XAVIER BECERRA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General
EMILY Y. WADA
Deputy Attorney General
State Bar No. 241845
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-8944
Facsimile: (213) 897-2804
Attorneys for Complainant

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

In the Matter of the Accusation Against: **QUARTZ HILL PHARMACY, RICHARD ARTHUR WOOD, OWNER** **42357 50th Street W. #101** **Quartz Hill, CA 93536** **Pharmacy Permit No. PHY 39118** **RICHARD ARTHUR WOOD** **5918 E. Alleppo Lane** **Palmdale, CA 93551** **Pharmacist License No. RPH 28308** Respondent.	Case No. 5892 OAH No. 2017010056 **FIRST AMENDED ACCUSATION**

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 March 8, 1993, the Board of Pharmacy issued Permit Number PHY 39118 to Quartz Hill Pharmacy, Richard Arthur Wood, owner. The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2018, unless renewed.

3. On or about July 31, 1973, the Board of Pharmacy issued Pharmacist License Number RPH 28308 to Richard Arthur Wood. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2019, unless renewed.

JURISDICTION

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

5. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board, Registrar, or Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

6. Section 4300 of the Code provides, in pertinent part, that:

> (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.
> . . . .
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

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

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

STATUTORY PROVISIONS

8. Section 4022 of the Code provides that:

"Dangerous drug" or "dangerous device" 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.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

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

9. Section 4036.5 of the Code provides that:

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

10. Section 4040.5 of the Code provides that:

"Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs.

11. Section 4043 of the Code provides that:

"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

12. Section 4059 of the Code provides, in pertinent part, that:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. . . .

13. Section 4059.5 of the Code provides, in pertinent part that:

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

14. Section 4081 of the Code provides, in pertinent part, that:

(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. . . .

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer 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. Section 4105 of the Code provides, in pertinent part that:

(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.

. . .

(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.

(e)

(1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

///

///

///

16. Section 4160 of the Code provides, in pertinent part, that: "(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board."

17. Section 4307 of the Code provides, in pertinent part, that:

> (a) 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, 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, associate, partner, or any other person with management or control had knowledge of 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, partner, or any other person with management or control 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. . . .

18. Health and Safety Code section 11153 provides, in pertinent part, that:

> (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. . . .

19. Health and Safety Code section 11158 provides, in pertinent part, that:

> (a) Except as provided in Section 11159 or in subdivision (b) of this section, no controlled substance classified in Schedule II shall be dispensed without a prescription meeting the requirements of this chapter. Except as provided in Section 11159 or when dispensed directly to an ultimate user by a practitioner, other than a pharmacist or pharmacy, no controlled substance classified in

Schedule III, IV, or V may be dispensed without a prescription meeting the requirements of this chapter. . . .

20. Health and Safety Code section 11165 provides, in pertinent part, that:

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

21. Nevada Revised Statute section 639.2328 provides, in pertinent part, that:

1. Every pharmacy located outside Nevada that provides mail order service to or solicits or advertises for orders for drugs available with a prescription from a resident of Nevada must be licensed by the Board. . . .

///

///

///

///

REGULATORY PROVISIONS

22. Code of Federal Regulations, title 21, section 1304.11, provides, in pertinent part, that:

> (a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

23. California Code of Regulations, title 16, section 1714, provides, in pertinent part, that:

> (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. . . .

///

///

///

24. California Code of Regulations, title 16, section 1715, provides, in pertinent part, that:

> (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
>
> . . .
>
> (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

25. California Code of Regulations, title 16, section 1718, provides, in pertinent part, that:

> "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
> The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

26. California Code of Regulations, title 16, section 1761 provides, in pertinent part, that:

> (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.

COST RECOVERY

27. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

///

///

///

DRUG CLASSIFICATIONS

28. Alprazolam is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057(d)(1) and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

29. Amoxicillin is a dangerous drug pursuant to Business and Professions Code section 4022.

30. Carisoprodol is a Schedule IV controlled substance pursuant to Code of Federal Regulations, title 21, section 1308.14(c)(6), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

31. Clavamox is a dangerous drug pursuant to Business and Professions Code section 4022.

32. Diphenoxylate/atropine combination is a Schedule V controlled substance pursuant to Health and Safety Code section 11058(c)(4) and is a dangerous drug pursuant to Business and Professions Code section 4022.

33. Hydrocodone and Acetaminophen is a Schedule III controlled substance pursuant to Health and Safety Code section 11056(e)(4) and Code of Federal Regulations, title 21, section 1308.12(b)(1)(vi), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

34. Methadone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055(c)(14) and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

35. Oxybutynin is a dangerous drug pursuant to Business and Professions Code section 4022.

36. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055(b)(1)(M) and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

///

///

37. Phendimetrazine is a Schedule III controlled substance pursuant to Health and Safety Code section 11056(b)(6) and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

38. Phenazopyridine is a dangerous drug pursuant to Business and Professions Code section 4022.

39. Promethazine with codeine is a Schedule V controlled substance pursuant to Health and Safety Code section 11058 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

40. Temazepam is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057(d)(29) and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

41. Trazadone is a dangerous drug pursuant to Business and Professions Code section 4022.

42. Vistaril (hydroxyzine) is a dangerous drug pursuant to Business and Professions Code section 4022.

FIRST CAUSE FOR DISCIPLINE

(Failure to Retain Records of Acquisition and Disposition of Dangerous Drugs on Premises)

Against Respondents Quartz Hill and Wood

43. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code sections 4105, subdivisions (a) and (c), and 4081, subdivisions (a) and (b), on the grounds that Respondents failed to retain records of acquisition and disposition of dangerous drugs on the licensed premises.

44. The facts and circumstances are that, on or around July 30, 2015, the Board initiated an inspection and audit of Quartz Hill Pharmacy. The inspection was prompted by an analysis performed by the Board whereby the controlled substance dispensing data from Quartz Hill as reported to the Controlled Substance Utilization Review and Evaluation System ("CURES") and controlled substance purchasing data for Quartz Hill as reported by California licensed wholesalers revealed a potential inventory discrepancy.

45. Specifically, Board inspectors asked to review all of Quartz Hill's records of acquisition and disposition of dangerous drugs. Respondent Wood admitted to the Board inspectors that approximately ten boxes of the pharmacy's records were stored at unlicensed off-site facilities, including, for example, Respondent Wood's home. Respondent Wood further admitted that Quartz Hill did not have a waiver for the off-site storage of records.

SECOND CAUSE FOR DISCIPLINE

(Failure to Complete a Self-Assessment)

Against Respondents Quartz Hill and Wood

46. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1715, on the grounds that Respondents failed to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law.

47. Specifically, during the inspection on or around July 30, 2015, Board inspectors asked Respondents for copies the most recent Community Pharmacy Self-Assessment and Compounding Self-Assessment for Quartz Hill. Although those assessments are required to be performed before July 1 of every odd-numbered year, Respondents could only locate a Community Pharmacy Self-Assessment from the year 2009 and could not locate any Compounding Self-Assessment.

THIRD CAUSE FOR DISCIPLINE

(Failure to Keep Biennial Inventory Available for Inspection)

Against Respondents Quartz Hill and Wood

48. Respondents are subject to disciplinary action Code section 4301, subdivision (o), in conjunction with Code section 4081, subdivision (a), Code of Federal Regulations, title 21, section 1304.11, subdivision (a), and California Code of Regulations, title 16, section 1718, on the grounds that Respondents failed to keep a copy of a United States Drug Enforcement Administration ("DEA") Biennial Inventory available for inspection.

49. Specifically, during the inspection on or around July 30, 2015, Board inspectors asked Respondent Wood for a copy of the most recent controlled substance inventory required to

be completed biennially by the DEA. Initially, Respondent Wood could not locate any DEA Biennial Inventory. On or around August 7, 2015, Respondent Wood was able to locate and produce a DEA Biennial Inventory dated May 31, 2013. Respondent Wood did not produce a DEA Biennial Inventory for the year 2015.

FOURTH CAUSE FOR DISCIPLINE

(Acting as a Reverse Distributor Without Obtaining a License From the Board)

Against Respondents Quartz Hill and Wood

50. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4160, subdivision (a), 4040.5, and 4043, on the grounds that Respondents acted as a reverse distributor and, therefore, as a wholesaler by collecting expired medications from patients, storing them, and disposing of them in the trash or via local waste management collections without being licensed to do so.

51. Specifically, during the inspection on or around July 30, 2015, Board inspectors observed bottles of medications from other pharmacies in a drawer beneath the pharmacy counter at Quartz Hill. Some of the bottles had patient-specific labeling indicating the medications had already been dispensed. Respondent wood admitted that Quartz Hill would "take back" expired or unwanted medications filled by other pharmacies, and that Respondent Wood would combine returned drugs into large bottles and eventually dispose of the bottles at a local waste management facility.

FIFTH CAUSE FOR DISCIPLINE

(Failure to report Controlled Substances Prescriptions to CURES)

Against Respondents Quartz Hill and Wood

52. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Health and Safety Code section 11165, subdivision (d), on the grounds that Respondents failed to report required information to CURES regarding prescriptions filled between November 2012 and November 2015 within seven days of the dispensing dates as required by law.

53. Specifically, during the inspection on or around July 30, 2015, Board inspectors asked Respondent Wood how Quartz Hill submitted its filled controlled substance prescriptions to the CURES database. Respondent Wood explained that pharmacy staff generated a report that was submitted through the pharmacy's software, but the software did not automatically submit the report to the CURES database. Respondent Wood then produced to the Board inspectors a copy of a "Controlled Substance Tracking Report" dated July 29, 2015, which showed 2002 prescription entries, most of which were filled in May, June, and July 2015. Respondent Wood informed the Board inspectors that the July 29 report was being submitted to the CURES database. Although certain controlled substances must be reported within seven days after they are dispensed, Respondent Wood admitted that he fell behind in submitting prescriptions to the CURES database and that prescriptions may not have been properly transmitted on previous attempts.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Drug Stock)

Against Respondents Quartz Hill and Wood

54. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), on the grounds that Respondents failed to maintain Quartz Hill so that drugs are safely and properly prepared, maintained, secured, and distributed and Respondents failed to ensure the security of the prescription department and/or failed to enact provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices.

55. Specifically, during an inspection on or around July 30, 2015, a Board inspector conducted an audit of selected controlled substances from June 1, 2013, through July 30, 2015. An inspector compared Quartz Hill's DEA Biennieal Inventory (*i.e.*, the initial amounts) with certified records of sales from wholesalers (*i.e.*, additional amounts purchased) and drug usage details (*i.e.*, the amounts dispensed); then compared the resulting amounts to be accounted for against a contemporaneous stock-on-hand inspection count performed by Respondent Wood. Based on the audit, the inspector determined that Quartz Hill could not account for inventory

shortages of 2,579 oxycodone 30mg tablets, 16,893 hydrocodone/acetaminophen 10/325mg tablets, 3,347 carisoprodol 350mg tablets, 1,518 alprazolam 2mg tablets, and 412 methadone 10mg tablets.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain A Current Inventory)

Against Respondents Quartz Hill and Wood

56. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4081, subdivision (a), Code of Federal Regulations, title 21, section 1304.11, subdivision (a), and California Code of Regulations, title 16, section 1718, on the grounds that Respondents failed to maintain a current inventory of Quartz Hill. Complainant refers to and hereby expressly incorporates the allegations contained within paragraph 54, above, as if fully set forth herein.

EIGHTH CAUSE FOR DISCIPLINE

(Furnishing Dangerous Drugs Without a Valid Prescription)

Against Respondents Quartz Hill and Wood

57. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4059, subdivision (a), on the grounds that, from approximately June 30, 2014, to March 29, 2017, Respondents filled and dispensed at least 48 prescriptions for dangerous drugs to a person without valid prescriptions.

58. Specifically, on or around June 27, 2016, and March 27, 2017, Board inspectors reviewed a series of corresponding drug utilization reports, patient profiles, original prescription documents, and surveys that were prepared by Respondents. In their review, the inspectors discovered that Respondents inappropriately filled and dispensed approximately 48 prescriptions to a person, Patient C.O., between June 30, 2014, and March 29, 2017. The prescriptions were for various controlled substances, such as alprazolam, phendimetrazine tartrate, diphenoxylate with atropine, temazepam, promethazine with codeine, and dangerous drugs, such as Vistaril,

trazodone, amoxicillin, Clavamox, oxybutynin, and phenazopyridine.[1] The prescriptions should not have been dispensed because the prescribing doctor had an expired license.[2]

NINTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

Against Respondents Quartz Hill and Wood

59. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1761, subdivision (a), on the grounds that, from approximately June 30, 2014, to March 29, 2017, Respondents filled and dispensed at least 48 erroneous or uncertain prescriptions for controlled substances and dangerous drugs to Patient C.O. and, in each instance, Respondents failed to contact the prescriber to obtain the information needed to properly validate those prescriptions.

TENTH CAUSE FOR DISCIPLINE

(Prohibited Dispensation of Controlled Substances Without a Prescription)

Against Respondents Quartz Hill and Wood

60. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Health and Safety Code section 11158, subdivision (a), on the grounds that, from approximately June 30, 2014, to March 29, 2017, Respondents filled and dispensed at least 37 prescriptions for controlled substances to Patient C.O. without a valid prescription. Complainant refers to and hereby expressly incorporates the allegations contained within paragraph 58, above, as if fully set forth herein.

ELEVENTH CAUSE FOR DISCIPLINE

(Corresponding Liability)

Against Respondents Quartz Hill and Wood

61. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Health and Safety Code section 11153, subdivision (a), on the grounds

[1] Of the 48 prescriptions, approximately 37 were for controlled substances and 11 were for non-controlled substances.

[2] All prescriptions were written by Dr. Eric Marshall Dash, doctor of podiatric medicine, California License No. 1647, expired on June 30, 2014.

that, from approximately June 30, 2014, to March 29, 2017, Respondents filled and dispensed at least 37 prescriptions for controlled substances to Patient C.O. without valid prescriptions. Complainant refers to and hereby expressly incorporates the allegations contained within paragraph 58, above, as if fully set forth herein.

62. In addition, Respondents are subject to disciplinary action because, from approximately June 30, 2014, to March 29, 2017, Respondents filled and dispensed at least 37 prescriptions for controlled substances to Patient C.O. wherein the subject prescriptions were not issued in the usual course of professional treatment or in a legitimate and authorized research. Indeed, Respondents were aware of several warning factors, such as that: (i) Dr. Dash was Patient C.O.'s husband; (ii) many of the prescriptions appeared to be outside of Patient C.O.'s known diagnosis of cancer; (iii) many of the prescriptions appeared to be outside of Dr. Dash's scope of practice as a podiatrist (*e.g.*, phendimetrazine tartrate is a stimulant used in weight loss programs); and (iv) Dr. Dash was not a local physician.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Nevada Law)

Against Respondents Quartz Hill and Wood

63. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Nevada Revised Statute 639.2328, subdivision (1), on the grounds that, from approximately June 30, 2014, to March 29, 2017, Respondents filled and dispensed at least 48 prescriptions for controlled substances and dangerous drugs to Patient C.O. by mail to an address in Nevada, yet Respondents were not licensed by the Nevada State Board of Pharmacy as required under Nevada law.

OTHER MATTERS

64. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 39118 issued to Quartz Hill Pharmacy, Richard Arthur Wood, owner, then Quartz Hill Pharmacy 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 39118 is placed on probation or until Pharmacy Permit Number PHY 39118 is reinstated if it is revoked.

65. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 39118 issued to Quartz Hill Pharmacy, Richard Arthur Wood, owner, while Richard Arthur Wood has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, then Richard Arthur Wood 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 39118 is placed on probation or until Pharmacy Permit Number PHY 39118 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 Permit Number PHY 39118, issued to Quartz Hill Pharmacy, Richard Arthur Wood, owner;

2. Revoking or suspending Pharmacist License Number RPH 28308, issued to Richard Arthur Wood;

3. Prohibiting Quartz Hill Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 39118 is placed on probation or until Pharmacy Permit Number PHY 39118 is reinstated if Pharmacy Permit Number 39118 issued to Quartz Hill Pharmacy is revoked;

4. Prohibiting Richard Arthur Wood from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 39118 is placed on probation or until Pharmacy Permit Number PHY 39118 is reinstated if Pharmacy Permit Number 39118 issued to Quartz Hill Pharmacy is revoked;

5. Ordering Richard Arthur Wood 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,

///

///

///

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

DATED: 7/7/17

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

LA2016602068
52488761.doc

KAMALA D. HARRIS
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General
EMILY Y. WADA
Deputy Attorney General
State Bar No. 241845
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-8944
Facsimile: (213) 897-2804
E-mail: Emily.Wada@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: **QUARTZ HILL PHARMACY, RICHARD ARTHUR WOOD** **42357 50th Street W. #101** **Quartz Hill, CA 93536** **Permit No. PHY 39118** **RICHARD ARTHUR WOOD** **5918 E. Alleppo Lane** **Palmdale, CA 93551** **Pharmacist License No. RPH 28308** Respondents.	Case No. 5892 **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 March 8, 1993, the Board of Pharmacy issued Permit Number PHY 39118 to Quartz Hill Pharmacy, Richard Arthur Wood. The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2017, unless renewed.

3. On or about July 31, 1973, the Board of Pharmacy issued Pharmacist License Number RPH 28308 to Richard Arthur Wood. The Pharmacist License was in full force and

effect at all times relevant to the charges brought herein and will expire on May 31, 2017, unless renewed.

JURISDICTION

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

5. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board, Registrar, or Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

STATUTORY PROVISIONS

6. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board, Registrar, or Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

7. Section 4081 provides, in pertinent part, that:

> (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. . . .
> (b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer 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. . . .

8. Section 4105 provides, in pertinent part that:

> (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.
> . . .

(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.
(e)
(1) Notwithstanding subdivisions (a), (b), and (c), the boardmay, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.
(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

9. Section 4160 provides, in pertinent part, that: "(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board."

10. Health and Safety Code section 11165 provides, in pertinent part, that:

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:
(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
(4) National Drug Code (NDC) number of the controlled substance dispensed.
(5) Quantity of the controlled substance dispensed.
(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1304.11, provides, in pertinent part, that:

> (a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

12. California Code of Regulations, title 16, section 1714, provides, in pertinent part, that:

> (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. . . .

13. California Code of Regulations, title 16, section 1715, provides, in pertinent part, that:

> (a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.
>
> . . .
>
> (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed.

14. California Code of Regulations, title 16, section 1718, provides, in pertinent part, that:

> "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
> The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

COST RECOVERY

15. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUG CLASSIFICATIONS

16. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055(b)(1)(M) and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

17. Hydrocodone and Acetaminophen is a Schedule II controlled substance pursuant to Health and Safety Code section 11055(e)(4) and Code of Federal Regulations, title 21, section

1308.12(b)(1)(vi), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

18. Carisoprodol is a Schedule IV controlled substance pursuant to Code of Federal Regulations, title 21, section 1308.14(c)(6), and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

19. Alprazolam is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057(d)(1) and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

20. Methadone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055(c)(14) and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

FIRST CAUSE FOR DISCIPLINE

(Failure to Retain Records of Acquisition and Disposition of Dangerous Drugs on the Licensed Premises)

21. Respondent is subject to disciplinary action under Code sections 4105, subdivisions (a) and (c), and 4081, subdivisions (a) and (b), on the grounds that Respondent failed to retain records of acquisition and disposition of dangerous drugs on the licensed premises.

22. The facts and circumstances are that, on or around July 30, 2015, the Board initiated an inspection and audit of Quartz Hill Pharmacy. The inspection was prompted by an analysis performed by the Board whereby the controlled substance dispensing data from Quartz Hill as reported to the Controlled Substance Utilization Review and Evaluation System ("CURES") and controlled substance purchasing data for Quartz Hill as reported by California licensed wholesalers revealed a potential inventory discrepancy.

23. Specifically, Board inspectors asked to review all of Quartz Hill's records of acquisition and disposition of dangerous drugs. Respondent admitted to the Board inspectors that approximately ten boxes of the pharmacy's records were stored at unlicensed off-site facilities, including, for example, Respondent's home. Respondent further admitted that Quartz Hill did not have a waiver for the off-site storage of records.

SECOND CAUSE FOR DISCIPLINE

(Failure to Complete a Self-Assessment)

24. Respondent is subject to disciplinary action under California Code of Regulations, title 16, section 1715, on the grounds that Respondent failed to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law.

25. Specifically, during the inspection on or around July 30, 2015, Board inspectors asked Respondent for copies the most recent Community Pharmacy Self-Assessment and Compounding Self-Assessment for Quartz Hill. Although those assessments are required to be performed before July 1 of every odd-numbered year, Respondent could only locate a Community Pharmacy Self-Assessment from the year 2009 and could not locate any Compounding Self-Assessment.

THIRD CAUSE FOR DISCIPLINE

(Failure to Keep Biennial Inventory Available for Inspection)

26. Respondent is subject to disciplinary action Section 4081, subdivision (a), in conjunction with under Code of Federal Regulations, title 21, section 1304.11, subdivision(a), and California Code of Regulations, title 16, section 1718, on the grounds that Respondent failed to keep a copy of a United States Drug Enforcement Administration ("DEA") Biennial Inventory available for inspection.

27. Specifically, during the inspection on or around July 30, 2015, Board inspectors asked Respondent for a copy of the most recent controlled substance inventory required to be completed biennially by the DEA. Initially, Respondent could not locate any DEA Biennial Inventory. On or around August 7, 2015, Respondent was able to locate and produce a DEA Biennial Inventory dated May 31, 2013. Respondent did not produce a DEA Biennial Inventory for the year 2015.

///

///

///

///

FOURTH CAUSE FOR DISCIPLINE

(Acting as a Reverse Distributor Without Obtaining a License From the Board)

28. Respondent is subject to disciplinary action under Code section 4160, subdivision (a), in conjunction with Code sections 4040.5 and 4043, on the grounds that Respondent acted as a reverse distributor and, therefore, as a wholesaler by collecting expired medications from patients, storing them, and disposing of them in the trash or via local waste management collections without being licensed to do so.

29. Specifically, during the inspection on or around July 30, 2015, Board inspectors observed bottles of medications from other pharmacies in a drawer beneath the pharmacy counter at Quartz Hill. Some of the bottles had patient-specific labeling indicating the medications had already been dispensed. Respondent admitted that Quartz Hill would "take back" expired or unwanted medications filled by other pharmacies, and that Respondent would combine returned drugs into large bottles and eventually dispose of the bottles at a local waste management facility.

FIFTH CAUSE FOR DISCIPLINE

(Failure to report Controlled Substances Prescriptions to CURES)

30. Respondent is subject to disciplinary action under Health and Safety Code section 11165, subdivision (d), on the grounds that Respondent failed to report required information to CURES regarding prescriptions filled between November 2012 and November 2015 within seven days of the dispensing dates as required by law.

31. Specifically, during the inspection on or around July 30, 2015, Board inspectors asked Respondent how Quartz Hill submitted its filled controlled substance prescriptions to the CURES database. Respondent explained that pharmacy staff generated a report that was submitted through the pharmacy's software, but the software did not automatically submit the report to the CURES database. Respondent then produced to the Board inspectors a copy of a "Controlled Substance Tracking Report" dated July 29, 2015, which showed 2002 prescription entries, most of which were filled in May, June, and July 2015. Respondent informed the Board inspectors that the July 29 report was being submitted to the CURES database. Although certain controlled substances must be reported within seven days after they are dispensed, Respondent

admitted that he fell behind in submitting prescriptions to the CURES database and that prescriptions may not have been properly transmitted on previous attempts.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Drug Stock)

32. Respondent is subject to disciplinary action under California Code of Regulations, title 16, section 1714, subdivisions (b) and (d), on the grounds that Respondent failed to maintain Quartz Hill so that drugs are safely and properly prepared, maintained, secured, and distributed and Respondent failed to ensure the security of the prescription department and/or failed to enact provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices.

33. Specifically, during the inspection on or around July 30, 2015, Board inspectors conducted an audit of selected controlled substances from June 1, 2013, through July 30, 2015. Inspectors compared Quartz Hill's DEA Biennieal Inventory (*i.e.*, the initial amounts) with certified records of sales from wholesalers (*i.e.*, additional amounts purchased) and drug usage details (*i.e.*, the amounts dispensed); then compared the resulting amounts to be accounted for against a contemporaneous stock-on-hand inspection count performed by Respondent. Based on the audit, the inspectors determined that Quartz Hill could not account for inventory shortages of 2,579 oxycodone 30mg tablets, 16,893 hydrocodone/acetaminophen 10/325mg tablets, 3,347 carisoprodol 350mg tablets, 1,518 alprazolam 2mg tablets, and 412 methadone 10mg tablets.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain A Current Inventory)

34. Respondent is subject to disciplinary action under Code section 4081, subdivision (a), in conjunction with Code of Federal Regulations, title 21, section 1304.11, subdivision(a), and California Code of Regulations, title 16, section 1718, on the grounds that Respondent failed to maintain a current inventory of Quartz Hill. Complainant refers to and hereby expressly incorporates the allegations contained within paragraph 32, above, as if fully set forth 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 Permit Number PHY 39118, issued to Quartz Hill Pharmacy, Richard Arthur Wood

2. Revoking or suspending Pharmacist License Number RPH 28308, issued to Richard Arthur Wood;

3. Ordering Richard Arthur Wood 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: 10/10/16

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

LA2016602068
52227690.doc