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

11 In the Matter of the Accusation Against:

Case No. 6314

12 **KELSEYVILLE PHARMACY**
13 **3720 Main Street**
14 **Kelseyville, CA 95451**
15 **Pharmacy License No. PHY 46140**

A C C U S A T I O N

16 **COYOTE VALLEY PHARMACY**
17 **18990 Coyote Valley Road #2**
18 **Hidden Valley Lake, CA 95467**
19 **Pharmacy License No. PHY 50618**

20 **RUTH STEWART**
21 **PO Box 727**
22 **Kelseyville, CA 95451**
23 **Pharmacist License No. RPH 48093**

24 Respondents.

25 Complainant alleges:

26 **PARTIES**

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

2. On or about January 3, 2003, the Board issued Pharmacy License Number PHY
46140 to Kelseyville Pharmacy (Respondent Kelseyville). The Pharmacy License was in full

1 force and effect at all times relevant to the charges brought herein and will expire on January 1,
2 2019, unless renewed.

3 3. On or about April 28, 2011, the Board issued Pharmacy License Number PHY 50618
4 to Coyote Valley Pharmacy (Respondent Coyote Valley). The Pharmacy License was in full
5 force and effect at all times relevant to the charges brought herein and will expire on April 1,
6 2019, unless renewed.

7 4. On or about August 10, 1995, the Board issued Pharmacist License Number RPH
8 48093 to Ruth Anne Stewart (Respondent Stewart). The Pharmacist License was in full force and
9 effect at all times relevant to the charges brought herein and will expire on July 31, 2019, unless
10 renewed.

11 JURISDICTION

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

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

18 7. Code section 4300, subdivision (a), provides that every license issued by the Board
19 may be suspended or revoked.

20 8. Code section 4300.1 provides that the expiration, cancellation, forfeiture, suspension,
21 or voluntary surrender of a license "shall not deprive the board of jurisdiction to commence or
22 proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to
23 render a decision suspending or revoking the license."

24 9. Code section 4307, subdivision (a), states:

25 (a) Any person who has been denied a license or whose license has been revoked or is
26 under suspension, or who has failed to renew his or her license while it was under
27 suspension, or who has been a manager, administrator, owner, member, officer,
28 director, associate, partner, or any other person with management or control of any
partnership, corporation, trust, 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,

1 associate, partner, or any other person with management or control had knowledge of
2 or knowingly participated in any conduct for which the license was denied, revoked,
3 suspended, or placed on probation, shall be prohibited from serving as a manager,
4 administrator, owner, member, officer, director, associate, partner, or in any other
5 position with management or control of a licensee as follows:

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

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

10 STATUTORY PROVISIONS

11 10. Code section 4081, subdivision (a), states in pertinent part:

12 (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of
13 dangerous drugs or dangerous devices shall be at all times during business hours open to
14 inspection by authorized officers of the law, and shall be preserved for at least three years from
15 the date of making. A current inventory shall be kept by every . . . pharmacy, . . . institution, or
16 establishment holding a currently valid and unrevoked certificate, license, permit, registration, or
17 exemption [...] who maintains a stock of dangerous drugs or dangerous devices.

18 11. Code section 4105, subdivisions (a) and (c), state in pertinent part:

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

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

24 12. Code section 4116, subdivision (a), states:

25 (a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the
26 law, or a person authorized to prescribe shall be permitted in that area, place, or premises
27 described in the license issued by the board wherein controlled substances or dangerous drugs or
28 dangerous devices are stored, possessed, prepared, manufactured, derived, compounded,
dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who
enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing

1 clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to
2 the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized
3 individual is present.

4 13. Code section 4126.5, subdivision (a), states in pertinent part:

5 (a) A pharmacy may furnish dangerous drugs only to the following:

6 ...

7 (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous
8 drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs
9 pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary
10 shortage.

11 ...

12 (7) To another pharmacy under common control.

13
14 14. Code section 4301 states, in pertinent part:

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

18 ...

19 (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
20 corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
21 whether the act is a felony or misdemeanor or not.

22 ...

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

25 ...

26 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
27 violation or conspiring to violate any provision or term of this chapter or of the applicable federal
28

1 and state laws and regulations governing pharmacy, including regulations established by the
2 board or by any other state or federal regulatory agency.

3 ...

4 REGULATORY PROVISIONS

5 15. California Code of Regulations, title 16, section 1714(d), states:

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

10 16. California Code of Regulations, title 16, section 1715, states in pertinent part:

11 (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section
12 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's
13 compliance with federal and state pharmacy law. The assessment shall be performed before July
14 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote
15 compliance through self-examination and education.

16 ...

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

19 COST RECOVERY

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

24 FACTUAL BACKGROUND

25 18. Respondent Stewart is part-owner and pharmacist-in-charge (PIC) at Respondent
26 Kelseyville, which is co-owned with T.S. Respondent Stewart is also PIC at Respondent Coyote
27 Valley, where she is the sole owner. Respondent Stewart has been the PIC at Respondent
28

1 Kelseyville since January 3, 2003, and the PIC at Respondent Coyote Valley since April 28,
2 2011.

3 19. On or about August 10, 2015, the Department of Health Care Services notified the
4 Board that a Medi-Cal billing review of Respondent Kelseyville revealed that Respondents
5 Kelseyville and Stewart failed to provide adequate acquisition and disposition records of atypical
6 antipsychotic drugs. Auditors discovered that Respondent Kelseyville had significant shortages
7 in their inventory for brand-name atypical antipsychotic drugs. During the period of July 1, 2012,
8 through July 31, 2014, Respondents Kelseyville and Stewart billed various strengths of brand
9 name Geodon, Seroquel, and Zyprexa for an overpayment of \$227,657.79. Based on the billing
10 review, Respondents Kelseyville and Stewart billed Medi-Cal for brand-name drugs, but filled
11 prescriptions with generics, resulting in the overbilling.

12 20. During a subsequent Board inspection at Respondent Kelseyville on or about
13 September 28, 2015, Respondent Stewart was unable to provide a current pharmacy self-
14 assessment, and instead provided a copy of the self-assessment conducted on June 21, 2013.
15 Respondent Stewart also could not provide a current copy of the DEA biennial inventory, instead
16 providing a copy of a DEA biennial inventory dated May 20, 2013.

17 21. During the September 28, 2015 inspection at Respondent Kelseyville, several
18 prescription stock bottles were located at Respondent Kelseyville with the listing "COYOTE
19 PHCY." Respondent Stewart indicated that she transferred inventory between Respondents
20 Kelseyville and Coyote Valley. Respondents Kelseyville and Coyote Valley are not under
21 common ownership, in that Respondent Kelseyville is co-owned by T.S. Moreover, Respondents
22 did not transfer inventory between pharmacies to alleviate a temporary shortage of a dangerous
23 drug that could result in the denial of health care.

24 22. Both Respondent Kelseyville and Respondent Coyote Valley had substantial
25 variances in drug inventories for numerous dangerous drugs, including Geodon, Ziprasidone,
26 Seroquel, Quetiapine, Zyprexa, and Olanzapine. Respondent Kelseyville failed to maintain
27 records of acquisition and disposition of drug inventories, resulting in overages and shortages for
28 a total of 33 prescription drugs, with no records to explain the variances. Respondent Coyote

1 Valley failed to maintain records of acquisition and disposition of drug inventories, resulting in
2 overages and shortages for a total of 27 prescription drugs, with no records to explain the
3 variances.

4 23. On or about July 14, 2017, the Board conducted an inspection at Respondent Coyote
5 Valley following a complaint by a consumer. The Board inspector arrived before the pharmacy
6 opened, and observed a woman use a key to enter Respondent Coyote Valley and open the
7 pharmacy. The Board inspector entered the pharmacy and found two pharmacy technicians
8 working at the front counter. The prescription drug section of Respondent Coyote Valley was
9 dark and locked, but will-call prescription medications were hanging in bags behind the front
10 counter. Respondents Coyote Valley and Stewart (as PIC) wrongfully allowed the pharmacy
11 technicians to use a key to unlock the pharmacy without the presence of a pharmacist. The will-
12 call medications were stored in an unlocked portion of Respondent Coyote Valley without a
13 pharmacist present.

14 **FIRST CAUSE FOR DISCIPLINE**

15 **(Respondents Kelseyville, Coyote Valley, and Stewart—Failure to Retain Records)**

16 24. Respondent Kelseyville, Respondent Coyote Valley, and Respondent Stewart are
17 subject to disciplinary action under Code section(s) 4081(a) and/or 4105(a) and (c) for failure to
18 maintain records of acquisition and disposition of medications for a period of at least three years,
19 as described above in paragraphs 18-19 and 22, and incorporated herein.

20 **SECOND CAUSE FOR DISCIPLINE**

21 **(Respondents Kelseyville, Coyote Valley, and Stewart—Furnishing Dangerous Drugs)**

22 25. Respondent Kelseyville, Respondent Coyote Valley, and Respondent Stewart are
23 subject to disciplinary action under Code section 4126.5, subdivisions (a)(4) and (7), for
24 transferring dangerous drugs from Respondent Coyote Valley to Respondent Kelseyville not to
25 alleviate a temporary shortage of the product and where Respondent Coyote Valley and
26 Respondent Kelseyville are not under common control by the same owner, as described above in
27 paragraphs 18 and 21, and incorporated herein.

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THIRD CAUSE FOR DISCIPLINE

(Respondents Kelseyville and Stewart—Unprofessional Conduct)

26. Respondent Kelseyville and Respondent Stewart are subject to disciplinary action under Code section 4301 for billing Medi-Cal for brand-name prescriptions, with no records of acquisition or disposition of the billed medications, as described above in paragraphs 18-19, and incorporated herein.

FOURTH CAUSE FOR DISCIPLINE

(Respondents Kelseyville and Stewart—Failure to Maintain Pharmacy Self-Assessment)

27. Respondent Kelseyville and Respondent Stewart are subject to disciplinary action under California Code of Regulations, title 16, section 1715(a) and (d), for failing to produce the required self-assessment at the time of inspection, and failing to maintain the self-assessment at Respondent Kelseyville, as described above in paragraphs 18-19, and incorporated herein.

FIFTH CAUSE FOR DISCIPLINE

(Respondents Coyote Valley and Stewart—Improper Security of Dangerous Drugs)

28. Respondent Coyote Valley and Respondent Stewart are subject to disciplinary action under Code section 4116(a) and/or California Code of Regulations, title 16, section 1714(d), for allowing pharmacy technicians to possess keys to the pharmacy and to access storage of dangerous drugs at Respondent Coyote Valley in the absence of a supervising pharmacist, as described above in paragraphs 18 and 23, and incorporated herein.

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 License No. PHY 46140 issued to Kelseyville Pharmacy (Respondent Kelseyville);
- 2. Revoking or suspending Pharmacy License No. PHY 50618 issued to Coyote Valley Pharmacy (Respondent Coyote Valley);
- 3. Revoking or suspending Pharmacist License No. RPH 48093 issued to Ruth Stewart (Respondent Stewart);

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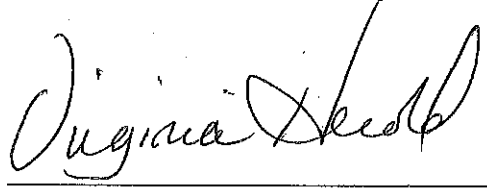
4. Prohibiting Ruth Stewart from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License Number PHY 46140 is placed on probation, or until reinstatement if Pharmacy License No. PHY 46140 is revoked;

5. Prohibiting Ruth Stewart from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License Number PHY 50618 is placed on probation, or until reinstatement if Pharmacy License No. PHY 50618 is revoked;

6. Ordering Respondent Kelseyville, Respondent Coyote Valley, and Respondent Stewart, jointly and severally, 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: 9/18/18



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

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