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

12 In the Matter of the Accusation Against:

Case No. 5745

13 **PACIFIC WEST PHARMACY, INC.**
14 **ARTHUR C. WHITNEY, PRES./SHAREHOLDER**
15 **HELEN S. WHITNEY, SEC./TREAS./SHAREHOLDER**
16 **HORIZON WEST, INC., SHAREHOLDER**
17 **TOM ROGERS aka THOMAS STEVEN ROGERS,**
18 **PHARMACIST-IN-CHARGE**
19 **4363 Pacific Street**
20 **Rocklin, CA 95677**

ACCUSATION

21 **Pharmacy Permit No. PHY 40592**

22 **and**

23 **THOMAS STEVEN ROGERS**
24 **20291 Rim Rock Court**
25 **Foresthill, CA 95631**

26 **Pharmacist License No. RPH 30137**

27 Respondents.

28 Complainant alleges:

PARTIES

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

2. On or about December 16, 1994, the Board issued Pharmacy Permit Number PHY 40592 to Pacific West Pharmacy, Inc. ("Respondent Pacific West Pharmacy" or "Pacific West

1 Pharmacy”), with Arthur C. Whitney as president and 38 percent shareholder, Helen S. Whitney
2 as secretary, treasurer, and 12 percent shareholder, and Horizon West, Inc. as 50 percent
3 shareholder. On or about October 25, 2005, Tom Rogers, also known as Thomas Steven Rogers
4 (“Respondent Rogers” or “PIC Rogers”), became the pharmacist-in-charge. The pharmacy
5 permit was in full force and effect at all times relevant to the charges brought herein and will
6 expire on December 1, 2016, unless renewed.

7 3. On or about May 4, 1976, the Board issued Pharmacist License Number RPH 30137
8 to Respondent Rogers. The pharmacist license was in full force and effect at all times relevant to
9 the charges brought herein and will expire on June 30, 2016, unless renewed.

10 JURISDICTION

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

14 5. Section 4300 of the Code states, in pertinent part:

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

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

18 (1) Suspending judgment.

19 (2) Placing him or her upon probation.

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

22 (4) Revoking his or her license.

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

24 6. Section 4300.1 of the Code states:

25 The expiration, cancellation, forfeiture, or suspension of a board-issued
26 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
27 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
28 a decision suspending or revoking the license.

STATUTORY AND REGULATORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

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

....

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

....

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

8. Section 4115 of the Code states:

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

9. Section 4023.5 of the Code states that “‘direct supervision and control’ means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.”

10. Title 16, California Code of Regulations, section 1793.2 defines “nondiscretionary tasks,” as used in Business and Professions Code section 4115, as:

- (a) removing the drug or drugs from stock;
- (b) counting, pouring, or mixing pharmaceuticals;
- (c) placing the product into a container;
- (d) affixing the label or labels to the container;
- (e) packaging and repackaging.

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1 11. Section 4081 of the Code states, in pertinent part:

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

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

17 12. Section 4105, subdivision (a), of the Code states:

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

21 13. Section 4113, subdivision (c), of the Code states that “[t]he pharmacist-in-charge
22 shall be responsible for a pharmacy’s compliance with all state and federal laws and regulations
23 pertaining to the practice of pharmacy.”

24 14. Section 4115 of the Code states, in pertinent part:

25 (a) A pharmacy technician may perform packaging, manipulative,
26 repetitive, or other nondiscretionary tasks, only while assisting, and while under the
27 direct supervision and control of a pharmacist. The pharmacist shall be responsible
28 for the duties performed under his or her supervision by a technician.

....

29 (d) The board shall adopt regulations to specify tasks pursuant to
30 subdivision (a) that a pharmacy technician may perform under the supervision of a
31 pharmacist. Any pharmacy that employs a pharmacy technician shall do so in
32 conformity with the regulations adopted by the board.

....

33 (f)(1) A pharmacy with only one pharmacist shall have no more than one
34 pharmacy technician performing the tasks specified in subdivision (a). The ratio of
35 pharmacy technicians performing the tasks specified in subdivision (a) to any
36 additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to
37 personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio
38 is applicable to all practice settings, except for an inpatient of a licensed health
facility, a patient of a licensed home health agency, as specified in paragraph (2), an

1 inmate of a correctional facility of the Department of Corrections and Rehabilitation,
2 and for a person receiving treatment in a facility operated by the State Department of
3 State Hospitals, the State Department of Developmental Services, or the Department
4 of Veterans Affairs.

5 (2) The board may adopt regulations establishing the ratio of pharmacy
6 technicians performing the tasks specified in subdivision (a) to pharmacists applicable
7 to the filling of prescriptions of an inpatient of a licensed health facility and for a
8 patient of a licensed home health agency. Any ratio established by the board pursuant
9 to this subdivision shall allow, at a minimum, at least one pharmacy technician for a
10 single pharmacist in a pharmacy and two pharmacy technicians for each additional
11 pharmacist, except that this ratio shall not apply to personnel performing clerical
12 functions pursuant to Section 4116 or 4117 . . .

13 15. Title 16, California Code of Regulations ("CCR"), section 1714 states, in part:

14

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

19 16. Title 16, CCR, section 1718 states:

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

23 The controlled substances inventories required by Title 21, CFR, Section
24 1304 shall be available for inspection upon request for at least 3 years after the date of
25 the inventory.

26 17. Title 16, CCR, section 1793.7 states, in pertinent part:

27 (a) Except as otherwise provided in section 1793.8, any function
28 performed by a pharmacy technician in connection with the dispensing of a
prescription, including repackaging from bulk and storage of pharmaceuticals, must
be verified and documented in writing by a pharmacist. Except for the preparation of
prescriptions for an inpatient of a hospital and for an inmate of a correctional facility,
the pharmacist shall indicate verification of the prescription by initialing the
prescription label before the medication is provided to the patient.

(b) Pharmacy technicians must work under the direct supervision of a
pharmacist and in such a relationship that the supervising pharmacist is fully aware of
all activities involved in the preparation and dispensing of medications, including the
maintenance of appropriate records.

. . . .

(e) A pharmacist shall be responsible for all activities of pharmacy
technicians to ensure that all such activities are performed completely, safely and
without risk of harm to patients . . .

1 **COST RECOVERY**

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

6 **DRUG CLASSIFICATIONS**

7 19. "Xanax," a brand name for alprazolam, is a Schedule IV controlled substance
8 pursuant to Health and Safety Code section 11057, subdivision (d)(1). Xanax is used to treat
9 anxiety.

10 20. "Soma", a brand name for carisoprodol, is a Schedule IV Controlled Substance
11 pursuant to Title 21, Code of Federal Regulations ("CFR"), section 1308.14, subdivision (c)(6).
12 Soma is used as a muscle relaxant.

13 21. "Norco", a brand name for hydrocodone/acetaminophen (APAP), was a Schedule III
14 controlled substance pursuant to Health and Safety Code section 11056, subdivision (e). Norco
15 was reclassified as a Schedule II controlled substance pursuant to Title 21, CFR, section 1308.12,
16 effective October 6, 2014. Norco is used to treat pain.

17 22. "Dilaudid," a brand name for hydromorphone, is a Schedule II controlled substance
18 pursuant to Health and Safety Code section 11055, subdivision (b)(1)(J). Dilaudid is used to treat
19 pain.

20 23. "Ativan," a brand name for lorazepam, is a Schedule IV controlled substance
21 pursuant to Health and Safety Code section 11057, subdivision (d)(16). Ativan is used to treat
22 anxiety.

23 24. "Dolophine", a brand name for methadone, is a Schedule II controlled substance
24 pursuant to Health and Safety Code section 11055, subdivision (c)(14). Dolophine is used to treat
25 pain.

26 25. "Roxanol", a brand name for morphine sulfate, is a Schedule II controlled substance
27 pursuant to Health and Safety Code section 11055, subdivision (b)(1)(L). Roxanol is used to treat
28 pain.

1 26. "Percolone" and "Roxicodone" are brand names for oxycodone. Oxycodone is a
2 Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision
3 (b)(1)(M). Percolone and Roxicodone are used to treat pain.

4 27. All of the above controlled substances are dangerous drugs pursuant to section 4022.

5

6 **STATEMENT OF FACTS**

7 28. On or about October 15, 2015, Board Inspector S. K. went to Pacific West Pharmacy
8 to conduct an inspection. The pharmacy was not open for walk-in retail business as it provided
9 services to skilled nursing and assisted living facilities. The pharmacy maintained Talyst
10 Automated Drug Delivery Systems (ADDS) and emergency kits (E-kits) in some of the facilities
11 they serviced. Upon arrival, there was only one pharmacist on duty and in the building,
12 Respondent Thomas Rogers, the pharmacist-in-charge (PIC). Pharmacist K. D. arrived later
13 during the inspection. There was a closed door labeled "IV Room" near the front of the
14 pharmacy. Inspector S. K. opened the door and observed pharmacy technician (TCH) C. Y.
15 filling and compounding sterile prescription preparations in the room. There was no one else in
16 the room, and there were no unobstructed windows on the walls nor a window in the door.

17 29. Inspector S. K. went to the main pharmacy area and observed: TCH P. P. filling and
18 labeling prescriptions, TCH Y. Y. filling prescriptions, TCH K. B. pulling drugs from stock for
19 prescriptions and filling prescriptions, and TCH D. L. handling controlled substances and other
20 drugs. D. L. was organizing controlled substances and putting them away on the drug stock
21 shelves. PIC Rogers was in the main pharmacy area during the inspection.

22 30. Inspector S. K. went into an open, separate room in the rear of the main filling area
23 and observed TCH R. B. filling cells with drugs for the ADDS. There was no one else in the
24 room. There was no door on this room.

25 31. PIC Rogers provided various documents to Inspector S. K., including inventories of
26 controlled substances conducted by the pharmacy on October 1, 2015 through October 5, 2015.
27 Inspector S. K. reviewed the pharmacy's invoices and found that they purchased controlled
28 substances from Cardinal Health ("Cardinal"), ParMed, and ANDA, Inc. ("ANDA").

1 32. Upon completion of the inspection, Inspector S. K. issued an inspection report and
2 provided PIC Rogers with a copy. Inspector S. K. requested that PIC Rogers provide complete
3 records of all acquisitions and dispositions of all controlled substances from December 13, 2013
4 to October 4, 2015, other than from Cardinal, ParMed, and ANDA. The 2013 and 2014
5 controlled substance inventories did not include a count of controlled substances in the ADDS
6 and E-kits. PIC Rogers stated that these controlled substances were stored at the off site facilities
7 in the ADDS and E-kits in order to provide emergency access to medications needed by patients.
8 Inspector S. K. requested an accounting of all controlled substances which were not on the
9 premises during the previous inventories.

10 33. On or about October 21, 2015, Inspector S. K. received the pharmacy's dispensing
11 data and the 2013 and 2014 offsite inventory information.

12 34. On or about October 22, 2015, Inspector S. K. sent Cardinal/ParMed and ANDA
13 letters, requesting records of all Schedule II to V controlled substances sold to Pacific West
14 Pharmacy from December 13, 2013 to October 4, 2015, including all credits. ANDA and
15 Cardinal/ParMed provided the information to Inspector S. K. on October 26, 2015 and November
16 10, 2015, respectively.

17 35. Inspector S. K. conducted an audit based on the 2013 inventory, 2015 inventory,
18 disposition data from Pacific West Pharmacy, and acquisition and credit data from Cardinal/
19 ParMed and ANDA. Inspector S. K. found that the pharmacy had significant shortages and
20 overages of controlled substances from December 13, 2014 to October 4, 2015, as set forth
21 below.

22 36. On or about November 18, 2015, Board Inspector S. K. returned to the pharmacy with
23 Board Inspector J. H. to conduct an inspection and follow up on the audit results. Inspector S. K.
24 found that PIC Rogers was the only pharmacist on duty and in the building. Inspector S. K.
25 observed TCH A. M. pulling drugs for prescriptions from stock and filling prescriptions, TCH's
26 P. P. and Y. Y. filling and labeling prescriptions, and TCH C. Y. compounding sterile
27 prescription preparations.

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1 **FIRST CAUSE FOR DISCIPLINE**

2 **(Violations of the Pharmacy Law/Pharmacy Technician to Pharmacist Ratio)**

3 37. Respondent Pacific West Pharmacy is subject to disciplinary action for
4 unprofessional conduct pursuant to section 4301, subdivision (o), of the Code in that Respondent
5 violated section 4115, subdivisions (a) and (f)(1), of the Code and Title 16, CCR, section 1793.7,
6 subdivision (b), as follows: On or about October 15, 2015, and November 18, 2015, Respondent
7 authorized or allowed at least four pharmacy technicians to fill prescriptions, compound sterile
8 prescription preparations, stock ADDS', or pull drugs from stock for prescriptions, as set forth in
9 paragraphs 28 - 36, above, when, in fact, Respondent Rogers was the only pharmacist on duty and
10 in the building. Further, Respondent Rogers was not in a position to directly supervise, and/or
11 was not fully aware of, all of the activities of the technicians, who were preparing and dispensing
12 medications.

13 **SECOND CAUSE FOR DISCIPLINE**

14 **(Failure to Maintain Pharmacy, Fixtures, and Equipment**
15 **so that Drugs Were Safely and Properly Secured)**

16 38. Respondent Pacific West Pharmacy is subject to disciplinary action for
17 unprofessional conduct pursuant to section 4301, subdivisions (o) and (j), of the Code in that on
18 and between December 13, 2013 and October 4, 2015, Respondent failed to maintain the
19 pharmacy and its facilities, space, fixtures and/or equipment so that drugs were safely and
20 properly secured, in violation of title 16, CCR, section 1714, subdivision (b), resulting in
21 significant shortages and overages of controlled substances, as follows:

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Drug	Shortage or Overage
alprazolam 2 mg	-908
carisoprodol 350 mg	-94
hydrocodone/APAP 10/325 mg	-27,980
hydrocodone/APAP 5/325 mg	-10,400
hydrocodone/APAP 7.5/325 mg	-945
hydromorphone 2 mg	-544
lorazepam 0.5 mg	-8,216
lorazepam 1 mg	2,862
methadone 10 mg	507
methadone 5 mg	104
morphine 100 mg/5 ml sol.	-324
oxycodone 10 mg	-715
oxycodone 30 mg	-638
oxycodone 5 mg	-356
oxycodone/APAP 10/325 mg	-2,454
oxycodone/APAP 5/325 mg	-398
Total units unaccounted for by the pharmacy	57,445

THIRD CAUSE FOR DISCIPLINE

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

39. Respondent Pacific West Pharmacy is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), of the Code in that Respondent violated sections 4081, subdivision (a), and 4105, subdivision (o), of the Code as follows: Respondent failed to maintain an accurate or current inventory of all dangerous drugs in the pharmacy, resulting in significant shortages and overages of controlled substances, as set forth in paragraph 38, above.

1 **FOURTH CAUSE FOR DISCIPLINE**

2 **(Violations of the Pharmacy Law/Pharmacy Technician to Pharmacist Ratio)**

3 40. Respondent Rogers is subject to disciplinary action for unprofessional conduct
4 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated section 4115,
5 subdivisions (a) and (f)(1), of the Code and Title 16, CCR, section 1793.7, subdivision (b), as
6 follows: On or about October 15, 2015, and November 18, 2015, Respondent authorized or
7 allowed at least four pharmacy technicians to fill prescriptions, compound sterile prescription
8 preparations, stock ADDS', or pull drugs from stock for prescriptions, as set forth in paragraphs
9 28 - 36, above. Respondent Rogers was the only pharmacist on duty and in the building. Further,
10 Respondent Rogers was not in a position to directly supervise and/or was not fully aware of all of
11 the activities of the technicians, who were preparing and dispensing medications.

12 **FIFTH CAUSE FOR DISCIPLINE**

13 **(Failure to Maintain Pharmacy, Fixtures, and Equipment**
14 **so that Drugs Were Safely and Properly Secured)**

15 41. Respondent Rogers is subject to disciplinary action for unprofessional conduct
16 pursuant to section 4301, subdivisions (o) and (j), of the Code in that on and between December
17 13, 2013 and October 4, 2015, Respondent failed to maintain Pacific West Pharmacy, Inc. and its
18 facilities, space, fixtures and/or equipment so that drugs were safely and properly secured, in
19 violation of title 16, CCR, section 1714, subdivision (b), resulting in significant shortages and
20 overages of controlled substances, as set the paragraph 38 above.

21 **SIXTH CAUSE FOR DISCIPLINE**

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

23 42. Respondent Rogers is subject to disciplinary action for unprofessional conduct
24 pursuant to section 4301, subdivision (o), of the Code in that Respondent violated sections 4081,
25 subdivision (a), and 4105, subdivision (o), of the Code as follows: Respondent failed to maintain
26 an accurate or current inventory of all dangerous drugs in Pacific West Pharmacy, Inc., resulting
27 in significant shortages and overages of controlled substances, as set forth in paragraph 38 above.

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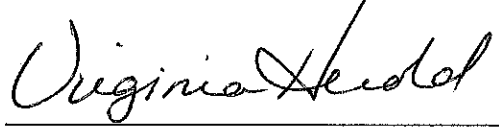
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PRAYER

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 40592, issued to Pacific West Pharmacy, Inc.;
2. Revoking or suspending Pharmacist License Number RPH 30137, issued to Tom Rogers, also known as Thomas Steven Rogers;
3. Ordering Pacific West Pharmacy, Inc. and Tom Rogers, also known as Thomas Steven Rogers, 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: 7/30/16



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

SA2016100465