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

In the Matter of the First Amended Accusation Against**:** **KVP PHARMACY, INC.** **440 W. Broadway #B** **Glendale, CA 91204** **Pharmacy Permit No. PHY 50535** **KHACHATUR POGOSYAN** **Sole owner of KVP PHARMACY, INC.** **Designated Representative License No. EXC 19398** **PAUL CUMMINGS** **11343 Segrell Way** **Culver City, CA 90230** **Pharmacist License No. RPH 44852** **KAROLIN ABEDI** **8400 Irondale Ave** **Canoga Park, CA 91306** **Pharmacist License No. RPH 66363** **PAMELA LIAO** **27929 Ridgebrook Court** **Rancho Palos Verdes, CA 90275** **Pharmacist License No. RPH 68228** Respondents.	Case No. 4802 **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 January 14, 2008, the Board issued pharmacy license PHY 48900 to NCL Pharmaceutical Inc., located at 440 W Broadway #C, Glendale, CA 91204, which was owned by Khachatur Pogosyan (POGOSYAN) and Maryamdsadat Ahmadi under the corporation name NCL Pharmaceuticals Inc. On March 1, 2011, NCL Pharmaceutical Inc. had a change of ownership and pharmacy name change. POGOSYAN became 100% owner under the corporation name KVP Pharmacy Inc. (KVP PHARMACY).

3. On or about March 1, 2011, the Board of Pharmacy issued Pharmacy Permit Number PHY 50535 to KVP PHARMACY. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2016, unless renewed. POGOSYAN is and was the sole owner of KVP PHARMACY since March 1, 2011. The Statement of Information filed with the Secretary of State on November 24, 2010, provides that POGOSYAN was the Chief Executive Office, Chief Financial Officer, Director, Officer, Shareholder and Secretary of KVP PHARMACY.

4. On or about December 2, 2008, the Board of Pharmacy issued Designated Representative License Number EXC 19398 to POGOSYAN. The Designated Representative License will expire on December 1, 2015, unless renewed.

5. On or about September 3, 1991, the Board issued Pharmacist License No. RPH 44852 to Paul Cummings (CUMMINGS). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2015, unless renewed. CUMMINGS was the Pharmacist-In-Charge (PIC) of KVP PHARMACY from March 1, 2011 to April 9, 2012.

6. On or about October 19, 2011, the Board issued Pharmacist License No. RPH 66363 to Karolin Abedi (ABEDI). The Pharmacist License was in full force and effect at all

times relevant to the charges brought herein and will expire on December 31, 2014, unless renewed. ABEDI was the PIC of KVP PHARMACY from May 14, 2012 to June 9, 2013.

7. On or about October 5, 2012, the Board issued Pharmacist License No. RPH to Pamela Liao (LIAO). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2014, unless renewed. LIAO was the PIC of KVP PHARMACY from June 10, 2013 to July 5, 2013.

JURISDICTION

8. 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 unless otherwise indicated.

9. The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

10. **Section 4033** of the Code states:

(a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

11. **Section 4036.5** of the Code states:

"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."

12. **Section 4037** of the Code states:

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored,

possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Public Health where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

13. **Section 4059.5** of the Code states:

…

(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 4076** of the Code states:

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) …Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other

means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

15. **Section 4081** of the Code states:

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

…

16. **Section 4104** of the Code states:

(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

17. **Section 4110** of the Code states:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

…

18. **Section 4113** of the Code states:

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

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

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

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

19. **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.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

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

(e) No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio 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 inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

20. **Section 4169** of the Code states in pertinent part:

(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

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(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

...

21. **Section 4301** of the Code states:

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:

…

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

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

…

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

22. **Section 4306.5** of the Code states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the

dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

23. **Section 4307** of the Code states:

(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, or partner of any partnership, corporation, 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, or partner 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, or partner 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.

(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been

given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

24. **Section 4342** of the Code states:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336.

25. **Health and Safety Code section 11165** states:

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

26. **Health and Safety Code section 111255** states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

27. **Health and Safety Code section 111340** states:

Any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

28. **Health and Safety Code section 111440** states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

29. **Health and Safety Code section 111445** states:

It is unlawful for any person to misbrand any drug or device.

30. **Health and Safety Code section 111450** states:

It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

31. **Health and Safety Code section 111450** states:

No person shall manufacture any drug or device in this state unless he or she has a valid license from the department. The license is valid for two calendar years from the date of issue, unless it is revoked. The license is not transferable. The department may require any manufacturer, wholesaler, or importer of any prescription ophthalmic device in this state to obtain a license.

32. **Health and Safety Code section 111615** states:

No person shall manufacture any drug or device in this state unless he or she has a valid license from the department. The license is valid for two calendar years from the date of issue, unless it is revoked. The license is not transferable. The department may require any manufacturer, wholesaler, or importer of any prescription ophthalmic device in this state to obtain a license.

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REGULATORY PROVISIONS

33. California Code of Regulations, title 16, **section 1707.2** states:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

…

34. California Code of Regulations, title 16, **section 1707.5** states:

(a) (a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

35. California Code of Regulations, title 16, **section 1715** states:

(a) The pharmacist-in-charge of each pharmacy as defined under section 4036.5 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.

36. California Code of Regulations, title 16, **section 1714** states:

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

(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.

…

37. California Code of Regulations, title 16, **section 1718** states:

"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.

38. California Code of Regulations, title 16, **section 1717.3** states:

(a) No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank.

39. California Code of Regulations, title 16, **section 1735.2** states:

…

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

…

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

…

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board.

40. California Code of Regulations, title 16, **section 1735.3** states:

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

…

41. California Code of Regulations, title 16, **section 1735.4** states:

(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

42. California Code of Regulations, title 16, **section 1735.8** states:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

43. California Code of Regulations, title 16, **section 1793.7** states:

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

44. "**Controlled substance**" means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

45. Section 4022 of the Code states, in pertinent part:

"**'Dangerous drug'** or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

"(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import…

…

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

46. **Alprazolam** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057 (d)(1) and a dangerous drug as designated by Business and Professions Code section 4022.

47. **Clonazepam** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057 (d)(7) and a dangerous drug as designated by Business and Professions Code section 4022.

48. **Ketamine** is a Schedule III controlled substance as designated by Health and Safety Code section 11056 (g) and a dangerous drug as designated by Business and Professions Code section 4022.

49. **Flurazepam** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057 (d)(14) and a dangerous drug as designated by Business and Professions Code section 4022.

50. **Hydrocodone/apap** (acetaminophen) is a narcotic and analgesic combination used to relieve moderate to moderately severe pain. Also known under the brand name Norco and Vicodin, it is among the most abused pain killers. Hydrocodone is a Schedule III controlled substance as designated by Health and Safety Code section 11056 (e)(4) and a dangerous drug as designated by Business and Professions Code section 4022.

51. **Lorazepam** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057 (d)(16) and a dangerous drug as designated by Business and Professions Code section 4022.

52. **Testosterone** is a Schedule III controlled substance as designated by Health and Safety Code section 11056 (f)(30) and a dangerous drug as designated by Business and Professions Code section 4022.

53. **Zolpidem** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057 (d)(32) and a dangerous drug as designated by Business and Professions Code section 4022.

54. **Baclofen** is a dangerous drug as designated by Business and Professions Code section 4022.

55. **Cyclobenzaprine** is a dangerous drug as designated by Business and Professions Code section 4022.

56. **Gabapentin** is a dangerous drug as designated by Business and Professions Code section 4022.

57. **Diclofenac** is a dangerous drug as designated by Business and Professions Code section 4022.

58. **Lidocaine** is a dangerous drug as designated by Business and Professions Code section 4022.

59. **Flurbiprofen** is a dangerous drug as designated by Business and Professions Code section 4022.

60. **Bupropion** is a dangerous drug as designated by Business and Professions Code section 4022.

61. **Baclofen** is a dangerous drug as designated by Business and Professions Code section 4022.

62. **Carisoprodol** is a dangerous drug as designated by Business and Professions Code section 4022.

63. **Cimetidine** is a dangerous drug as designated by Business and Professions Code section 4022.

64. **Fluorourcil** is a dangerous drug as designated by Business and Professions Code section 4022.

65. **Clonidine** is a dangerous drug as designated by Business and Professions Code section 4022.

66. **Imipramine** is a dangerous drug as designated by Business and Professions Code section 4022.

67. **Ketoprofen** is a dangerous drug as designated by Business and Professions Code section 4022.

68. **Indomethacin** is a dangerous drug as designated by Business and Professions Code section 4022.

69. **Amantadine** is a dangerous drug as designated by Business and Professions Code section 4022.

70. **Amitriptyline** is a dangerous drug as designated by Business and Professions Code section 4022.

71. **Verapamil** is a dangerous drug as designated by Business and Professions Code section 4022.

72. **Tetracaine** is a dangerous drug as designated by Business and Professions Code section 4022.

73. **Orphenadrine** is a dangerous drug as designated by Business and Professions Code section 4022.

74. **Acyclovir** is a dangerous drug as designated by Business and Professions Code section 4022.

75. **Levocetirizine** is a dangerous drug as designated by Business and Professions Code section 4022.

76. **Pyridoxine** is a dangerous drug as designated by Business and Professions Code section 4022.

77. **Nifedipine** is a dangerous drug as designated by Business and Professions Code section 4022.

78. **Pentoxifylline** is a dangerous drug as designated by Business and Professions Code section 4022.

79. **Ibuprofen** is a dangerous drug as designated by Business and Professions Code section 4022.

80. **Dexamethasone** is a dangerous drug as designated by Business and Professions Code section 4022.

81. **Doxepin** is a dangerous drug as designated by Business and Professions Code section 4022.

82. **Betamethasone** is a dangerous drug as designated by Business and Professions Code section 4022.

83. **Levofloxacin** is a dangerous drug as designated by Business and Professions Code section 4022.

84. **Lisinopril** is a dangerous drug as designated by Business and Professions Code section 4022.

85. **Misoprostol** is a dangerous drug as designated by Business and Professions Code section 4022.

86. **Phenytoin** is a dangerous drug as designated by Business and Professions Code section 4022.

87. **Mupirocin** is a dangerous drug as designated by Business and Professions Code section 4022.

88. **Itraconazole** is a dangerous drug as designated by Business and Professions Code section 4022.

89. **Naproxen** is a dangerous drug as designated by Business and Professions Code section 4022.

90. **Omeprazole** is a dangerous drug as designated by Business and Professions Code section 4022.

91. **Ondansetron** is a dangerous drug as designated by Business and Professions Code section 4022.

92. **Ranitidine** is a dangerous drug as designated by Business and Professions Code section 4022.

93. **Tizanidine** is a dangerous drug as designated by Business and Professions Code section 4022.

94. **Tramadol** is a dangerous drug as designated by Business and Professions Code section 4022.

95. **Venlafaxine** is a dangerous drug as designated by Business and Professions Code section 4022.

96. **Tramadol/apap** (acetaminophen) is a dangerous drug as designated by Business and Professions Code section 4022.

97. The following drugs are non-prescription drugs; however, when combined with a dangerous drug(s) and furnished as a prescription (as an extemporaneous compounded drug product), which would be considered to be **dangerous drugs**: **Capsaicin, menthol, camphor, salicylic acid**

98. Section **4021** of the Code provides that a "controlled substance" means any substance listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

99. Section **4022** of the Code states, in pertinent part:

"'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

"(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import

. . . .

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

100. OxyContin is a brand name for oxycodone, a Schedule II controlled substance as designated by Health and Safety Code section 11055(b)(1)(N) and a dangerous drug as designated by Business and Professions Code section 4022. It is an opioid analgesic.

COST RECOVERY

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

BOARD INSPECTION OF JANUARY 16, 2013

102. On or about January 16, 2013, the Board Inspector inspected KVP PHARMACY and noticed a chaotic scene of numerous large tubs of various colored creams and white plastic jars on the counters, shelves and floor. The floors were not clean. Several of the uncovered tubs had spatulas in them and it appeared that many prescriptions were being filled with different creams and formulations. The unlabeled jars, some filled, some not, were with "paperwork" (prescription labels, patient information, etc.), and were also on the counters, shelves and floor. Review of KVP PHARMACY's patient Prescription Log determined that the items compounded by KVP PHARMACY had been given "Specialty" drug names by KVP PHARMACY. These

names included “Flur-Mild”, “Keto-Flex”, as well as the abbreviated names such as “BCKL”, “TGHOT”, and “FCBL.” Physician order sheets showed these abbreviated names and this allowed the doctors to check off which compounded item the doctor wished for the patient.

103. The Board Inspector notified PIC ABEDI that all active ingredients must be listed on a patient label and that KVP PHARMACY was acting as a manufacturer since KVP PHARMACY used its own “Specialty” names. Review of all of KVP PHARMACY’s prescription log pages indicated that KVP PHARMACY was providing compounded drugs to patients all across the country.

104. The Board Inspector inquired from KVP PHARMACY’s owner, POGOSYAN, whether he provided samples of KVP PHARMACY’s products to the prescribers and POGOSYAN replied in negative. POGOSYAN stated that KVP PHARMACY filled only a “72-hour” supply to the physicians. POGOSYAN further indicated that the physicians would contact KVP PHARMACY and KVP PHARMACY would provide the compounded drugs to said physicians for their patients. POGOSYAN provided a binder to the Board’s Inspector which contained physician orders for “72 –hour” supply. Said binder was labeled as “72 Hour Sample Order 2013” and contained physician “Sample” and “Office Stock” orders from KVP PHARMACY.

105. During the inspection, the Board’s Inspector found a basket with at least 50 empty containers of Hydrocodone/APAP 10-325 #60, repackaged by Bryant Ranch Prepak. The Inspector asked POGOSYAN the reason why KVP PHARMACY removed the above referenced drug from the packaging, and why KVP PHARMACY had not purchased a larger volume bottle. POGOSYAN stated that KVP PHARMACY got a “deal” on the smaller containers from the repackager, and that KVP PHARMACY did not provide a large amount of Hydrocodone/APAP 10-325 to its patients.

106. The Board Inspector asked POGOSYAN several times how did the prescribers, including those in other states, find out about KVP PHARMACY and its products. POGOSYAN finally admitted that KVP PHARMACY used a service, a management company, “WSM”, that promoted KVP PHARMACY’s products to the prescribers and clinics across the country.

107. It was revealed during the inspection that some prescriptions showed that medication samples were sent to doctors' offices and large quantities of medications were sent to doctors' offices for office use. The prescriptions further revealed that office stock medications, either samples or office use medications, were being sent to doctors all across the country. Some prescriptions showed that large quantities were being sent to the same doctor on the same day, but to different office locations.

108. While reviewing the office stock prescriptions, the Board's Investigator noticed that one prescription was a re-order of a medication order which was previously sent by KVP PHARMACY. Further review indicated that a sample batch was received by a Dr. R.O[1].'s office that contained Lidocaine which was improperly compounded causing the cream to be lumpy and abrasive to the skin when applied.

109. On or about February 1, 2013, the Board received KVP PHARMACY's CURES[2] pharmacy compliance report. According to the CURES report, KVP PHARMACY transmitted 2888 prescriptions alone in the month of January of 2013 after the inspection of January 16, 2013, which indicates that KVP PHARMACY was not compliant in transmitting all of their controlled substance prescriptions (Schedule II though IV) as required. Further, the CURES report showed that KVP PHARMACY was transmitting data without the patient's name and date of birth, or were entering patient's name with a date of birth of 1/1/01 for many of the transmitted prescriptions.

110. The Board Inspector issued correction notices and written notices of non-compliance. POGOSYAN was asked to forward certain documents to the Board. On or about May 7, 2013, POGOSYAN responded to the Board's request and provided documentations summarized as follows:

- KVP PHARMACY has removed all tubs from the floor and has placed them on an elevated platform.
- KVP PHARMACY has changed its product labeling to reflect generic active ingredient name(s) in all compounds dispensed.

[1] To protect the individual's privacy, the first initial of his first and last name is used
[2] CURES (Controlled Substance Utilization Review & Evaluation System)

- Several pharmacists employed by KVP PHARMACY were using abbreviations to list the active ingredient names in several compounded medications.
- In response to the Board's January 16, 2013 inspection report, KVP PHARMACY has removed abbreviated compounding names from its claims processing system and has instructed all pharmacists that all drug labels for compound medications must include the full and complete generic active ingredient name(s) and drug strengths.
- KVP PHARMACY does not create or dispense samples of potential compound medications for or to physicians or any other healthcare practitioners. All compounding is done by KVP PHARMACY in response to a valid prescription for an individual patient or pursuant to prescriber order for compound medications for office use.
- Pursuant to title 16, CCR 1735.2, the pharmacy may compound a reasonable quantity of the drug for administration or application to patients in a prescriber's office, or for distribution of not more than a 72 hour supply to the prescriber's patients, as estimated by the prescriber.
- While KVP PHARMACY does maintain a contractual relationship with WSM for marketing services, WSM does not distribute "samples" of compounds to physicians or healthcare prescribers or "call" on physicians or other health care practitioners in or outside of California. WSM provides marketing services to and for KVP PHARMACY and, in this capacity, promotes KVP PHARMACY's compounding services/ abilities to physicians and other healthcare practitioners via mailings, brochures and the like.
- Compounded Self Assessment, the new Pharmacy Self-Assessment, Policy & Procedure for technician and theft and impairment have been completed.
- Quality Assurance policy has been updated.
- In reference with Dr. O. and the compounded cream (containing Lidocaine) that was gritty and rough on the patient's skin, KVP PHARMACY hired a new pharmacist who compounded a single batch of BCFL cream (lot # A3858) and it was not compounded optimally. The Lidocaine did not dissolve correctly in alcohol, which caused the gritty texture. This issue was resolved through communication with Dr. O. and Mr. G. The batch of BCFL cream (lot # A3858) was discarded, a new batch was made and a small sample was sent to Dr. O.
- In regard to policy changes, the quality and consistency of every batch is checked every time by the compounding technician and the pharmacist and is recorded.

FIRST CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements)

111. Respondents KVP PHARMACY and KAROLIN ABEDI are subject to disciplinary action under section 1735.2, subdivision (f) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, PIC ABEDI and KVP PHARMACY allowed tubs of compounding creams to be placed on a dirty floor in the pharmacy in order to fill plastic white containers which were not properly labeled for patients, in violation of section 1735.2, subdivision (f) of the California Code of Regulations. Complainant

refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

SECOND CAUSE FOR DISCIPLINE

(Adulterated Drugs & Devices)

112. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 111255 of the Health & Safety Code in that during a Board investigation of the KVP PHARMACY on January 16, 2013, KVP PHARMACY and ABEDI had containers that were filled with compounded cream products from large bins that were located on the dirty floor, in violation of section 111255 of the Health & Safety Code which provides that any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions where it may have been rendered injurious to health. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

THIRD CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements)

113. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under sections 1735.2, subdivision (i) and 1735.4, subdivision (a) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, PIC KAROLIN ABEDI allowed compounded products to be labeled as “BCKL”, “TGHOT”, “FLURIFLEX”, “FBCGL” with principle active ingredients not indicated on the prescription label, therefore, the compounded products were mislabeled, in violation of section 1735.2, subdivision (i) and 1735.4, subdivision (a) of the California Code of Regulations. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

FOURTH CAUSE FOR DISCIPLINE

(Labeling Requirements)

114. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 4076, subdivision (a) of the Code and section 1735.4, subdivision (a) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, PIC ABEDI allowed compounded products be labeled as "BCKL", "TGHOT", "FLURIFLEX", "FBCGL" with principle active ingredients not indicated on the prescription label, therefore, the compounded products were mislabeled, in violation of section 4076, subdivision (a) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

FIFTH CAUSE FOR DISCIPLINE

(Misbranded Drugs or Devices)

115. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under sections 111440, 111445 and 111450 of the Health & Safety Code, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, KVP PHARMACY and ABEDI compounded products which were labeled as "BCKL", "TGHOT", "FLURIFLEX", "FBCGL" with principle active ingredients not indicated on the prescription label, therefore, the compounded products were mislabeled, in violation of section 111440, 111445 and 111450 of the Health & Safety Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

SIXTH CAUSE FOR DISCIPLINE

(Misbranded Drugs or Devices)

116. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 111340, subdivisions (a) and (b) of the Health & Safety Code, in that during a Board's investigation of the KVP PHARMACY on January 16, 2013, KVP PHARMACY and ABEDI compounded products which were labeled as "BCKL", "TGHOT", "FLURIFLEX", "FBCGL" with principle active ingredients not indicated on the label, therefore, the compounded products were mislabeled, in violation of section 111340, subdivision (a) and (b) of the Health & Safety Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

SEVENTH CAUSE FOR DISCIPLINE

(Manufacturer)

117. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 4033, subdivision (a), subsection (1) of the Code and section 111615 of Health and Safety Code, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, KVP PHARMACY and ABEDI were providing compounded drug samples to physicians, both in and out of California, had a management group called "WSM" promoting their products to physicians, and was providing large quantities of compounded drug products for office use. Therefore, KVP PHARMACY was acting as a manufacturer without a manufacturing license, in violation of section 4033, subdivision (a), subsection (1) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

EIGHTH CAUSE FOR DISCIPLINE

(Self Assessment of the Pharmacy)

118. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 1715, subdivision (a) of the California Code of Regulations in conjunction with sections 4036.5 and 4037 of the Code, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, PIC ABEDI and KVP PHARMACY failed to complete a Community Pharmacy Self-Assessment after she became a PIC on May 14, 2012, in violation of section 1715, subdivision (a) of the California Code of Regulations in conjunction with sections 4036.5 and 4037 of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

NINTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements)

119. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 1735.2, subdivision (j) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, PIC ABEDI and KVP

PHARMACY failed to complete a Compounding Pharmacy Self-Assessment prior to allowing drug products to be compounded and after she became a PIC on May 14, 2012, in violation of section 1735.2, subdivision (j) of the California Code of Regulations. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

TENTH CAUSE FOR DISCIPLINE

(Requirements of Pharmacy Employing Pharmacy Technicians)

120. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 1793.7, subdivision (d) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, KVP PHARMACY and ABEDI were unable to provide a job description and a written copy of the policies & procedures of a pharmacy technician, in violation of section 1793.7, subdivision (d) of the California Code of Regulations. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

ELEVENTH CAUSE FOR DISCIPLINE

(Licensed Employee Theft or Impairment Policy & Procedures)

121. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 4104, subdivisions (a) and (b) of the Code, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, KVP PHARMACY and ABEDI were unable to provide a written copy of the policy & procedures for theft and impairment, in violation of section 4104, subdivisions (a) and (b) of the California Code of Regulations. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

TWELFTH CAUSE FOR DISCIPLINE

(Controlled Substance Utilization Review & Evaluation System)

122. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 11165 of the Health & Safety Code, in that during a Board investigation of the KVP PHARMACY on January 16, 2013, an inspection of KVP PHARMACY showed that KVP

PHARMACY and ABEDI were not compliant in transmitting all of their controlled substance prescriptions (schedule II through IV) as required on a weekly basis, since KVP PHARMACY transmitted 2888 controlled substance prescriptions alone in the month of January of 2013 after the inspection report conducted on January 16, 2013. The CURES report also showed that KVP PHARMACY was transmitting data without the patient's name and the date of birth or were using patient name with a date of birth of 1/1/01 for many of the transmitted prescriptions, in violation of section 11165 of the Health & Safety Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 102 through 110, as though set forth fully.

BOARD INSPECTION OF MAY 29, 2013

123. On or about May 29, 2013, the Board's Inspectors inspected KVP PHARMACY and the records of acquisition of April to July of 2011 revealed that KVP PHARMACY was purchasing under the old DEA number of NCL Pharmaceuticals, however, on or about March 3, 2011, NCL Pharmaceuticals had filed for discontinuance of business with the Board. Board Inspector, Inspector SP, observed PIC ABEDI, verifying compounded creams without the stock containers in her presence, and after verification, the prescriptions were moved to a mail room for packaging. The Board's Inspectors noticed that the worksheet had preprinted lot numbers and expiration dates with no documentation to show the compounding technician had compared the data on the worksheet against the stock containers. PIC ABEDI was unable to produce the master formula for at least 3 products that were waiting to be verified. The master formula for NCL Pharmaceuticals did not show stability data to support expiration dating. Some master formulas had an expiration date of more than 180 days.

124. A review of the end product testing reports from Eagle Analytical showed a test submitted on 6/5/2012 with results reported on 6/18/2012 that did not fall within USP standards and California law, +/- 10% of the labeled amount. PIC ABEDI told the inspectors that she was unaware of any recall that was conducted. Board Inspectors did not find any documentation of any investigation performed by KVP PHARMACY to determine why the above referenced testing results were abnormal.

125. The Board's Inspector asked Registered Pharmacist LIAO to explain the billing process and she stated that the billing for all prescriptions were performed offsite of KVP PHARMACY. PIC ABEDI was unaware of any billing which took place at the business office of POGOSYAN Corporation located approximately a block away from KVP PHARMACY.

126. Throughout the inspection, the Board's Inspectors observed PIC ABEDI deferring to and taking instructions from non-pharmacist POGOSYAN on workflow and product labeling. They reviewed pharmacy operations to verify if KVP PHARMACY addressed the issues written on the Board's Inspector report of 1/16/2013 and determined that KVP PHARMACY continued to be non-compliant as follows:

- Compounded drugs and bulk chemicals were placed on the floor, leaving no room to move around or clean, in direct contradiction of POGOSYAN's e-mail statement dated May 7, 2013;
- The prescription label was not convertible from 10 to 12 point type at the pharmacy level. The label could not accommodate each ingredient and its corresponding strength and portions of the drug name, strength were getting cut off. Proprietary abbreviations were still seen on pre-printed prescription blanks used by physicians to order medications, prepack labels stuck to compounded drugs and on white board located on the wall;
- The last controlled substance inventory presented by PIC ABEDI did not include Ketamine containing compounded formulations present on the pharmacy shelves;
- ABEDI and POGOSYAN referred to the compounded formulations provided to the physicians as "samples" on multiple occasions in spite of POGOSYAN e-mail statement dated 5/7/2013 stating "[K]VP Pharmacy does not create or dispense samples or potential compounded medications for or to physicians or any other healthcare practitioners." When asked if physicians were charged for the formulations, POGOSYAN first stated that they were not, then immediately stated that they were. POGOSYAN changed the way he referred to the compounded formulations from samples to office use drugs. Board's Inspectors observed many pre-packed

compounded formulations on the shelf with dates of manufacture from February and March of 2013 in contradiction of POGOSYAN's e-mail statement of dated 5/7/2013 stating "[A]ll compounding is done by KVP PHARMACY in response to a valid prescription for an individual patient or pursuant to prescriber order for compounded medications for office use. Pursuant to CCR §1735.2(c), the pharmacy may compound a reasonable quantity of the drug for administration or application to patients in a prescriber's office, or for distribution of not more than a 72 hours supply to the prescriber's patients, as estimated by the prescriber." A review of the prescription hard copies for physician offices showed many were requested as "samples", but the directions said "for office use".

- Upon review of the controlled substance inventory, dated February 21, 2013, Supervising Inspector, JD, found that the inventory did not include any compounded drugs on KVP PHARMACY's shelves with controlled substance such as Ketamine. The Board's Inspectors provided a list of 16 patients identified in the complaint filed with the Board and requested the original prescription documents, and provided another list of NDC[3] numbers for prescriptions drugs billed to the patient's insurance and asked for invoices for said NDC numbered drugs.

THIRTEENTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements)

127. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 1735.2, subdivisions (i) and (f) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on May 29, 2013, multiple drug containers were observed on the floor during inspection of KVP PHARMACY, in violation of section 1735.2, subdivisions (i) and (f) of the California Code of Regulations. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 126, as though set forth fully.

[3] National Drug Code

FOURTEENTH CAUSE FOR DISCIPLINE

(Dispensing controlled substance pursuant to a preprinted multiple check-off prescription blank)

128. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 1717.3, subdivision (a) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on May 29, 2013, KVP PHARMACY was dispensing compounded formulations containing Ketamine, a Schedule II Controlled Substance, pursuant to a preprinted multiple check-off prescription, in violation of section 1717.3, subdivision (a) of the California Code of Regulations. Further, a follow-up inspection on July 22, 2013 revealed that KVP PHARMACY failed to implement changes in the receipt and dispensing of compounded products written on preprinted, multiple check-off prescription blanks. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 126, as though set forth fully.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Conduct a Recall)

129. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 1735.8, subdivisions (a) and (d) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on May 29, 2013, PIC ABEDI and KVP PHARMACY failed to conduct a recall when product analysis discovered potency to be below minimum standards. The subsequent investigation revealed that KVP PHARMACY failed to ensure the integrity, potency, quality or labeled strength from approximately November 2009 to November 2013, in violation of section 1735.8, subdivisions (a) and (d) of the California Code of Regulations. KVP PHARMACY lacked implementation and record keeping of quality assurance measures and corrective actions (recall procedures) upon receipt of internal, outsourced drug testing reports on qualitative and quantitative analysis of compounded drug products which showed under-potent and over potent products. Specifically, 26 compounded drug products had over-potent ingredients, 22 compounded drug products had under-potent ingredients, and 4 compounded drug products had over-potent and under-potent ingredients. Complainant refers to,

and by this reference incorporates, the allegations set forth above in paragraphs 123 through 126, as though set forth fully.

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SIXTEENTH CAUSE FOR DISCIPLINE

(Labeling Failed to Meet the Requirements)

130. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 1707.5, subdivision (a) of the California Code of Regulations, in that during a Board investigation of the KVP PHARMACY on May 29, 2013, KVP PHARMACY's current labeling did not meet the requirements of patient centered labels, in violation of section 1707.5, subdivision (a) of the California Code of Regulations. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 126, as though set forth fully.

PIC ABEDI'S DECLARATION AND ADMISSIONS

131. On July 12, 2013, PIC ABEDI met with the Board's Inspector and stated the following:

- She was fired from KVP PHARMACY without a reason being given;
- She was overridden by POGOSYAN when she instructed KVP PHARMACY staff about pharmacy procedures;
- POGOSYAN continued to have non pharmacist staff open up KVP PHARMACY when the registered pharmacist was running late despite her warning that it was against the law to open KVP PHARMACY in the absence of a pharmacist.

132. PIC ABEDI provided a written declaration stating the following:

- "RX Processing: MD office faxes the prescription to KVP PHARMACY. The clerk printed them and input prescriptions in Digital RX computer. The compounding technician compound the cream and bring them to the front pharmacy to fill the prescriptions, the pharmacist signs off the prescriptions and put them on the cart.

The shipping clerks took them to the shipping room, packed them up, and put the label on and left the boxes by the front door for FedEx pick up;

- The shipping clerks put the prescriptions in a basket; one of KVP PHARMACY's managers took them to the corporate office to bill at the end of the day. The manager took the Workers Comp and private insurance prescriptions but not usually office sample prescriptions, which were filed in the pharmacy without being billed;
- The corporate office took care of all the billing of Rxs and possible MRI and lab also;
- The office took care of payroll and ordering Ultraderm cream base and Medrox patches. They were stored at the warehouse away from the pharmacy. The warehouse employee delivers them to the pharmacy after ordering. The corporate office held on to the invoices, PIC never saw the invoices.
- After the Board inspection in May of 2013, for the 2 weeks before she was let go [sic], KVP PHARMACY was still accepting and filling preprinted prescription forms with controlled substances on them;
- The keys to the front door / office area which connected to the pharmacy were given to [sic] clerks even after I[4] explained that it was against the law and KVP PHARMACY had been written up and reported by the inspector before my employment there;
- Initially, there was one alarm code for the alarm system, but around March 2013, they changed it to individual codes for the alarm. I explained to the clerk to [sic] not open the door and walk into the pharmacy without a pharmacist being present, but I was overruled by the management and the clerk continued doing it;
- I was never told if the out of state licenses that we needed to fill out RXs actually came through. I had discussed with him[5] the need of out of state licenses before we filled those RXs. Some of the states were: New York, Maryland, Colorado,

[4] PIC ABEDI
[5] POGOSYAN

Arizona, Pennsylvania. We started receiving and filling out of state RXs around December 2012 or January 2013;

- During [sic] inspection it was brought to my attention that we were refilling [patients RXs without confirming that they wanted to refill their RX or not. I was under the impression that the customer service reps [sic] were confirming it;
- All these were observed during my employment from 5/2012 to 6/2013."

133. On July 12, 2013, the Board Inspector determined that KVP PHARMACY shipped medications to several states in the United States.

BOARD INSPECTION OF JULY 16, 2013

134. On or about July 16, 2013, the Board Inspector S.P. conducted an inspection of Pharma-RX Inc. (hereinafter referred as Pharma-RX) located at 5405 located at 412 W. Broadway, Suite 200, Glendale, CA, with the Supervising Inspector J.D.. Office manager Davin Deb was present. Designated Representative in Charge, POGOSYAN, came in shortly after and they both assisted in the inspection.

135. Pharma-RX is licensed as a wholesaler, however, POGOSYAN stated that they did not store any drugs on location. Board Inspector SP noticed that the name on the side door leading to Suite 200 said "Pogosyan Corp."

136. Upon questioning POGOSYAN and Davin Deb, Inspector SP was told that Pharma-Rx purchased drugs from wholesalers, such as Preferred Pharmaceuticals, who shipped the drugs directly to Pharma-RX customers who were physicians. Pharma-RX was never in possession of any drug inventory. Preferred Pharmaceuticals billed Pharma-RX for the drugs shipped to physicians and Pharma-Rx, in turn, billed the physicians. Pharma-RX sold prescription drugs, controlled substances and over the counter medications. POGOSYAN indicated that he had his own billing company.

137. POGOSYAN was reluctant to talk about how Pharma-RX was connected to KVP PHARMACY. He indicated that he was under the impression that the inspectors were there to inspect KVP PHARMACY. When the inspectors notified him that the inspectors were there to inspect Pharma-RX, POGOSYAN called his lawyer, John Cronin, updated him on the status of

the Board's inspection and ended the phone call. After conducting the inspection, Inspector S.P. issued a written notice of non-compliance.

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COMPLAINT FILED BY PATIENT C.B.[6]

138. On March 7, 2013, the Board received a written complaint from Patient C.B. stating that she received another box of medicine (jars of compounded cream) from KVP PHARMACY on March 5, 2013. C.B. stated that she "did not authorize the refill" and that she told them last time not to send anymore medications. C.B. stated that she would return said box of medicine "unopened" to KVP PHARMACY. C.B. wrote in her complaint "[I] spoke with Tina today, the same person that said I could not return the medication last month because it was a special [sic] made medication. After I told her about my complaint she said to send it back and said my doctor had it on auto refill."

139. C.B. stated that her physician wrote a prescription for a compound cream. On February 2, 2013, C.B. received 2 jars of cream with no bill, no prices, no instructions as to how to use the jars of cream, and she had no information regarding drug interactions. C.B. stated that she took many medications and she was concerned about the jars of cream sent by KVP PHARMACY would have drug interaction with the medication she was taking. C.B. wrote in her complaint "[T]he pharmists [sic] said don't take it with your other meds but we can't take it back." C.B. stated that KVP PHARMACY billed her health insurance (Caremark) over $1,994.00 for the two jars of cream. Caremark paid KVP PHARMACY $1,994.00 for the cream. C.B. included a copy of KVP PHARMACY notice to consumers' letter she received with the two jars of cream and provided photos of the shipping package and the two jars of compounded product showing RX # 643495 with a date of January 29, 2013.

[6] In order to protect the privacy of the individual, the initial of her first and last name is being used

140. On May 29, 2013, Inspector S.P. and Supervising J.D. visited KVP PHARMACY for an inspection. Inspector S.P noted "Closed door pharmacy that mainly compounds formulations for pain management. Pharmacy also fills orders for routine prescriptions. All medications are mailed out using USPS and FEDEX. KVP PHARMACY mails prescriptions to several states in the United States including California."

141. Inspector S.P. discussed the following during her inspection:

- **Drug Samples**: Supervising J.D. reviewed a binder for compounded creams dispensed for physician office use. There were multiple variations of preprinted forms listing different compounded creams with Ketamine, a Schedule III Controlled Substance. Many of the preprinted forms had handwritten "Samples", "n/c", and the pharmacy labels adhere to the order forms were printed with "paid $0.00", "AAC: $0", and "Pat Due:$0.00." The preprinted order forms listed prescribers from California and out-of-state, including at least Colorado, Nevada, Connecticut, and many other states. When POGOSYAN was questioned if these were complimentary samples, he stated that they billed for creams used for physician office use. Supervising J.D. informed POGOSYAN if the pharmacy was providing the compounded creams as complimentary samples, KVP PHARMACY would be acting as a manufacturer, especially if KVP PHARMACY had marketing teams promoting specific compounded creams. POGOSYAN referred to the creams provided as physician's office use, on multiple occasions, as "samples". When POGOSYAN was questioned if KVP PHARMACY was licensed in the states KVP Pharmacy was shipping to, POGOSYAN stated that the out-of-state licenses were kept at the corporate office. POGOSYAN was informed that all the licenses must be kept on the pharmacy premise.
- **Master Formula**: Revise folder to include all formulas and to reflect the current business name.

- **Compounding Worksheet**: Lot numbers and expiration dates are preprinted on worksheet before it is taken into compounding room. PIC ABEDI must ensure that pharmacist verifies that each lot number and expiration date matches the bulk container from which each lot number of formulation is compounded.
- **Policy for Expiration Dating:** 16 CCR §1725.2 provides that the expiration date shall not exceed 180 days or shortest expiration date of any component in the compounded drug product.

142. Inspector SP retrieved the following documents from KVP PHARMACY:

1. Patient prescription history for Patient C.B., prescription document RX# 643495, and shipping documents:

- C.B. 's prescription history list provides that RX #643495 was dispensed on January 29, 2013 and billed for 180 grams for $2,366 under the plan name "CRK."
- RX #643495 was refilled on February 27, 2013 for 180 grams for $2,181, however, the charge was reversed.
- The prescription document for RX #643495 for C.B. was checked off for "Musculoskeletal pain-inflammation, Ketamine 10%, Gabapentin 6%, Baclofen 2%, Cyclobenzaprine 2%, Lidocaine 5%, Flurbiprofen 10% for 180 grams and two refills. There were no documents or any instructions requesting an auto refilling of C.B.'s prescription (RX #643495).

2. Original prescription documents, with respect to physician office use ("samples"), under "Patient Name" list;

3. Patient prescription histories;

4. Eagle Analytical Services laboratory report;

5. Document titled "Recall of Compounded Drug Product";

6. Examples of preprinted prescription documents;

7. Invoices and packing lists from several wholesalers.

143. Inspector S.P. requested original prescription documents from a list given to PIC ABEDI and invoices for drug NDC#s from another list given to PIC ABEDI. During the

inspection, photos were taken of the pharmacy area where large tubs of compounding ingredients were stored on the floor, boxes covering the window of the compounding room obstructing the pharmacist view and boxes and bins containing compounded drugs stored on the floor. Before leaving Inspector SP issued Written Notice of Pharmacy Non-Compliance, set forth above, as Thirteenth cause for Discipline through Sixteenth Cause for Discipline, for violating sections 1717.3, subdivision (a), 1735.2, subdivision (i), 1735.8 and 1707.5, subdivision (a), of the California Code of Regulations.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Unauthorized Activity)

144. Respondents KVP PHARMACY is subject to disciplinary action under section 4301, subsection (f) of the Code in conjunction with section 17200 of the Code, which prohibits the commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise. On or about March 5, 2013, KVP PHARMACY furnished auto refilled prescription RX# 643495 for patient C.B. without her authorization. A subsequent investigation of several patients revealed KVP PHARMACY was automatically refilling patient's prescriptions without prior authorization or consent from the patients. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 138 through 143, as though set forth fully.

BOARD INSPECTION OF JULY 22, 2013

145. On or about July 6, 2013, the Board received a written complaint from CVS Caremark alleging that KVP PHARMACY was compounding medications and shipping throughout the United States. On or about July 22, 2013, the Board's Inspectors revisited KVP PHARMACY to follow up on the complaint investigation. Inspector S.P. discovered that PIC LIAO disassociated from KVP PHARMACY as PIC on July 5, 2013, and PIC CUMMINGS became PIC on July 15, 2013.

During the inspection, Inspector S.P. reviewed the changes made since her last inspection and noticed the following:

- KVP PHARMACY still continued to fill the preprinted multiple check off prescription for controlled substances in spite of the written notice issued on May 29, 2013. This was a direct contradiction of POGOSYAN's written statement received by the Board on June 20, 2013 where he stated that KVP PHARMACY will modify its acceptance criteria for compounded formulations containing controlled substance and will cease to accept preprinted multiple check-off prescriptions for compounds containing controlled substances;
- KVP PHARMACY continued to process the prescriber's requests for office use as prescriptions, rather than as a sales/purchase order in spite of the Board's written notice issued on May 29, 2013;
- KVP PHARMACY's Recall policy stated that patients who received the recalled lot number must be contacted by phone immediately and instructed to discontinue use of the compounded drug product, that the name, address and phone number of the patient will be recorded in the recall of compounded drug product folder, and that the prescribing physician must be notified within 2 business days. However, during the inspection, KVP PHARMACY's registered pharmacist (Navid Doostan) was unaware of any implementation of any recall including the recall pursuant to the abnormal results of the Eagle Analytical Report of June 18, 2012. Inspector SP spoke with POGOSYAN who told her that he would look into it.

146. Inspector S.P. spoke with KVP PHARMACY's registered pharmacist Doostan about the process he used to verify the compounded formulations made by the technicians in the compounding area and she was informed that the bulk containers were stocked in or near the compounding room, the technicians measured and manipulated the ingredients according to the worksheet/master formula and subsequently brought the finished labeled prepackaged containers to the pharmacist for verification. KVP PHARMACY pharmacist usually did not go to the compounding room to check the bulk containers unless there was a question. The verified prepackaged containers were placed on the pharmacy shelves for dispensing future orders.

147. During the inspection, Inspector SP noticed a KVP PHARMACY technician processing prescription refills from a computer generated list, a report identifying prescriptions that were due to be filled. KVP PHARMACY technician was instructed to fill all prescriptions without calling the patient unless there were specific notes that showed in a pop-up window when the patient profile was displayed on the screen. Once the prescription was processed, KVP PHARMACY technician generated prescription labels and placed them in the fill area for order fulfillment, verification, and mailing to the customer. If the patients did not want a prescription they received, they would call the customer service and return the product for credit. Davin Dab of KVP PHARMACY informed the inspector that the returned product was never restocked but was quarantined for destruction. KVP PHARMACY's registered pharmacist Doostan stated that the authorization to fill was sometimes documented on the computer if there was a conversation with a customer or documented on the prescription hard copy by the prescriber during the patient's visit. When asked to show examples of the documentation by the prescriber, KVP PHARMACY's registered pharmacist Doostan was unable to find one in the pile of about 15 prescriptions that had recently been processed to fill by KVP PHARMACY's technician. Inspector SP pointed out the discrepancy in the CURES[7] transmission of the quantity of Ketamine in the compounded formulations. The Board's inspectors collected documents showing KVP PHARMACY's continued non-compliance.

148. The Board inspector requested a listing of states to which KVP PHARMACY shipped medications. On or about July 30, 2013, Inspector SP received an email from Devin Deb of KVP PHARMACY. One of the attachment documents Mr. Deb provided was a spreadsheet report on out-of-state prescriptions from 3/1/2011 to 7/22/2013. Mr. Deb further provided a spreadsheet report summarizing states that KVP PHARMACY shipped to and copies of licenses. On or about August 3, 2013, Inspector SP received a written response from KVP PHARMACY which included the hardcopy of the spreadsheet report on out-of-state prescriptions. Further, Inspector S.P. determined that auto refill report prepared every Monday, Wednesday and Friday.

[7] Controlled Substance Utilization, Review and Evaluation System

All prescriptions were filled unless otherwise noted. If a patient did not want a prescription refill, said patient would call KVP PHARMACY's customer service and return the product for credit. The returned product was quarantined for destruction. Inspector S.P. issued a Written Notice of Pharmacy Non Compliance for violating sections 1717.3, subdivision (a), of the California Code of Regulations.

149. On July 24, 2013, Inspector S.P. sent questionnaires to several physicians who practiced in the State of California and outside the State of California. Inspector S.P. asked the following questions in the questionnaire; (1) list the names of the compounded formulations shipped by KVP PHARMACY; (2) How were the formulations delivered to your practice? (3) Was a signature obtained by the person making the delivery? (4) What sort of paperwork was included with the formulations? (5) Was the practice or the prescriber charged for the formulations? Inspector S.P. received responses to her questionnaire.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Unauthorized Activity)

150. Respondents KVP PHARMACY, ABEDI, LIAO and CUMMINGS are subject to disciplinary action under section 4059.5 (e) the Code, in that during a Board investigation of the KVP PHARMACY on July 22, 2013, an inspection of KVP PHARMACY revealed the delivery (shipping, mailing, or furnishing) of dangerous drugs, controlled substances, and/or compounded drug products to prescribers and patients located in several states outside of the State of California. From approximately August 1, 2010 to August 17, 2013, KVP PHARMACY (and previously known as NCL Pharmaceuticals, Inc.) shipped or furnished approximately over 21,777 prescriptions (dangerous drugs, controlled substances and/or compounded drug product) to 48 states and/or territory without appropriate licensure in the State to where the dangerous drugs, controlled substances, and/or compounded drug products were delivered. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 131 through 149, as though set forth fully.

NINETEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

151. Respondents KVP PHARMACY, ABEDI, LIAO and CUMMINGS are subject to disciplinary action under section 4301(j) of the Code, in that during a Board investigation of the KVP PHARMACY on July 22, 2013, an inspection of KVP PHARMACY revealed the delivery (shipping, mailing, or furnishing) of dangerous drugs, controlled substances, and/or compounded drug products to prescribers and patients located in several states outside of the State of California. From approximately August 1, 2010 to August 17, 2013, KVP PHARMACY (and previously known as NCL Pharmaceuticals, Inc.) shipped or furnished approximately over 21,777 prescriptions (dangerous drugs, controlled substances and/or compounded drug product) to 48 states and/or territory without appropriate licensure in the State to where the dangerous drugs, controlled substances, and/or compounded drug products were delivered. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 131 through 149, as though set forth fully.

TWENTIETH CAUSE FOR DISCIPLINE

(Unauthorized Prescriptions)

152. Respondents KVP PHARMACY and ABEDI are subject to disciplinary action under section 1717.3, subdivision (a), of the California Code of Regulations, in that an inspection of KVP PHARMACY on May 29, 2013 revealed the dispensing (furnishing) of compounded products (compounded formulations containing Ketamine, a Schedule III Controlled Substance) from preprinted, multiple check-off prescription blanks (scripts). Further, a follow-up inspection on July 22, 2013 revealed KVP PHARMACY failed to implement changes in the receipt and dispensing of compounded products written on preprinted, multiple check-off prescription blanks. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 149, as though set forth fully.

TWENTY FIRST CAUSE FOR DISCIPLINE

(Unlicensed Manufacturer)

153. Respondent KVP PHARMACY is subject to disciplinary action under sections 4033, subdivision (a), subsection (1) and 4061 of the Code, section 111615 of Health and Safety Code, and Title 21, U.S. Code section 353, subsection (d)(2)(A), in that during a Board

investigation of the KVP PHARMACY on May 29, 2013 and July 22, 2013, KVP PHARMACY was not in compliance with section 4033(a)(1) of the Code which defines "manufacturer" and include every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer. Such a distribution od drug samples may only be made (1) in response to a written request for drug samples made on a form, and (2) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record. Approximately from August 2010 to August 2013, KVP PHARMACY shipped approximately over 8,051 prescriptions (compounded drug products identified under a RX number instead of sales and purchase records to prescribers within California and to other states outside the State of California. Further, the Board's inspector was informed that compounded drug "samples" (the above 8,051 prescriptions) were distributed to physicians for "physician office use". The "samples" were provided at no costs. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 149, as though set forth fully.

TELEPHONIC INTERVIEW OF PATIENT CB ON JULY 29, 2013

154. On or about July 29, 2013, Board Inspector SP spoke with the patient CB who confirmed that she had complained to the Board about KVP PHARMACY sending her medications she had not asked for, via mail, and billing her insurance for a huge sum of money. Further Patient CB did not receive any instructions from KVP PHARMACY for use on the prescription label nor any patient education paper insert to give her information about the formulation. Patient CB saw a physician, Dr. D., who was not her primary physician, in early January of 2013. On her second visit, she received a written prescription from said physician, dated January 8, 2013, and took the prescription home with her. She took the prescription back to said physician's office and inquired what she supposed to do with the prescription. She was informed that the prescription should have been sent to a special pharmacy. Thereafter, she received prescription fills from KVP PHARMACY. KVP PHARMACY failed to call Patient CB to obtain medical history allergies information. KVP PHARMACY did not know that Patient

CB was on oral gabapentin and Topamax when KVP PHARMACY sent her the topical preparation containing Ketamine, Flurbiprofen, Baclofen and Cyclobenzaprine.

155. Patient CB's first prescription fill dated January 29, 2013, came in a brown cardboard box without instructions on the prescription label and without any patient education documentation. Patient CB called KVP PHARMACY in order to return the first fill, however, KVP PHARMACY refused to let her return it claiming that the prescription had been made especially for her. When she asked about the instructions for use, she was placed on hold for awhile and subsequently, she was given general directions on how often to use it. She did not receive an offer for consultation with a pharmacist.

156. Patient CB's second prescription fill dated March 5, 2013, was mailed to her before she had started using the first one. She called KVP PHARMACY to find out why the second prescription was filled and she was informed that the prescription was "automatically" filled upon authorization from the doctor. Patient CB informed KVP PHARMACY that she had not even used any of the first fill and had not asked her doctor to authorize automatic fills on her behalf. KVP PHARMACY finally agreed to reverse the billing to CVS Caremark and asked her to return the second fill.

STATEMENTS BY PIC CUMMINGS

157. On or about August 13, 2013, Inspector SP sent an e-mail to PIC CUMMINGS requesting the billing invoice and proof of payment for 50 prescriptions of physician office use compounded formulations. Inspector SP spoke with PIC CUMMINGS who acknowledged receiving Board's inspection report dated July 22, 2013.

158. On August 15, 2013, Inspector SP received an e-mail from PIC CUMMINGS which contained a forwarded e-mail from Davin Deb of KVP PHARMACY. PIC CUMMINGS stated the following:

- "KVP PHARMACY did not send an invoice to the physicians;
- There was no expectation of payment as the prescriptions were provided as "samples" solely for office administration and patient education to demonstrate the product;
- The physician was told they were not for sale."

BOARD INSPECTION OF AUGUST 19, 2013

159. On or about August 19, 2013, Board's Inspector SP and Inspector J.W. revisited KVP PHARMACY to follow up on the complaint investigations. In addition to assisting Inspector SP on her follow-up, Inspector J.W. was conducting additional investigation related to KVP PHARMACY from a different and separate complaint investigation relating to compounded products from KVP PHARMACY and physician office use which was also similar to the pharmacy non-compliances discovered by Inspector SP during her inspections of KVP PHARMACY. Inspector J.W. requested and retrieved drug usage reports from August of 2010 to August of 2013 and also a "customer order history-physician office use" and a "master formula worksheets-templates" to assist in the investigations of KVP PHARMACY. Prior to leaving, Inspector SP issued a written notice of pharmacy non-compliance on Business & Professional Code section 4059.5, subsection (e), in that between 3/1/2011 to 7/22/13, KVP PHARMACY was shipping dangerous drugs (in excess of 16,000 prescriptions) to 48 states/territories in the United States, however, KVP PHARMACY had proof of recent licensure only for 4 states (Alabama, Delaware, Wisconsin and West Virginia.) Supervising Inspector JD conducted a license verification of KVP PHARMACY in all the States and/or territories in the United States and tabulated a chart as follows:

State	**State requiring license for non-resident pharmacies**	**Does KVP PHARMACY have a license in this state?**	**License number/type of license**	**Date issued**	**# RX shipped into the state without a license**
Alaska (AK)	Y	N	------	----	1
Alabama (AL)	Y	Y	114178 (pharmacy permit) 202189 (mail order permit)	7/22/13	455
Arizona (AZ)	Y	N Application pending	Y005701 Application pending	Applied 7/29/13	316
Arkansas (AK)	Y	N	----	----	742

Colorado (CO)	Y	Y	OSP 0.0006235 (prescription drug outlet out-of-state)	7/25/13	215
Connecticut (CT)	Y (registered not licensed)	N Application pending	PCN.0002542 Non-resident pharmacy application pending	---	1151
Delaware (DE)	Y	Y	A9-0001287 Non-resident pharmacy PH-0009554 Pharmacy controlled substance	7/22/13	327 (out of 333)
District of Columbia (DC)	N	N	---	---	37
Florida (FL)	Y	N	---	---	549
Georgia (GA)	N	N	---	---	752
Guam (GU)	N	---	---	---	---
Hawaii (HI)	Y	Y	PMP-874	8/12/13	---
Idaho (IA)	Y	N Application pending for mail service pharmacy	---	---	10
Illinois (IL)	Y	N	---	---	178
Indiana (IN)	Y	N Application pending for non-resident pharmacy	---	---	54
Iowa (IO)	Y	N	---	---	22
Kansas (KS)	Y	N	---	---	1
Kentucky (KY)	Y	N	---	---	193
Louisiana (LA)	Y	N Application pending for non-resident pharmacy	---	---	1330

Maine (ME)	Y Registered, not licensed	N	---	---	35
Maryland (MD)	Y	Y	P06046 Pharmacy	7/31/13	3393
Massachusetts (MA)	N In process of changing the law requiring out-of-state pharmacy licensure	N	---	---	50
Michigan (MI)	Current law prohibits dispensing RX by mail if received by mail	Y	5315062566 Controlled substance facility 5301010160 Pharmacy	8/19/13	456
Minnesota (MN)	Y	N	---	---	3
Mississipi (MI)	Y	N	---	---	25
Missouri (MO)	Y	Y Unknown, out of state pharmacy	2013032037	8/26/13	16
Montana (MT)	Y	N	---	---	4
Nebraska (NE)	Y	N	---	---	2
Nevada (NV)	Y	Y Pharmacy	PH03018	9/23/13	153
New Hampshire (NH)	Y	N	---	---	174
New Jersey (NJ)	Y Out-of-state pharmacy	N	---	---	521
New Mexico (NM)	Y	N	---	---	123

New York (NY)	Y	N	---	---	859
North Carolina (NC)	Y	N	---	---	189
North Dakota (ND)	Y	N	---	---	---
Ohio OH)	Y	N	---	---	217
Oklahoma (OK)	Y	N	---	---	89
Oregon	Y	N	---	---	12
Pennsylvania (PA)	N	N	---	---	659
Puerto Rico PR)	Not addressed in pharmacy act or by board regulations	---	---	---	---
Rhode Island (RI)	Y	Y	PHN 10456 Pharmacy non-resident	7/18/13	287 (out of 307)
South Carolina (SC)	Y	N	---	---	55
South Dakota (SD)	Y	N	400-1131	8/2/13	---
Tennessee (TN)	Y	N	---	---	519
Texas (TX)	Y Non-resident pharmacy	N	---	---	567
Utah (UT)	Y Out of state mail order pharmacy	N	---	---	---

Vermont (VT)	Y	Y	036.0098862 Non-resident pharmacy	9/23/13	4
Virginia (VR)	Y Non-resident pharmacy	N	---	---	1074
Washington (WA)	Y	N Pending application	PHNRFO.6041645 Non-resident pharmacy application pending	---	31
West Virginia (WV)	Y	Y	MO0560530 Mail order distributor	7/12/13	258 (out of 302)
Wisconsin (WI)	Y	Y Pharmacy out of state	963-43 (regular)	7/16/13	6
Wyoming (WY)	Y	Y	NR-50631	7/29/13	4
Virgin Islands (VI)	---	---	---	---	1

160. Supervising Inspector J.D. and Inspector J.W. determined that approximately 21,708 prescriptions were shipped out-of-state based upon KVP PHARMACY pharmacist-in-charge tenures, as indicated below.

State	PIC Cummings (3/1/11-4/9/12)	**NO PIC** on record from 4/10/12-5/13/12	PIC Abedi (5/14/12-6/9/13)	PIC Liao (6/10/13-7/5/13)	**NO PIC** on record from 7/6/13-8/17/13)	Grand Total of prescriptions shipped out of state
AK					17	17
AL			491	50	26	567
AR			361	248	348	957
AZ	25	6	268	139	217	655
CO	2		315	21	34	372

CT			1121	296	465	1882
DE			323	93	37	453
FL			556	194	212	962
HI		1				1
IA			32	2	5	39
ID			11	4	2	17
IL			34	124	166	324
IN	3		73	44	32	152
KS	15	3	39	3	1	61
KY			133	60	72	265
LA			999	248	420	1667
MD			2788	718	510	4016
ME			39	3	5	47
MI			276	151	218	645
MN		1	1	2		4
MO			11	7	6	24
MS			22	3	2	27
MT			2	1	1	4
NC		3	183	74	147	407
NE			2		2	4
NH			218	28	62	308
NJ			465	103	137	705
NM			82	21	48	151
NV	26	4	307	32	102	471
NY	1		686	122	191	1010
OH			273	33	19	325
OK			74	11	25	110

OR	1		7	9	4	21
RI			141	108	40	289
SC			37	18	77	132
TN			447	275	336	1058
TX	7	1	363	193	471	1035
VA	2		1498	129	19	1648
VI				1		1
VT			4			4
WA	1	4	437	13	31	486
WI			20	42	1	63
WO			2	1	1	4
WV			184	98	25	307
WY			2	2		4
Unknown			6	1		7
Totals	83	23	13343	3725	4534	21,708

161. Board's Inspector issued written notice of pharmacy non-compliance of Code section 4059.5, subsection (e) in that KVP PHARMACY was shipping dangerous drugs (more than 16,000 prescriptions to 48 states/territories in the United States), however, KVP PHARMACY did not have proof of licensure for all of the states/territories in the United States.

162. Further, on August 19, 2013, Inspector S.P. noticed the following were still being conducted in spite of corrections and violations issued and discussed in prior inspections with POGOSYAN, PIC ABEDI, PIC LIAO, Registered Pharmacist Doostan and CUMMINGS:

- KVP PHARMACY continued to accept faxed multiple check-off prescriptions for controlled substances (Ketamine) from prescribers;
- KVP PHARMACY continued to have prescription labels that were not patient centered label compliant;

- KVP PHARMACY continued to ship samples of compounded formulations to prescribers and not charging them for it;
- KVP PHARMACY continued to fail to follow their policies and procedures for product recall. POGOSYAN stated that the abnormal test was so old that he decided not to conduct a recall. Inspector SP explained that he still needed to implement a recall and provide documentation of such. Inspector SP asked POGOSYAN when the last end product was submitted to a laboratory for testing. POGOSYAN replied that he was not sure, but not since May of 2013, when Inspector SP conducted her first inspection of KVP PHARMACY.

163. On August 19, 2013, Inspector SP noticed a big brown box containing boxes with shipping labels to many different states within the United States. Inspector SP asked for an update on the process of obtaining appropriate out of state licensure. Davin Deb stated he would forward an e-mail with the latest updated information. POGOSYAN had to leave before the conclusion of the Board's inspection. Before leaving, POGOSYAN stated his business was expanding and he would pay the fine incurred while KVP PHARMACY continued to ship out of state without appropriate licensures.

164. Inspector SP noticed that KVP PHARMACY still had drug products on its shelves that had been compounded in March of 2013. At the conclusion of the inspection, Inspector S.P. and Inspector JW asked Registered Pharmacist Doostan to share their findings and discussions with PIC CUMMINGS and POGOSYAN in order to respond to product recall documentation request. The inspectors emphasized the following:

- KVP PHARMACY is not allowed to ship out of state prescriptions to those states where they did not have licensure;
- KVP PHARMACY is to stop using multiple check off prescription forms for prescriptions with controlled substances.

165. At the conclusion of the inspection, Davin Deb returned to KVP PHARMACY and promised to provide up to date licensure information for KVP PHARMACY and the data about requirements for shipping into each state. On August 20, 2013, Inspector SP received from Davin

Deb copies of licensures from the states of Colorado, Wyoming, Rhode Island, Maryland and South Dakota. On or about September 25, 2013, Patient CB agreed to mail the compounded drug products in his possession to the Board for testing.

TWENTY SECOND CAUSE FOR DISCIPLINE

(Unauthorized Activity)

166. Respondents KVP PHARMACY, ABEDI, PAMELA LIAO and PAUL CUMMINGS are subject to disciplinary action under section 4059.5, subsection (e) of the Code, in that during a Board investigation of the KVP PHARMACY on August 19, 2013, an inspection of KVP PHARMACY revealed that from 3/1/2011 to 8/17/2013, KVP Pharmacy shipped approximately 21,708 prescriptions (dangerous drugs, controlled substances, compounded drug products and/or over-the-counter products identified as a prescriptions) to 45 states and/or territories without appropriate licensure in the state to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4059.5, subsection (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 122 through 164, as though set forth fully.

167. Further, during a Board investigation of the KVP PHARMACY on August 19, 2013, an inspection of KVP PHARMACY revealed that PIC LIAO while acting as pharmacist-in-charge of KVP PHARMACY shipped and/or furnished approximately 3,725 prescriptions (dangerous drugs, controlled substances, compounded drug products and/or over-the-counter products identified as a prescriptions) to 41 states and/or territories without appropriate licensure in the state to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4059.5, subsection (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 122 through 164, 209 through 214, as though set forth fully.

168. Moreover, during a Board investigation of the KVP PHARMACY on August 19, 2013, an inspection of KVP PHARMACY revealed that PIC ABEDI while acting as pharmacist-in-charge of KVP PHARMACY shipped and/or furnished approximately 13,343 prescriptions (dangerous drugs, controlled substances, compounded drug products and/or over-the-counter

products identified as a prescriptions) to 42 states and/or territories without appropriate licensure in the state to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4059.5, subsection (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 122 through 164, 209 through 214, as though set forth fully.

169. During a Board investigation of the KVP PHARMACY on August 19, 2013, an inspection of KVP PHARMACY revealed that PIC CUMMINGS while acting as pharmacist-in-charge of KVP PHARMACY shipped and/or furnished approximately 83 prescriptions (dangerous drugs, controlled substances, compounded drug products and/or over-the-counter products identified as a prescriptions) to 10 states and/or territories without appropriate licensure in the state to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4059.5, subsection (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 165, 210 through 215, as though set forth fully.

TWENTY THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

170. Respondents KVP PHARMACY, ABEDI, PAMELA LIAO and PAUL CUMMINGS are subject to disciplinary action under section 4301, subsection (j) of the Code, in that during a Board investigation of the KVP PHARMACY on August 19, 2013, an inspection of KVP PHARMACY revealed that KVP PHARMACY, ABEDI, PAMELA LIAO and PAUL CUMMINGS shipped and/or furnished prescriptions (dangerous drugs, controlled substances, compounded drug products and/or over-the-counter products identified as a prescriptions) to 43 states and/or territories without appropriate licensure in the state to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (j) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 158 through 168, as though set forth fully. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 165, 210 through 215, as though set forth fully.

TWENTY FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

171. Respondents KVP PHARMACY, PAMELA LIAO and PAUL CUMMINGS are subject to disciplinary action under section 4301, subsection (f) of the Code as it relates to moral turpitude, dishonesty, fraud, deceit, corruption, in that during a Board investigation of the KVP PHARMACY on August 19, 2013, an inspection of KVP PHARMACY revealed that KVP PHARMACY, PAMELA LIAO and PAUL CUMMINGS filled prescription # 643495 for Patient CB on January 29, 2013 and February 27, 2013, without the patient's authorization for filling, in violation of section 4301, subsection (f) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph paragraphs 158 through 168, as though set forth fully. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 165, 210 through 215, as though set forth fully.

CEASE & DESIST DEMAND FROM NEVADA STATE BOARD OF PHARMACY

172. On or about June 27, 2013, Nevada State Board Pharmacy (Nevada Board) received notice that KVP PHARMACY and NCL Pharmaceuticals Inc.[8] were marketing, selling and/or shipping drugs (RX only) and/or controlled substances into the State of Nevada. Nevada law allows non-Nevada pharmacies to distribute prescription drugs and controlled substances into the state, but only if they are fully licensed by the state of Nevada to do so. Nevada Board determined that neither KVP PHARMACY nor NCL Pharmaceuticals Inc. were licensed in Nevada.

173. On or about June 27, 2013, Nevada Board's general counsel sent a letter to KVP PHARMACY and NCL Pharmaceuticals which provides: "I am therefore writing to demand that KVP PHARMACY AND NCL PHARMACEUTICALS INC. ***CEASE TO MARKET, SELL AND/OR SHIP PRESCRIPTION DRUGS AND/OR CONTROLLED SUBSTANCES INTO THE STATE OF NEVADA*, IMMEDIATELY**. The unlicensed activities of these companies are in violation of Nevada law. Their activities also appear to violate Federal law and regulations

[8] NCL Pharmaceuticals Inc.'s address is 440 w. Broadway #C, in Glendale, CA 91204 and the address of KVP PHARMACY is 440 w. Broadway #B, in Glendale, CA 91204

established by the United Sates Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA)."

TWENTY FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

174. Respondents KVP PHARMACY and LIAO are subject to disciplinary action under sections 4301, subsection (j) and 4059.5, subdivision (e) of the Code as it relates to violating any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs, in that on or about June 27, 2013, KVP PHARMACY and NCL Pharmaceuticals Inc.[9] were marketing, selling and/or shipping drugs (RX only) and/or controlled substances into the State of Nevada, without appropriate licensure in the state of Nevada to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (j) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 172 through 173, as though set forth fully.

TWENTY SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

175. Respondents KVP PHARMACY and LIAO are subject to disciplinary action under section 4301, subsection (f) of the Code as it relates to moral turpitude, dishonesty, fraud, deceit, corruption, in that on or about June 27, 2013, KVP PHARMACY and NCL Pharmaceuticals Inc.[10] were marketing, selling and/or shipping drugs (RX only) and/or controlled substances into the State of Nevada, without appropriate licensure in the state of Nevada to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (f) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 172 through 173, as though set forth fully.

TWENTY SEVENTH CAUSE FOR DISCIPLINE

[9] NCL Pharmaceuticals Inc.'s address is 440 w. Broadway #C, in Glendale, CA 91204 and the address of KVP PHARMACY is 440 w. Broadway #B, in Glendale, CA 91204

[10] NCL Pharmaceuticals Inc.'s address is 440 w. Broadway #C, in Glendale, CA 91204 and the address of KVP PHARMACY is 440 w. Broadway #B, in Glendale, CA 91204

(Unprofessional Conduct)

176. Respondents KVP PHARMACY and LIAO are subject to disciplinary action under section 4301 of the Code for unprofessional conduct in that on or about June 27, 2013, KVP PHARMACY and NCL Pharmaceuticals Inc.[11] were marketing, selling and/or shipping drugs (RX only) and/or controlled substances into the State of Nevada, without appropriate licensure in the state of Nevada to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301 of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 172 through 173, as though set forth fully.

COMPLAINT FROM ARKANSAS STATE BOARD OF PHARMACY

177. On September 6, 2013, the Board received a referral complaint from Brenda McCredy, Assistant Director of Arkansas State Board of Pharmacy (Arkansas Board). Arkansas Board notified the owner of KVP PHARMACY, POGOSYAN, that KVP PHARMACY was dispensing or causing to be delivered prescription drugs to consumers in Arkansas in direct violation of the laws and regulations of Arkansas Board which provides that the Out of State Pharmacy Regulations 04-04-0001 required that KVP PHARMACY be licensed by the Arkansas Board and that KVP PHARMACY had to have an Arkansas licensed pharmacist on staff. Arkansas Board further provided "[t]his letter will serve as official notification by Arkansa State Board of Pharmacy to correct this situation immediately. Please let us know the status of providing medications into Arkansas" Arkansas Board further served a Subpoena Duces Tecum to KVP PHARMACY commanding KVP PHARMACY to produce and permit inspection and copying the following documents: "[A] printout and/or copy of all invoices and/or copy of any documents, orders, prescriptions or other records or physical objects created or maintained by or behalf of KVP Pharmacy for prescription (legend) drugs shipped or caused to be shipped by your firm since January 1, 2012 into Arkansas. The printout shall include the name and address of the

[11] NCL Pharmaceuticals Inc.'s address is 440 w. Broadway #C, in Glendale, CA 91204 and the address of KVP PHARMACY is 440 w. Broadway #B, in Glendale, CA 91204

recipient, name, strength and quantity of the items shipped, date of shipment, and any other pertinent information available."

TWENTY EIGHT CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

178. Respondent KVP PHARMACY is subject to disciplinary action under section 4301, subsection (j) and 4059.5, subdivision (e) of the Code as it relates to violating any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs, in that on or about on or about September 6, 2013, KVP PHARMACY was dispensing or causing to be delivered prescription drugs to consumers in Arkansas in direct violation of the laws and regulations of Arkansas Board which provides that the Out of State Pharmacy Regulations 04-04-0001 required that KVP PHARMACY be licensed by the Arkansas Board and that KVP PHARMACY had to have an Arkansas licensed pharmacist on staff, in violation of section 4301, subsection (j) and 4059.5, subdivision (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 177, as though set forth fully.

TWENTY NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

179. Respondent KVP PHARMACY is subject to disciplinary action under section 4301, subsection (f) of the Code as it relates to moral turpitude, dishonesty, fraud, deceit, corruption, in that on or about September 6, 2013, KVP PHARMACY was dispensing or causing to be delivered prescription drugs to consumers in Arkansas in direct violation of the laws and regulations of Arkansas Board which provides that the Out of State Pharmacy Regulations 04-04-0001 required that KVP PHARMACY be licensed by the Arkansas Board and that KVP PHARMACY had to have an Arkansas licensed pharmacist on staff, in violation of section 4301, subsection (f) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 177, as though set forth fully.

THIRTIETH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

180. Respondent KVP PHARMACY is subject to disciplinary action under section 4301 of the Code for unprofessional conduct in that on or about September 6, 2013, KVP PHARMACY was dispensing or causing to be delivered prescription drugs to consumers in Arkansas in direct violation of the laws and regulations of Arkansas Board which provides that the Out of State Pharmacy Regulations 04-04-0001 required that KVP PHARMACY be licensed by the Arkansas Board and that KVP PHARMACY had to have an Arkansas licensed pharmacist on staff, in violation of section 4301 of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 177, as though set forth fully.

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COMPLAINT FROM LOUISIANA STATE BOARD OF PHARMACY

181. On or about September 4, 2013, the Board received a referral complaint from the General Counsel of Louisiana Board of Pharmacy (Louisiana Board) and enclosed a copy of the complaint filed with the Louisiana Board alleging KVP PHARMACY was shipping over 1000 compounded medications into the state of Louisiana. The General Counsel of the Louisiana Board stated that KVP PHARMACY appears to have a non-resident application that the Louisiana Board was processing, however, KVP PHARMACY was actively shipping compounded medications that were non-patient specific since February of 2013. KVP PHARMACY's application with the Louisiana Board or an out-of-state pharmacy has been placed on hold until the conclusion of the Louisiana Board's investigation.

THIRTY FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

182. Respondents KVP PHARMACY, LIAO and ABEDI are subject to disciplinary action under section 4301, subsection (j) and 4059.5, subdivision (e) of the Code as it relates to violating any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs, in that from on or about February of 2013 to on or about September 4, 2013, KVP PHARMACY, LIAO and ABEDI were shipping over 1000 compounded medications into the state of Louisiana, without appropriate licensure in the state of

Louisiana to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (j) and 4059.5, subdivision (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 181, as though set forth fully.

THIRTY SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

183. Respondents KVP PHARMACY, LIAO and ABEDI are subject to disciplinary action under section 4301, subsection (f) of the Code as it relates to moral turpitude, dishonesty, fraud, deceit, corruption, in that from on or about February of 2013 to on or about September 4, 2013, KVP PHARMACY, LIAO and ABEDI were shipping over 1000 compounded medications into the state of Louisiana, without appropriate licensure in the state of Louisiana to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (f) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 181, as though set forth fully.

THIRTY THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

184. Respondents KVP PHARMACY, LIAO and ABEDI are is subject to disciplinary action under section 4301 of the Code for unprofessional conduct in that from on or about February of 2013 to on or about September 4, 2013, KVP PHARMACY, LIAO and ABEDI were shipping over 1000 compounded medications into the state of Louisiana, without appropriate licensure in the state of Louisiana to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301 of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 181, as though set forth fully.

COMPLAINT FROM OHIO STATE BOARD OF PHARMACY

185. On or about September 10, 2013, the Board received a referral complaint from the Compliance Specialist of the Ohio State Board of Pharmacy (Ohio Board) pertaining to two complaints filed against KVP PHARMACY and the pending issuance of a Cease & Desist Order

to KVP PHARMACY to stop shipping into Ohio until they were licensed by the Ohio Board. The two complaints were as follows:

a. A patient complained that she received a cream from KVP PHARMACY which she did not order. During the investigation, the Ohio Board interviewed the patient's physician and obtained approximately 4 lotion containers of cream from the physician's office. The physician disclosed that the jars of cream were for personal use only and that he obtained the jars through a communication with a marketing group. The physician was unable to provide invoices or copies of the order form for the creams.

b. The Compliance Specialist of the Ohio Board filed a complaint to stop and cease KVP PHARMACY from shipping medications into Ohio. On or about September 12, 2013, the Compliance Specialist of the Ohio Board planned on transferring 3 of the 4 lotion containers that were shipped to Ohio by KVP PHARMACY to the Board for drug testing. The Compliance Specialist provided a copy of the label and a photocopy image of the lotion containers that were shipped to Ohio by KVP PHARMACY. Review of said label and lotion contained showed RX#651383 under patient name; filled date of 2/26/2013; Diclofenac 10%/Flurbiprofen 10%/ Gabapentin 10%/ Lidocaine[12] 5% sent to Dr. A. P. (RX#651383). On or about November 20, 2013, the Board received 3 out of the 4 containers of RX#651383 sent by KVP PHARMACY from the Ohio Board. The three containers were lodged into Evidence Locker for the transfer to the California Department of Public Health for drug testing. On November 25, 2013, Board Inspector met with the Supervising Food & Drug Inspector, California Department of Public Health and transferred the three containers of RX#651383 sent by KVP PHARMACY to the Supervising Food & Drug Inspector, California Department of Public Health for drug testing.

THIRTY FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

[12] Lidocaine is a common local anesthetic injected as a dental anesthetic or as a local anesthetic for minor surgery.

186. Respondent KVP PHARMACY is subject to disciplinary action under section 4301, subsection (j) and 4059.5, subdivision (e) of the Code as it relates to violating any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs, in that on or about September 10, 2013, KVP PHARMACY was shipping controlled substances and dangerous drugs into the State of Ohio, without appropriate licensure in the state of Ohio to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (j) and 4059.5, subdivision (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 185, as though set forth fully.

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THIRTY FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

187. Respondent KVP PHARMACY is subject to disciplinary action under section 4301, subsection (f) of the Code as it relates to moral turpitude, dishonesty, fraud, deceit, corruption, in that on or about September 10, 2013, KVP PHARMACY was shipping controlled substances and dangerous drugs into the State of Ohio, without appropriate licensure in the state of Ohio to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (f) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 185, as though set forth fully.

THIRTY SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

188. Respondent KVP PHARMACY is subject to disciplinary action under section 4301 of the Code for unprofessional conduct in that on or about September 10, 2013, KVP PHARMACY was shipping controlled substances and dangerous drugs into the State of Ohio, without appropriate licensure in the state of Ohio to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301 of the Code.

Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 185, as though set forth fully.

COMPLAINT FROM NEW HAMPSHIRE STATE BOARD OF PHARMACY

189. On or about September 19, 2013, the Board received a referral complaint from the Chief Compliance Inspector of the New Hampshire Board of Pharmacy (New Hampshire Board) pertaining to KVP PHARMACY shipping compound medicines from California to New Hampshire while being unlicensed in the state of New Hampshire. New Hampshire regulation NH RSA 318:37 (II) (a) requires Non-Resident pharmacies to become licensed prior to shipping prescriptions into New Hampshire.

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THIRTY SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

190. Respondents KVP PHARMACY is subject to disciplinary action under section 4301, subsection (j) and 4059.5, subdivision (e) of the Code as it relates to violating any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs, in that on or about September 19, 2013, KVP PHARMACY was shipping compound medicines from California to New Hampshire, without appropriate licensure in the state of New Hampshire to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (j) and 4059.5, subdivision (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 189, as though set forth fully.

THIRTY EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

191. Respondent KVP PHARMACY is subject to disciplinary action under section 4301, subsection (f) of the Code as it relates to moral turpitude, dishonesty, fraud, deceit, corruption, in that on or about September 19, 2013, KVP PHARMACY was shipping compound medicines

from California to New Hampshire, without appropriate licensure in the state of New Hampshire to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (f) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 189, as though set forth fully.

THIRTY NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

192. Respondent KVP PHARMACY is subject to disciplinary action under section 4301 of the Code for unprofessional conduct in that on or about September 19, 2013, KVP PHARMACY was shipping compound medicines from California to New Hampshire, without appropriate licensure in the state of New Hampshire to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301 of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 189, as though set forth fully.

COMPLAINT FROM NEW MEXICO STATE BOARD OF PHARMACY

193. On February 10, 2014, the Board received a referral complaint from Bobby Padilla, RPH Pharm.D. (State Drug Inspector of the New Mexico Board of Pharmacy (New Mexico Board)). On or about September 5, 2013, The New Mexico Board received a complaint against KVP PHARMACY for being unlicensed in New Mexico and for shipping compounded medications into the state of New Mexico. After reviewing the complaint and contacting KVP PHARMACY, the New Mexico Board decided that KVP PHARMACY would be required to be licensed in the New Mexico with a Non-Resident Pharmacy License. KVP PHARMACY initially sent in the initial application which was incomplete and returned on October 22, 2013, and never continued with the licensing process. The New Mexico Board of Pharmacy asked for this case to be referred to the California Board of Pharmacy due to KVP PHARMACY's failure to obtain a license in New Mexico. Mr. Padilla forwarded a copy of his investigation report and the initial complaint to the New Mexico Board.

FORTIETH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

194. Respondent KVP PHARMACY is subject to disciplinary action under section 4301, subsection (j) and 4059.5, subdivision (e) of the Code as it relates to violating any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs, in that on or about September 5, 2013, The New Mexico Board received a complaint against KVP PHARMACY for being unlicensed in New Mexico and for shipping compounded medications into the state of New Mexico, without appropriate licensure in the state of New Mexico to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (j) and 4059.5, subdivision (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 193, as though set forth fully.

FORTY FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

195. Respondent KVP PHARMACY is subject to disciplinary action under section 4301, subsection (f) of the Code as it relates to moral turpitude, dishonesty, fraud, deceit, corruption, in that on or about September 5, 2013, The New Mexico Board received a complaint against KVP PHARMACY for being unlicensed in New Mexico and for shipping compounded medications into the state of New Mexico, without appropriate licensure in the state of New Mexico to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (f) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 193, as though set forth fully.

FORTY SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

196. Respondents KVP PHARMACY is subject to disciplinary action under section 4301 of the Code for unprofessional conduct in that on or about September 5, 2013, The New Mexico Board received a complaint against KVP PHARMACY for being unlicensed in New Mexico and for shipping compounded medications into the state of New Mexico, without appropriate licensure in the state of New Mexico to where the dangerous drugs, controlled substances,

compounded drug products were delivered, in violation of section 4301 of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 193, as though set forth fully.

COMPLAINT FROM ARIZONA STATE BOARD OF PHARMACY

197. On or about July of 2013, KVP PHARMACY filed an application with the Arizona State Board of Pharmacy (Arizona Board) to obtain a permit. Subsequently, the Arizona Board became aware that KVP PHARMACY was shipping prescriptions (including controlled substances), OTC and/or DME product into the State of Arizona without a proper licensure in the State of Arizona. Under Arizona law, non-resident facilities are required to hold a permit in order to legally ship to patients located within the State of Arizona. Specifically Arizona Administrative Code R4-23-607 provides that a person who is not a resident of Arizona shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without processing a current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or non-resident nonprescription drug permit. On or about April 17, 2014, the Arizona Board notified KVP PHARMACY that its application filed with the Arizona Board in July of 2013 has been voided.

FORTY THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

198. Respondents KVP PHARMACY and LIAO are subject to disciplinary action under section 4301, subsection (j) and 4059.5, subdivision (e) of the Code as it relates to violating any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs, in that on or about July of 2013, KVP PHARMACY and LIAO were shipping prescriptions (including controlled substances), OTC and/or DME product into the State of Arizona without appropriate licensure in the state of Arizona to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (j) and 4059.5, subdivision (e) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 197, as though set forth fully.

FORTY FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

199. Respondents KVP PHARMACY and LIAO are subject to disciplinary action under section 4301, subsection (f) of the Code as it relates to moral turpitude, dishonesty, fraud, deceit, corruption, in that on or about July of 2013, KVP PHARMACY and LIAO were shipping prescriptions (including controlled substances), OTC and/or DME product into the State of Arizona without appropriate licensure in the state of Arizona to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301, subsection (f) of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 197, as though set forth fully.

FORTY FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

200. Respondents KVP PHARMACY and LIAO are subject to disciplinary action under section 4301 of the Code for unprofessional conduct in that on or about July of 2013, KVP PHARMACY was shipping prescriptions (including controlled substances), OTC and/or DME product into the State of Arizona without appropriate licensure in the state of Arizona to where the dangerous drugs, controlled substances, compounded drug products were delivered, in violation of section 4301 of the Code. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraph 197, as though set forth fully.

FORTY SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

201. Respondent KVP PHARMACY is subject to disciplinary action under sections 4301, subsection (f) and 4301, subsection (g) of the Code, in that during a Board investigation of the KVP PHARMACY on July 10, 2013, the Board received a "Change of PIC" form from KVP PHARMACY identifying CUMMINGS as the new PIC of KVP PHARMACY, effective July 15, 2013, which was false and additionally, on August 7, 2013, the Louisiana Board of Pharmacy (Louisiana Board) received an application for a Louisiana Pharmacy Permit for Nonresident

Pharmacy from KVP PHARMACY wherein KVP PHARMACY identified Janice Knight-Cooper (CA RPH 40781) as its PIC, which was false in that Janice Knight-Cooper was not a PIC of KVP PHARMACY, in violation of sections 4301, subsection (f) and 4301, subsection (g) of the Code.

BOARD OF PHARMACY ORDERED KVP PHARMACY TO CEASE PHARMACY OPERATION AT PHARMA-RX

202. On November 19, 2013, Board Inspector AY and Inspector JW visited Pharma-Rx and discovered KVP PHARMACY was operating, conducting, practicing and acting as a pharmacy at Pharma-RX located at 412 W. Broadway, Suite 200, in Glendale, California 91204 (PHARMA-RX), an "unlicensed" pharmacy location. Numerous employees were processing prescriptions at PHARMA-RX , with no pharmacist present on-site. Inspector AY was informed that prescriptions were received electronically through e-mail accounts, then processed by the staff (prescription entry and adjudication) with the actual dispensing (filling, printing & labeling of containers with prescription labels) by the staff located at the licensed premise of KVP PHARMACY. Pharmacists at KVP PHARMACY then verify the furnished prescription. Said operation first started at PHARMA-RX approximately on mid-October of 2013. The printing of prescription labels were at PHARMA-RX and walked over to KVP PHARMACY for dispensing, in addition to the prescription entry and adjudication, however, was changed to the procedure set forth above by the end of October. Inspector AY took photographs and contacted Supervising Inspector J.D. KVP PHARMACY was issued an order for running an unlicensed pharmacy, pursuant to Code section 4110. Accordingly**, KVP PHARMACY was ordered to immediately cease pharmacy operations at the unlicensed pharmacy location** and transfer all records back to the licensed pharmacy premise by noon the following day. It should be noted that POGOSYAN was the designated representative-in-charge of PHARMA-RX.

FORTY SEVENTH CAUSE FOR DISCIPLINE

(Unlicensed Activity)

203. Respondent KVP PHARMACY is subject to disciplinary action under section 4110 of the Code which provides that no person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the Board. A license shall be required for

each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. On November 19, 2013, an inspection of an unlicensed location (Pharma-RX) acting as a pharmacy revealed that KVP PHARMACY was conducting, operating, acting, practicing as a pharmacy at Pharma-RX located at 412 W. Broadway, Suite 200, Glendale, CA 91024. The inspection revealed that pharmacy staff, without the presence and supervision of a pharmacist, received prescription orders from physicians which were then processed to be filled at the licensed pharmacy (KVP PHARMACY). Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 134 through 137, as though set forth fully.

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DRUG TESTING

204. On November 19, 2013, Inspector A.Y. and Inspector J.W. re-visited KVP PHARMACY to follow up on the complaint investigations. Inspector J.W. reviewed pharmacy records and the inventory of compounded drug production the pharmacy shelves. Inspector J.W. examined the pharmacy shelves for two compounded drug product combinations: (1) Ketamine / Flurbiprofen /Baclofen/Cyclobenzaprine/Lidocaine (KBCFL) and (2) Diclofenac/ Flurbiprofen/ Gabapentin/ Lidocaine (DFGL). Inspector J.W. located approximately 23 tubes or jars of DFGL compounded drug on the pharmacy shelves available for furnishing. He retrieved two binders consisting of testing reports and one binder of physician office use furnishing. Inspector J.W. reviewed the testing reports and tabulated the significant findings.

205. Inspector J.W. discovered that KVP PHARMACY maintained an area where retention samples of compounded drug product were kept in bins. Registered Pharmacist (RPH) Doostan stated that KVP PHARMACY retained approximately a 30-gram jar “quality control sample” of every batch of compounded drug product prepared. RPH Doostan added that these “quality control samples” were retained about six months (which corresponds to the beyond use dating on the compounded drug product) for random drug testing. Inspector J.W. asked Inspector A.Y. to randomly select samples (approximately 10 jars each) of three compounded drug

products for subsequent drug testing by the Board: (1) Ketamine / Baclofen / Cyclobenzaprine/ Flurbiprofen Gabapentin/ Lidocaine (KBCFGL); (2) Ketamine / Baclofen / Cyclobenzaprine/ Diclofenac/ Gabapentin/ Lidocaine (KBCDGL; and (3) Diclofenac/ Flurbiprofen Gabapentin/ Lidocaine (DFGL). Photographs were taken and the compounding records were retrieved. The evidence collected were checked with the Enforcement manager of the Board of Pharmacy and immediately checked out the document evidence for review and the drug evidence for transfer to the California Department of Public Health (CDPH).

206. On November 25, 2013, Inspector J.W. met with the Supervising Food and Drug Investigator J.H. to transfer the drug evidence. On March 25, 2014, Inspector J.W. received an e-mail from CDPH regarding the drug testing results of the samples provided to CDPH. The drugs tested included the compounded drugs obtained from KVP Pharmacy on 11/19/2013, CB cream dispensed as Rx643495 on 1/29/2013 by KVP Pharmacy, and 3 creams compounded by KVP obtain from the Ohio State Board of Pharmacy (related case CI 2013 58627). The result reports numerous compounded drugs with potency exceeding the +/- 10% as low as 48% and as high as 225% of the label strength by %. The Board's drug testing of compounded drug product continues to show deficiencies in the compounding processes of the pharmacy in ensuring the integrity, potency, quality and strength of said compounded drug products. The Table below is a summary of the compounded drugs the board obtained from KVP Pharmacy on 11/19/2013 that were sent to the California Department of Public Health, Food and Drug Laboratory Branch:

ketamine 10% / baclofen 2% / cyclobenzaprine 2% / flurbiprofen 10% / gabapentin 6% / lidocaine 5%

(KBCFGL)

labeled strength (%)			**2**		**2**		**6**		**10**		**5**		**10**	
potency +10%			2.2		2.2		6.6		11		5.5		11	
potency - 10%			1.8		1.8		5.4		9		4.5		9	
Lot #	Date Made	Expiration	bacl ofen	potency (%)	cycloben zaprine	potency (%)	gabape ntin	potency (%)	keta mine	poten cy (%)	lidoc aine	potency (%)	flurbi profe n	poten cy (%)
c3172	11/6/2013	5/6/2014	3.7	**185**	2.4	**120**	6.6	110	9.6	96	6.1	**122**	11.1	**111**
c2944	10/1/2013	4/4/2014	2.6	130	2.2	110	5.8	96.667	8.5	85	5.3	106	13.3	133

c2816	9/16/2013	3/16/2014	1.9	95	1.6	80	4.9	81.667	7.5	75	4.9	98	10.5	105
c2708	9/3/2013	3/3/2014	2.6	130	2.6	130	6.6	110	9.5	95	5.9	118	14.6	146
c2580	8/19/2013	2/19/2014	2.7	135	1.7	85	4.9	81.667	7.2	72	4.8	96	11.3	113
c2444	8/1/2013	2/1/2014	2.5	125	2	100	5.4	90	7.8	78	5.1	102	10.9	109
c2431	7/30/2013	1/30/2014	2.6	130	1.6	80	4.7	78.333	7.1	71	4.7	94	10.4	104
c2297	7/11/2013	1/1/2014	2.5	125	1.9	95	4.7	78.333	7.1	71	4.7	94	10	100
c2190	6/27/2013	12/27/2013	2.6	130	2.3	115	6.2	103.33	8.2	82	5.1	102	14.5	145
c2128	6/19/2013	12/19/2013	3	150	2	100	5.6	93.333	7.9	79	5.1	102	12.5	125

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iclofenac 10% / flurbiprofen 10% / gabapentin 10% / lidocaine 5%

(DFGL)

labeled strength (%)			10		5		10		10	
potency +10%			11		5.5		11		11	
potency - 10%			9		4.5		9		9	
Lot #	Date Made	Expiration	gabapentin	potency (%)	lidocaine	potency (%)	diclofenac	potency (%)	flurbiprofen	potency (%)
c3052	10/15/2013	4/15/2014	8	80	4.5	90	10.4	104	13.4	134
c2817	9/16/2013	3/16/2014	9.7	97	5.2	104	11.3	113	14.3	143
c2768	9/10/2013	3/10/2014	9.4	94	5.2	104	11.1	111	14.5	145
c2615	8/21/2013	2/21/2014	10	100	5.6	112	9	90	11.9	119
c2443	8/1/2013	2/1/2014	8.7	87	4.8	96	11.4	114	12.7	127
c2174	6/25/2013	12/25/2013	9.4	94	5.2	104	11.4	114	14.4	144
c2273	7/9/2013	1/9/2014	9.1	91	5	100	10.4	104	13.3	133
c2380	7/23/2013	1/23/2014	8.9	89	4.9	98	9.8	98	12.7	127
c2027	6/7/2013	12/7/2013	9.1	91	5.1	102	10.2	102	13	130
c1978	5/31/2013	12/1/2013	9.3	93	5.1	102	11.6	116	14.7	147

ketamine 10% / baclofen 2% / cyclobenzaprine 2% / diclofenac 3% / gabapentin 6% / lidocaine 2%

(KBCDGL)

labeled strength	2		2		6		10		2		3	

(%)														
potency +10%			2.2		2.2		6.6		11		2.2		3.3	
potency - 10%			1.8		1.8		5.4		9		1.8		2.7	
Lot #	Date Made	Expiration	Baclofen	potency (%)	cyclobenzapri ne	potency (%)	gabapentin	potency (%)	ketamine	potency (%)	lidocaine	potency (%)	diclofenac	potency (%)
c2902	9/26/2013	3/26/2014	2.9	**145**	2	100	4.9	**81.667**	**6.5**	**65**	2.1	105	2.9	96.667
c2984	10/4/2013	4/4/2014	2.4	**120**	1.9	95	**5.2**	**86.667**	**6.8**	**68**	2.2	110	3	100
c2649	8/26/2014	2/26/2014	2.7	**135**	2	100	5.5	91.667	**7.3**	**73**	2.8	**140**	3	100
c2726	9/4/2013	3/4/2014	2.7	**135**	1.8	90	**5.3**	88.333	**7.1**	**71**	2.2	110	3	100
c2387	7/24/2013	1/24/2014	3.7	**185**	2.8	**140**	7.6	**126.67**	10	100	3.3	**165**	3	100
c3058	10/16/2013	4/16/2014	4.5	**225**	1.9	95	**5.2**	**86.667**	**6.9**	**69**	2.2	110	3.1	103.33
c2447	8/1/2013	2/1/2014	2	100	2	100	**5.3**	**88.333**	**7.9**	**79**	2.2	110	2.9	96.667
c2300	7/12/2013	1/24/2014	2.5	**125**	2.1	105	5.5	91.667	**8.3**	**83**	2.3	**115**	3	100
c2186	6/26/2013	12/26/2013	2.6	**130**	2.1	105	**5.2**	**86.667**	**7.5**	**75**	2.2	110	2.9	96.667
c2091	6/14/2013	12/14/2013	3.3	**165**	2.5	**125**	6.4	106.67	9.6	96	2.7	**135**	3.1	103.33

diclofenac 10% / flurbiprofen 10% / gabapentin 10% / lidocaine 5%

(DFGL)

labeled strength (%)			**10**		**5**		**10**		**10**	
potency +10%			11		5.5		11		11	
potency - 10%			9		4.5		9		9	
Lot #	Date Made	Expiration	gabapentin	potency (%)	lidocaine	potency (%)	diclofenac	potency (%)	flurbiprofen	potency (%)
RX# 651383		8/25/2013	11	110	6.1	**122**	10.2	102	13.3	**133**

ketamine 10% / gabapentin 6% / baclofen 2% / cyclobenzaprine 2% / lidocaine 5% / flurbiprofen 10%

(KGBCLF)

labeled strength (%)			**2**		**2**		**6**		**10**		**5**		**10**	
potency +10%			2.2		2.2		6.6		11		5.5		11	
potency - 10%			1.8		1.8		5.4		9		4.5		9	
Lot #	Date	Expiration	baclofe	pote	cyclobenzapri	poten	gabapent	poten	ketamin	potenc	lidoca	potenc	flurbiprof	pote

	Made		n	ncy (%)	ne	cy (%)	in	cy (%)	e	y (%)	ine	y (%)	en	ncy (%)
c1204		7/1/2013	3.1	155	2.1	105	5.7	95	8.4	84	2.4	48	11.4	114

	Number of compounded drug products with over-potent ingredient(s)	Number of compounded drug products with under-potent ingredient(s)	Number of compounded drug products with over-potent and under-potent ingredient(s)
Number of samples from KBCFGL group	2	1	7
Number of samples from DFGL group	8	0	2
Number of samples from KBCDGL group	2	1	7
DFGL sample	1		
KGBCLF			1

FORTY EIGHT CAUSE FOR DISCIPLINE

(Drugs Lacking Quality or Strength)

207. Respondent KVP PHARMACY is subject to disciplinary action under section 4342 of the Code and sections 1735.8, subsection (a), and section 1735.1, subsection (c) of the California Code of Regulations in that the Board's subsequent analysis of compounded drug products (30 out of 34 samples were tested) retrieved from KVP PHARMACY revealed that said samples were (1) over-potent in their active ingredient(s) beyond the +10% of the labeled amount; (2) under-potent in their inactive ingredient(s) below the -10% of the labeled amount; (3) over-potent and under-potent in their active ingredient(s) beyond and below the +/_ 10% of the labeled amount. Further, samples retrieved from two complainants were also tested which revealed one sample over-potent in their active ingredient(s) beyond the +/-10% of the labeled amount. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 204, 123 through 165, 210 through 215, as though set forth fully.

FORTY NINTH CAUSE FOR DISCIPLINE

(Failure to Maintain Current Inventory)

208. Respondent KVP PHARMACY is subject to disciplinary action under section 1718, of the California Code of Regulations, in conjunction with section 4081, subsection (a) of the Code, which requires pharmacies to maintain complete accountability of all controlled substances and/or dangerous drugs. A subsequent verification audit of 22 month period from September 3, 2011 to July 21, 2013 revealed that KVP PHARMACY could not account for the loss of controlled substances and/or dangerous drugs of approximately 3,599 dosage of Hydrocodone/apap 10 mg/325 mg. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 204, 123 through 165, 210 through 215, as though set forth fully.

FIFTIETH CAUSE FOR DISCIPLINE

(Unsecure Pharmacy)

209. Respondent KVP PHARMACY is subject to disciplinary action under section 1714, subsection (b) of the California Code of Regulations which requires pharmacies to maintain an effective control on the security of the prescription department against the theft or loss of controlled substances and/or dangerous drugs. A subsequent verification audit of 22 month period from September 3, 2011 to July 21, 2013 revealed that KVP PHARMACY could not account for the loss of controlled substances and/or dangerous drugs of approximately 3,599 dosage of Hydrocodone/apap 10 mg/325 mg. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 204, 123 through 165, 210 through 215, as though set forth fully.

PIC LIAO'S ADMISSION AND DECLARATION

210. On March 18, 2014, Investigator J.W. met with PIC LIAO to discuss KVP PHARMACY. PIC LIAO stated that she was employed at KVP PHARMACY from December of 2012 to July of 2013. She resigned from KVP PHARMACY due to KVP PHARMACY's failure to stop furnishing prescriptions to out-of-state patients and/or physicians and lack of licensure in those states. PIC LIAO worked as a staff pharmacist under PIC ABEDI where she mainly verified prescriptions, provided consultations, and oversaw compounding. She stated that she was not involved in the prescription typing and processing aspect.

211. PIC LIAO was asked to describe the physician office use drugs, in particular their reference as "drug samples" and whether physicians were charged for them. PIC LIAO stated that KVP PHARMACY would receive prescription orders from the physicians similar to a patient specific prescription. PIC LIAO was not clear during said conversation since early on she stated that they were not drug "samples" and that the physicians were charged for them, however, later on, she stated she didn't know whether the physicians were charged for them or not.

212. PIC LIAO indicated that the so-called drug representatives would call KVP PHARMACY and asked questions about the compounded drugs. PIC LIAO was asked about her understanding of the auto-refills and she remembered patients calling and complaining about the unwanted medications. She told KVP PHARMACY's management that they should not be refilling prescriptions without contacting the patient first to verify.

213. PIC LIAO sated that she didn't know whether KVP PHARMACY had licenses in other states and was told by KVP PHARMACY's management that KVP PHARMACY was working on it. PIC LIAO sated that she told KVP PHARMACY's management that KVP PHARMACY had to stop shipments until KVP PHARMACY became licensed, however, KVP PHARMACY's management didn't want to stop.

214. PIC LIAO was questioned about the drug testing results and she stated that the drug testing results would go to KVP PHARMACY's management and had only resumed when she assumed the role of PIC, however, any corrective actions taken was non-existent.

215. PIC LIAO provided a written statement stating the following:

- I had become a staff pharmacist for KVP PHARMACY through RX Relief late 2012. The pharmacy was operating at a much smaller scale, then. As it grew in the later months, toward to the time I decided to resign (late June or early July of 2013), I started to see larger issues. As a staff I worried about drug consistency, patient consultations, and regular duties as a staff pharmacist. In the later months I was with KVP PHARMACY, the volume of prescriptions significantly increased, most likely due to KVP PHARMACY's involvement with several marketing groups consisting of representatives in various states. When

questioning why they were increased volume out-of-state prescriptions, I was told the licenses were taken care of, as there are lawyers and other pharmacists as part of the team."

- As the original PIC (PIC ABEDI) was fired, I was asked to be the PIC. I was not aware of a lot of issues I had later discovered. My main concerns for the pharmacy were the usual daily responsibilities the pharmacy could improve, such as bookkeeping, maintaining inventory, compounded drug consistencies, etc., and PIC duties for compliance by the Board of Pharmacy. However, through my calls and correspondences with a few doctors' offices, I discovered that KVP PHARMACY was not licensed in several states they were sending medications to. I then told the owner and management that all the shipping out-of-state had to be stopped, and that all physicians or prescribers need to be informed, and that they should only ship to those states after making sure that licenses were obtained. I stopped signing off prescriptions that went out of state. When I felt that they were not informing the physicians about their state licensure, I decided to resign.
- Another new issue was that after KVP PHARMACY expanded the "office use" prescriptions were sent to physicians. They all came with prescriptions, and office use medications came to be used with patients at the doctor's offices, and the ordering physicians were charged with a fee (office use medications were not given out as free "samples".) This falls into a grey area of pharmacy practice and was also one of the contributing factor of my resignation.
- The pharmacy was compartmentalized and I mainly dealt with the dispensing, patient consultation and compounded drug consistency issues. As I became the PIC, I realized many of the concerns were addressed but could not be easily improved, as the pharmacy owner verbally had told me he only wanted the medications sent out, he didn't care much for the other issues such as patient safety. This is completely opposite of my personal and professional beliefs, as I only wanted to make sure my patients and their well-being taken care of, and that

I would treat them the way I wanted my family to be treated. The compartmentalized operation of the pharmacy and the lack of transparency for the pharmacists makes it very difficult to provide good and ethical patient care on my end: Instances where I would never know if the medications were auto-refilled without patient's consent because such calls were most likely filtered by other departments before getting to me. I was not allowed a thorough aspect of patient care, another contributing factor of my resignation.

- During my short period as the PIC, I had brought up the issues and started working on drug testing, as the previous PIC was fired and I wasn't sure if she was properly submitting drug samples for potency testing, analysis, etc. Again the importance of such practices was not very much understood and respected, as the non-pharmacist owner(s) did not understand the gravity of such tests.
- Before taking on the PIC duties, I had felt issues were smaller issues that can be improved, even though the previous PIC was not very proactive in implementing complaint, constructive changes and I had to bring up my concerns directly to management (such as lot number, record keeping, etc). However, after being PIC for a brief period of time, the issues I discovered were faced a lot of inertia for changes for correct and ethical pharmacy practice, as the company was not transparent, leaving the PIC being caught in the situation of wanting to provide patient safety but was unable to do so, also because they were not given true information.
- I had resigned because I only wanted to provide good service and patient safety. All the information provided on my end is sincerely true and I am willing to further assist the investigation.

FIFTY FIRST CAUSE FOR DISCIPLINE

(Strict Liability)

216. Respondent PIC LIAO is subject to disciplinary action under sections 4081[13], 4113, subdivision (c) and 4036.5 of the Code, in that PIC LIAO is strictly liable as a Pharmacist in charge for KVP PHARMACY, for shipping approximately 3,700 prescriptions (dangerous drugs, controlled substances) to 41 states, without appropriate licensure. As the pharmacist-in-charge, PIC LIAO was responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. A Pharmacist-in-charge as the supervisor or manager of a pharmacy is responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. The pharmacist-in-charge is responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 165, 210 through 215, as though set forth fully.

FIFTY SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

217. Respondent PIC LIAO is subject to disciplinary action under sections 4306.5 and 4301, subsection (j) of the Code, in that PIC LIAO, as a Pharmacist in charge for KVP PHARMACY, shipped approximately 3,700 prescriptions (dangerous drugs, controlled substances) to 41 states, without appropriate licensure. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 165, 210 through 215, as though set forth fully.

FIFTY THIRD CAUSE FOR DISCIPLINE

(Strict Liability)

218. Respondents PIC ABEDI and PIC CUMMINGS are subject to disciplinary action under sections 4081[14], 4113, subdivision (c) and 4036.5 of the Code, in that PIC ABEDI is strictly liable as a Pharmacist in charge for KVP PHARMACY, for shipping approximately

[13] *Sternberg v. California Board of Pharmacy* (2015) 239 Cal.App.4th 1159.
[14] *Sternberg v. California Board of Pharmacy* (2015) 239 Cal.App.4th 1159.

13,343 prescriptions (dangerous drugs, controlled substances) to 42 states, without appropriate licensure, and that that PIC CUMMINGS is strictly liable as a Pharmacist in charge for KVP PHARMACY, for shipping approximately 83 prescriptions (dangerous drugs, controlled substances) to 10 states, without appropriate licensure. As the pharmacist-in-charge, PIC LIAO was responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. A Pharmacist-in-charge as the supervisor or manager of a pharmacy is responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. The pharmacist-in-charge is responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 165, 210 through 215, as though set forth fully.

FIFTY FORTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

219. Respondent PIC LIAO and PIC CUMMINGS are subject to disciplinary action under sections 4306.5 and 4301, subsection (j) of the Code, in that PIC ABEDI is strictly liable as a Pharmacist in charge for KVP PHARMACY, for shipping approximately 13,343 prescriptions (dangerous drugs, controlled substances) to 42 states, without appropriate licensure, and that that PIC CUMMINGS is strictly liable as a Pharmacist in charge for KVP PHARMACY, for shipping approximately 83 prescriptions (dangerous drugs, controlled substances) to 10 states, without appropriate licensure. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 123 through 165, 210 through 215, as though set forth fully.

OWNERSHIP PROHIBITION

220. Business and Professions Code section 4307(a) provides, in pertinent part that any person whose license has been revoked or is under suspension shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate or partner of a licensee.

221. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50535 issued to KVP PHARMACY, and Khachatur Pogosyan (POGOSYAN) while acting as the manager, administrator, owner, member, officer, director, associate, or partner of KVP PHARMACY, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 50535 issued to KVP PHARMACY was revoked, suspended or placed on probation, POGOSYAN 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 50535, issued to KVP PHARMACY is placed on probation or until Pharmacy Permit Number PHY 50535, issued to KVP PHARMACY is reinstated if it is revoked.

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DISCIPLINE CONSIDERATIONS AGAINST KVP PHARMACY

222. To determine the degree of discipline, if any, to be imposed on Respondent KVP PHARMACY, Complainant alleges that on or about June 12, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 48774 and ordered Respondent KVP PHARMACY to restrict the possession of a key to the pharmacy where dangerous drugs are stored to a pharmacist and imposed a penalty of $500 for violating California Code of Regulations, Title 16, Section 1714 subdivisions (b) and (e). That Citation is now final and is incorporated by reference as if fully set forth.

DISCIPLINE CONSIDERATIONS AGAINST PAUL CUMMINGS

223. To determine the degree of discipline, if any, to be imposed on Respondent CUMMINGS, Complainant alleges that on or about June 7, 2011, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 48428 and ordered Respondent CUMMINGS the followings:

a. Not to exceed 180 days beyond the use date of the compounded drug product. The Board imposed a penalty of $750 for violating California Code of Regulations, Title 16, Section

1735.2 subdivision (h). That Citation is now final and is incorporated by reference as if fully set forth;

b. Document the name of the compounding individual or the name of the verifying pharmacist for the compound prepared in the compounding worksheets. The Board imposed a penalty of $500 for violating California Code of Regulations, Title 16, Section 1735.3 subdivision (a)(3). That Citation is now final and is incorporated by reference as if fully set forth;

c. Prescriptions to contain a written notice of the patients' right to consultation. The Board imposed a penalty of $750 for violating California Code of Regulations, Title 16, Section 1707.2, subdivision (B)(2)(A). That Citation is now final and is incorporated by reference as if fully set forth;

d. A pharmacy with only one pharmacist shall have no more than one pharmacy technician and any additional pharmacist shall not exceed 1:2. The Board imposed a penalty of $500 for violating Business and Professions Code section 4115, subdivision (f)(1). That Citation is now final and is incorporated by reference as if fully set forth.

224. To determine the degree of discipline, if any, to be imposed on Respondent CUMMINGS, Complainant alleges that on or about July 12, 2012, in a prior action, the Board of Pharmacy issued Citation Number CI 2010 48428 and ordered Respondent CUMMINGS the following:

a. To restrict the possession of a key to the pharmacy where dangerous drugs are stored to a pharmacist and imposed a penalty of $500 for violating California Code of Regulations, Title 16, Section 1714 subdivisions (b) and (e). That Citation is now final and is incorporated by reference as if fully set forth.

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 50535, issued to KVP Pharmacy, Inc.;

2. Revoking or suspending Designated Representative License Number EXC 19398,

7. Ordering KVP Pharmacy, Inc., Paul Cummings, Karolin Abedi and Pamela Liao 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;

8. Prohibiting Khachatur Pogosyan from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50535 to KVP Pharmacy, Inc. is placed on probation or until Pharmacy Permit Number PHY 50535 to KVP Pharmacy, Inc. is reinstated if Pharmacy Permit Number PHY 50535 to KVP Pharmacy, Inc. is revoked;

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

DATED: 11/12/15

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

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