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

In the Matter of the Accusation Against: **KAISER PERMANENTE CORP.,** **DBA KAISER PERMANENTE PHARMACY #833** **3800 Dale Rd.** **P. O. Box 577680** **Modesto, CA 95357** **Pharmacy Permit Number PHY 46384** **And** **DARIN L. SISE, RPH** **Pharmacist-In-Charge** **P. O. Box 578987** **Modesto, CA 95357** **Pharmacist Permit Number RPH 43429** Respondents.	Case No. 5533 **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 April 17, 2003, the Board of Pharmacy , Department of Consumer Affairs, ("Board") issued Pharmacy Permit Number PHY 46384 to Kaiser Permanente Corp., doing business as Kaiser Permanente Pharmacy #833, ("Respondent Kaiser"). The Pharmacy

Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2016, unless renewed.

3. On or about July 25, 1990, the Board issued Pharmacist Permit Number RPH 43429 Darin L. Sise ("Respondent Sise"). The Pharmacist Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2018, unless renewed. From November 21, 2010, to June 20, 2014, Respondent Sise was the Pharmacist-in-Charge of Kaiser Permanente Corp., doing business as Kaiser Permanente Pharmacy #833, within the meaning of Business and Professions Code section 4113.

4. As used herein, "Respondents" shall collectively refer to Respondent Kaiser and Respondent Sise.

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. Section 4300 of the Code 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. . . .

7. Section 4300.1 of the Code states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with

any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

8. Code section 4301 states, in pertinent part:

(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.

9. Section 4022 of the Code states

Dangerous drug" . . . 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.

. . .

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

10. Code section 4081 states, in pertinent part:

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

11. Code section 4105 states:

(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.

12. Code section 4113 states, in pertinent part:

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

REGULATORY PROVISIONS

13. California Code of Regulations, title 16, section 1714 states, 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. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

DRUGS

14. **Hydrocodone/APAP 10/325mg,** the generic name for the brand name Norco, is a Schedule II controlled substance as designated by Health and Safety Code section 11055, subdivision (b)(1)(I), and a dangerous drug within the meaning of Code section 4022. The drug contains a combination of Acetaminophen (a pain reliever that increases the effects of Hydrocodone) and Hydrocodone (an opioid pain medication) and is used to treat pain.

15. **Zolpidem,** a generic name for the brand Ambien, is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(32), and a dangerous drug within the meaning of Code section 4022. The drug is a sedative used to treat insomnia.

COST RECOVERY

16. 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.

BACKGROUND

17. On or about December 6, 2013, Respondent Sise discovered a low inventory of Hydrocodone/APAP 10/325 mg on Respondent Kaiser's drug shelf; the shelf had been full the previous night.

18. From on or about December 7 through 9, 2013, Respondent Kaiser's internal investigation and surveillance disclosed that janitor A.G. was stealing the Hydrocodone/APAP 10/325 mg from the shelves of Respondent Kaiser. A.G. confessed he had been stealing the drug for the past six months for self-use and for supplying to his friends. A.G. was terminated on or about January 6, 2014. Respondents' internal investigation revealed a shortage of 64,460 tablets of Hydrocodone/ APAP 10/325mg for the period of June 27, 2013, to December 10, 2013.

19. On or about January 9, 2014, Respondents notified the Board that Respondent Pharmacy had experienced a loss of 64,460 tablets of Hydrocodone/APAP 10/325mg. On or about May 7, 2014, Respondent Kaiser submitted an amended report of loss of controlled substances indicating the amended loss of 77,115 tablets of Hydrocodone/APAP 10/325mg.

20. From on or about January 14, 2014, through May 13, 2015, the Board's assigned inspector conducted an investigation of Respondents reported drug loss.

21. On or about August 27, 2014, the inspector received Respondent's acquisition and disposition records for Hydrocodone/APAP 10/325mg for the period of March 17, 2013 to December 9, 2103. Based upon those records, the inspector's audit results concluded that Respondents' actual shortage of Hydrocodone/APAP 10/325 mg was 75,266 tablets.

22. On or about May 13, 2015, the Board issued a notice of non-compliance to Respondent Kaiser and Respondent Sise due to their failure to maintain their dangerous drugs in a safe and secure manner and failure to have records of disposition to account for the inventory shortage of 75,266 tablets of Hydrocodone/APAP 10/325 mg.

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FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Dangerous Drugs in Safe and Secure Manner)

23. Respondent Kaiser is subject to disciplinary action under Code sections 4300 and 4301, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivision (b), in that Respondent Kaiser failed to maintain its facilities, space, fixtures, and equipment so that drugs in its stock were safely and properly prepared, maintained, secured and distributed. Respondent Kaiser's failures resulted in the loss of 75,266 tablets of the dangerous drug Hydrocodone/ APAP 10/325mg as set forth in paragraphs 17 through 22, above, incorporated herein by reference.

24. Respondent Sise, the Pharmacist-in-Charge, is subject to disciplinary action sections 4300 and 4300.1, subdivisions (j) and (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivision (d), in that Respondent Sise failed to secure the prescription department of Respondent Kaiser and failed to provide for the effective control against theft or diversion of dangerous drugs resulting in the loss of 75,266 tablets of Hydrocodone/APAP 10/325mg as set forth in paragraphs 17 through 22, above, incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Disposition of Dangerous Drugs)

25. Respondent Kaiser and Respondent Sise, the Pharmacist-in-Charge, are subject to disciplinary action under Code sections 4300 and 4300.1, subdivisions (j) and (o), in conjunction with Code sections 4081, subdivision (a), and 4105, in that they failed to maintain and preserve all records of acquisition, disposition, and current inventory of dangerous drugs which resulted in their failure to have records of disposition to account for an inventory shortage of 75,266 tablets of the dangerous drug Hydrocodone/APAP 10/325mg as set forth in paragraphs 17 through 22, above, incorporated herein by reference.

DISCIPLINARY CONSIDERATION

26. In determining the level of discipline to be imposed on Respondent Kaiser, Complainant respectfully requests that the following be considered:

27. On or about February 8, 2011, pursuant to Code sections 4314 and 4301, subdivision (o), and California Code of Regulations ("CCR"), title 16, section 1775, the Board issued Citation No. 2009 44600 against Respondent Kaiser for violating CCR, title 16, section 1714, subdivision (b), in that from June 27, 2008, through May 31, 2010, Respondent could not account for 7,627 tablets of Zolpidem 10mg. A civil penalty was not imposed.

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 46384 issued to Kaiser Permanente Corp., doing business as Kaiser Permanente Pharmacy #833;

2. Revoking or suspending Pharmacy License Number RPH 43429 issued to Darin L. Sise, Pharmacist-In-Charge for Kaiser Permanente Corp., doing business as Kaiser Permanente Pharmacy #833;

3. Ordering Kaiser Permanente Corp., doing business as Kaiser Permanente Pharmacy #833 and Darin L. Sise, RPH, 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

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

DATED: 2/20/16

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

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