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

11 In the Matter of the Accusation Against:

Case No. 6212

12 **KAISER FOUNDATION HOSPITAL**
13 **INPATIENT/OUTPATIENT PHARMACY**
14 **2425 Geary Boulevard**
San Francisco, CA 94115

A C C U S A T I O N

15 **Original Permit Number No. HSP 6602**

16 and

17 **CHARLES C. LINO**
18 **1301 Myrtle Beach Way**
Modesto, CA 95357

19 **Original Pharmacist License No. RPH42290**

20 Respondents.

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22 Complainant alleges:

23 **PARTIES**

- 24 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
25 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 26 2. On or about October 9, 1990, the Board of Pharmacy (Board) issued Original Permit
27 Number HSP 6602 (Permit) to Kaiser Foundation Hospital Inpatient / Out Patient Pharmacy
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1 (Respondent Kaiser). The Permit was in full force and effect at all times relevant to the charges
2 brought in this Accusation and will expire on November 1, 2018, unless renewed.

3 3. On or about January 19, 1989, the Board issued Original Pharmacist License Number
4 RPH 42290 (Pharmacist License) to Charles C. Lino (Respondent Lino). The Pharmacist License
5 was in full force and effect at all times relevant to the charges brought in this Accusation and will
6 expire on October 31, 2018, unless renewed.

7 JURISDICTION

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

11 5. Section 4300 of the Code states:

12 "(a) Every license issued may be suspended or revoked.

13 "(b) The board shall discipline the holder of any license issued by the board, whose default
14 has been entered or whose case has been heard by the board and found guilty, by any of the
15 following methods:

16 "(1) Suspending judgment.

17 "(2) Placing him or her upon probation.

18 "(3) Suspending his or her right to practice for a period not exceeding one year.

19 "(4) Revoking his or her license.

20 "(5) Taking any other action in relation to disciplining him or her as the board in its
21 discretion may deem proper.

22 "(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The
23 board may, in its sole discretion, issue a probationary license to any applicant for a license who is
24 guilty of unprofessional conduct and who has met all other requirements for licensure. The board
25 may issue the license subject to any terms or conditions not contrary to public policy, including,
26 but not limited to, the following:

27 "(1) Medical or psychiatric evaluation.

28 "(2) Continuing medical or psychiatric treatment.

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

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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 4113 of the Code states:

“(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

1 “(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The
2 board shall not issue or renew a pharmacy license without identification of an approved
3 pharmacist-in-charge for the pharmacy.

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

6 “(d) Every pharmacy shall notify the board in writing, on a form designed by the board,
7 within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge,
8 and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge.
9 The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If
10 disapproved, the pharmacy shall propose another replacement within 15 days of the date of
11 disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is
12 approved by the board.

13 “(e) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30
14 days a permanent replacement pharmacist-in-charge to propose to the board on the notification
15 form, the pharmacy may instead provide on that form the name of any pharmacist who is an
16 employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who
17 is actively involved in the management of the pharmacy on a daily basis, to act as the interim
18 pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns
19 the pharmacy, shall be prepared during normal business hours to provide a representative of the
20 board with the name of the interim pharmacist-in-charge with documentation of the active
21 involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and
22 with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-
23 in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the
24 identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the
25 name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent
26 pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall
27 propose another replacement within 15 days of the date of disapproval, and shall continue to
28 name proposed replacements until a pharmacist-in-charge is approved by the board.”

1 10. California Code of Regulations (CCR), Title 16, Section 1714 states:

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

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

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

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

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

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

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

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1 11. CCR, Title 16, section 1718, states:

2 "Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
3 Code shall be considered to include complete accountability for all dangerous drugs handled by
4 every licensee enumerated in Sections 4081 and 4332.

5 "The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
6 available for inspection upon request for at least 3 years after the date of the inventory."

7 12. CCR, Title 16, section 1793.7, states:

8 "(a) In addition to employing a pharmacy technician to perform the tasks specified in
9 section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or
10 otherwise enter prescription information into a computer record system, but the responsibility for
11 the accuracy of the prescription information and the prescription as dispensed lies with the
12 registered pharmacist who initials the prescription or prescription record. At the direction of the
13 registered pharmacist, a non-licensed person may also request and receive refill authorization.

14 "(b) A pharmacist may supervise the number of non-licensed personnel performing the
15 duties specified in subdivision (a) that the pharmacist determines, in the exercise of his or her
16 professional judgment, does not interfere with the effective performance of the pharmacist's
17 responsibilities under the Pharmacy Law.

18 "(c) A pharmacist who, exercising his or her professional judgment pursuant to subdivision
19 (b), refuses to supervise the number of non-licensed personnel scheduled by the pharmacy, shall
20 notify the pharmacist-in-charge in writing of his or her determination, specifying the
21 circumstances of concern with respect to the pharmacy or the non-licensed personnel that have
22 led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting
23 of the relevant schedule.

24 "(d) No entity employing a pharmacist may discharge, discipline, or otherwise discriminate
25 against any pharmacist in the terms and conditions of employment for exercising or attempting to
26 exercise in good faith the right established pursuant to this section."

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1 COST RECOVERY

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

6 DRUGS

7 14. Hydrocodone/APAP, sometimes marketed under the brand name of Norco, is a
8 narcotic substance (hydrocodone) and a non-narcotic substance (acetaminophen abbreviated as
9 APAP) and is scheduled II controlled substance pursuant to Health and Safety code section
10 11055(b)(1)(I) and a dangerous drug pursuant to Business and Professions Code section 4022. It
11 is used to treat moderate to severe pain.

12 15. Promethazine with codeine, sometimes marketed under the brand name of Phenergan
13 with codeine, is a scheduled V controlled substance pursuant to Health and Safety code section
14 11058(c)(1) and a dangerous drug pursuant to Business and Professions Code section 4022.

15 16. Alprazolam, sometimes marketed under the brand name of Xanax, is a scheduled IV
16 controlled substance pursuant to Health and Safety code section 11057, subdivision (d)(1), and a
17 dangerous drug pursuant to Business and Professions Code section 4022. It is used to treat
18 anxiety.

19 17. Carisoprodol, sometimes marketed under the brand name of Soma, is a scheduled IV
20 controlled substance pursuant to Health and Safety code section 11057, subdivision (d), and a
21 dangerous drug pursuant to Business and Professions Code section 4022. It is used to treat
22 muscle spasms.

23 18. Sildenafil, sometimes marketed under the brand name of Viagra, is a dangerous drug
24 pursuant to Business and Professions Code section 4022 in that it is only available by
25 prescription. It is used to treat erectile dysfunction and pulmonary hypertension.

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1 FIRST CAUSE FOR DISCIPLINE

2 (Security of the Pharmacy)

3 19. Respondent Kaiser has subjected its Permit to discipline under Code section 4301,
4 subdivisions (j) and (o), in that it failed to maintain security of the pharmacy such that large
5 quantities of dangerous drugs and controlled substances were diverted and/or lost. On November
6 18, 2016, Respondent Kaiser reported a loss of at least 105,204 tablets of alprazolam 2 mg, 4,115
7 tablets of alprazolam 1 mg, 7,564 tablets of carisoprodol 350 mg, and 35,475 ml of promethazine
8 with codeine 6.25 mg/ 10 mg/ 5 ml. A subsequent investigation and audit by a Board inspector
9 for the period of November 12, 2013, through November 15, 2016, revealed Respondent Kaiser
10 could not account for a shortage of 69,906 tablets of hydrocodone/apap 10/325 mg, 94,296 tablets
11 of hydrocodone/apap 5/325 mg, 652 tablets of alprazolam 0.5 mg, 3,613 tablets of alprazolam 1
12 mg, 106,999 tablets of alprazolam 2 mg, 4,042 tablets of sildenafil 20 mg, and 12 tablets of
13 Viagra 50 mg, and an overage of 60 tablets of alprazolam 0.25 mg. (Cal. Code Reg., tit. 16, §
14 1714, subd. (b).)

15 SECOND CAUSE FOR DISCIPLINE

16 (Failure to Maintain Correct Inventory)

17 20. Respondent Kaiser has subjected its Permit to discipline under Code section 4301,
18 subdivisions (j) and (o), in that it failed to maintain a correct inventory of dangerous drugs. The
19 circumstances are described above in paragraph 19. (Bus. & Prof. Code, § 4081, subd. (a), Cal.
20 Code Reg., tit. 16, § 1718.)

21 THIRD CAUSE FOR DISCIPLINE

22 (Receipt of Dangerous Drugs)

23 21. Respondent Kaiser has subjected its Permit to discipline under Code section 4301,
24 subdivisions (j) and (o), in that it failed to provide pharmacist supervision of pharmacy technician
25 T. M. including maintenance of appropriate pharmacy records. Video surveillance of the
26 pharmacy showed of pharmacy technician T. M. receiving dangerous drugs without the
27 supervision of a pharmacist. (Cal. Code Reg., tit. 16, § 1793.7, subd. (b).)

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1 FOURTH CAUSE FOR DISCIPLINE

2 (Security of the Pharmacy)

3 22. Respondent Lino has subjected his Pharmacist License to discipline under Code
4 section 4301, subdivisions (j) and (o), in that he failed to maintain security of the pharmacy such
5 that large quantities of dangerous drugs and controlled substances were diverted and/or lost as
6 pharmacist-in-charge of Respondent Kaiser. Respondent Lino was pharmacist-in-charge of
7 Respondent Kaiser from January 30, 2010, to August 2, 2016. Additional circumstances are
8 described above in paragraph 19. (Cal. Code Reg., tit. 16, § 1714, subd. (b).)

9 FIFTH CAUSE FOR DISCIPLINE

10 (Failure to Maintain Correct Inventory)

11 23. Respondent Lino has subjected his Pharmacist License to discipline under Code
12 section 4301, subdivisions (j) and (o), in that he failed to maintain a correct inventory of
13 dangerous drugs as pharmacist-in-charge of Respondent Kaiser. Respondent Lino was
14 pharmacist-in-charge of Respondent Kaiser from January 30, 2010, to August 2, 2016.
15 Additional circumstances are described above in paragraph 19. (Bus. & Prof. Code, § 4081, subd.
16 (a), Cal. Code Reg., tit. 16, § 1718.)

17 SIXTH CAUSE FOR DISCIPLINE

18 (Receipt of Dangerous Drugs)

19 24. Respondent Lino has subjected his Pharmacist License to discipline under Code
20 section 4301, subdivisions (j) and (o), in that he failed to provide pharmacist supervision of
21 pharmacy technician T. M. including maintenance of appropriate pharmacy records. Video
22 surveillance of the pharmacy showed of pharmacy technician T. M. receiving dangerous drugs
23 without the supervision of a pharmacist. (Cal. Code Reg., tit. 16, § 1793.7, subd. (b).)

24 DISCIPLINE CONSIDERATIONS

25 25. To determine the degree of discipline, if any, to be imposed on Respondent Kaiser,
26 Complainant alleges that on or about February 4, 2014, in a prior action, the Board of Pharmacy
27 issued Citation Number CI 2012 56806 and ordered Respondent to pay a fine of \$3,000.00. That
28 Citation is now final and is incorporated by reference as if fully set forth.

1 26. To determine the degree of discipline, if any, to be imposed on Respondent Kaiser,
2 Complainant alleges that on or about February 4, 2014, in a prior action, the Board issued
3 Citation Number CI 2012 56806 and ordered Respondent Kaiser to pay a fine of \$2,750.00. That
4 Citation is now final and is incorporated by reference as if fully set forth.

5 27. To determine the degree of discipline, if any, to be imposed on Respondent Kaiser,
6 Complainant alleges that on or about July 18, 2016, in a prior action, the Board issued Citation
7 Number CI 2016 7186 and ordered Respondent Kaiser to pay a fine of \$5,000.00. That Citation
8 is now final and is incorporated by reference as if fully set forth.

9 28. To determine the degree of discipline, if any, to be imposed on Respondent Lino,
10 Complainant alleges that on or about February 4, 2014, in a prior action, the Board issued
11 Citation Number CI 2013 59753 and ordered Respondent Lino to pay a fine of \$1,250.00. That
12 Citation is now final and is incorporated by reference as if fully set forth.

13 PRAYER

14 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
15 Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

- 16 1. Revoking or suspending Original Permit Number HSP 6602, issued to Kaiser
17 Foundation Hospital Inpatient/Out Patient Pharmacy;
- 18 2. Revoking or suspending Original Pharmacist License Number RPH 42290, issued to
19 Charles C. Lino;
- 20 3. Ordering Kaiser Foundation Hospital Inpatient/Out Patient Pharmacy and Charles C.
21 Lino to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of
22 this case, pursuant to Business and Professions Code section 125.3; and,

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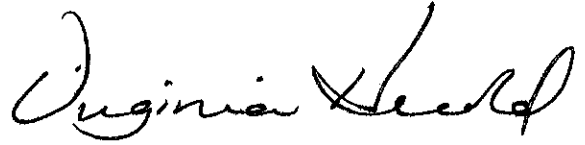
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4. Taking such other and further action as deemed necessary and proper.

DATED: 2/1/18



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

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