735.6, 1735.7, and 1716; and,
- CFR, title 21, sections 1301.75 and 1306.04.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Owner/Officer's Failure to Maintain a Current Inventory of All Dangerous Drugs)

124. Respondent Ma is subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that Ma, as Valley Pharmacy's President and 100% shareholder, did not maintain an accurate current inventory of all dangerous drugs, as set forth in paragraphs 59 through 63 and 65 through 68 above, in violation of Code section 4081,

subdivision (b).

NINETEENTH CAUSE FOR DISCIPLINE

(Owner/Officer's Failure to Provide Requested Records of Dangerous Drugs)

125. Respondent Ma is subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that Respondent, as Valley Pharmacy's President and 100% shareholder, did not provide records of dangerous drugs when requested, as set forth in paragraph 62 above, in violation of Code section 4105, subdivision (f).

TWENTIETH CAUSE FOR DISCIPLINE

(Unprofessional Conduct as to Respondent Ma)

126. Respondent Ma is subject to disciplinary action under Code sections 4301, subdivision (o), and 4306.5, subdivision (a), for unprofessional conduct in that Respondent failed to exercise his education, training, and/or experience as a pharmacist, in the course of ownership of Valley Pharmacy, to prevent the pharmacy's gross deviation from the standards of pharmacy practice.

127. As set forth in paragraphs 74 through 98 above, controlled substance prescriptions were dispensed in a gross deviation from the standards of pharmacy practice by not resolving and/or ignoring red flags of abuse or misuse. These actions and omissions led directly to patients receiving excessive controlled substances.

128. Further, as alleged in greater detail throughout this accusation, Respondents violated several statutes and regulations governing the practice of pharmacy as follows:

- Code sections 4333, 4081 and 4104;
- Health and Safety Code sections 11165 and 11153;
- CCR, title 16, sections 1707.2, 1707.3, 1714, 1714.1, 1711, 1735.2, 1735.3, 1735.4, 1735.6, 1735.7, and 1716; and,
- CFR, title 21, sections 1301.75 and 1306.04.

OTHER MATTERS

129. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 49845 issued to L & S Pharmacy, Inc., L & S Pharmacy, Inc. shall be prohibited from

serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number 49845 is placed on probation or until Pharmacy Permit Number 49845 is reinstated if it is revoked.

130. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 49845 issued to L & S Pharmacy, Inc. while Leland Kwong Ma has been an officer and/or owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Ma shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49845 is placed on probation or until Pharmacy Permit Number 49845 is reinstated if it is revoked.

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 49845, issued to L & S Pharmacy, Inc. dba Valley Pharmacy of Sacramento;

2. Revoking or suspending Original Pharmacist License Number RPH 36980, issued to Leonard Kwong Marr;

3. Revoking or suspending Original Pharmacist License Number RPH 32234, issued to Leland Kwong Ma;

4. Prohibiting L & S Pharmacy, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 49845 is placed on probation or until Pharmacy Permit Number 49845 is reinstated if it is revoked;

5. Prohibiting Leland Kwong Ma from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number 49845 is placed on probation or until Pharmacy Permit Number 49845 is reinstated if it is revoked;

6. Ordering L & S Pharmacy, Inc. dba Valley Pharmacy of Sacramento, Leonard

Kwong Marr and Leland Kwong Ma 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,

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

DATED: 11/30/16

Virginia Herold

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

SA2016102808/12448450.doc