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

In the Matter of the Accusation Against:	Case No. 5455
FARBOD MELAMED	OAH No. 2016050689
Pharmacist License No. RPH 68252	
Respondent.	

NOTICE OF DECISION AND ORDER

No action having been taken and processed timely on the attached Proposed Decision, pursuant to Government Code section 11517(c)(2) the attached decision is hereby deemed adopted by operation of law, by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in the above entitled matter.

Pursuant to Government Code section 11519, this Decision shall become effective at 5:00 p.m. on October 18, 2017.

Date September 18, 2017

Virginia Herold

VIRGINIA K. HEROLD, EXECUTIVE OFFICER
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

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

In the Matter of the Accusation Against:	
FARBOD MELAMED	Board Case No. 5455
Pharmacist License No. RPH 68252,	OAH No. 2016050689
Respondent.	

ORDER REJECTING PROPOSED DECISION AND PROPOSING WAIVER OF TRANSCRIPT

Pursuant to Government Code section 11517, subdivision (c), the Proposed Decision of the Administrative Law Judge in the above-entitled case is rejected. The California State Board of Pharmacy will decide the case upon the record, and upon such written argument as the parties may wish to submit.

The right to argue on any matter is limited to the facts as presented in the record. However, the board is especially interested in arguments as to whether, in order to protect the public, respondent should be prohibited from serving as a pharmacist in charge, consultant pharmacist, or a designated representative in charge during a probationary period. Stated alternately, the question is whether the board's standard term regarding such matters (Standard Term 7 from its Disciplinary Guidelines) should be imposed. (Disciplinary Guidelines, rev. 10/2007, p. 24.)

The board believes the issue above may be addressed without a review of the transcript of the hearing held. Unless the parties object in writing, it will be assumed the parties stipulate that the board may decide the case upon the record without including the transcript. The record will also include any written argument as the parties may wish to submit. In the event any party objects to not ordering the transcript, it should file a notice of objection to the stipulation by **April 28, 2017**, with a copy to the other party. The notice of objection may be served on the board at **1625 N. Market Blvd, Suite N219, Attention Susan Cappello, Enforcement Manager**.

If no party objects to the stipulation regarding the transcript, the parties shall have until **May 15, 2017**, to submit written argument.

In the event any party objects to the stipulation, the transcript will be ordered and the parties will be notified of a revised date for submission of such argument when the transcript of

the above-mentioned hearing becomes available. In that case, a copy of the record will be provided to you at the time of notification of the final filing date for written argument (the board may require payment of fees to cover the copying and mailing costs of the transcript and exhibits).

IT IS SO ORDERED this 17th day of April, 2017.

By _____

Amarylis "Amy" Gutierrez, Pharm.D.
Board President
California State Board of Pharmacy

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

In the Matter of the Accusation Against: FARBOD MELAMED, Pharmacist License No. 68252 Respondent.	Case No. 5455 OAH No. 2016050689

PROPOSED DECISION

John E. DeCure, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter on November 15, 2016, in Los Angeles.

Antonio Lopez, Jr., Deputy Attorney General, represented Virginia K. Herold (complainant), Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

Respondent Farbod Melamed (respondent), the pharmacist-in-charge (PIC) of Roxsan Pharmacy, Inc., was present and represented by Ivan Petrzelka, Attorney at Law, and Tony Park, Attorney at Law.

The Accusation was originally filed against respondent and two other respondents: Roxsan Pharmacy, Inc. (Roxsan), Pharmacy Permit number PHY 38297; and Shahla Keyvanfar Melamed (Shahla Melamed), Pharmacist License number RPH 42096. However, prior to the administrative hearing Roxsan and Shahla Melamed surrendered their licenses.

Evidence was taken and argument was heard.

At the administrative hearing the parties made a joint request for a protective order sealing confidential records contained in complainant's Exhibit 6 and in respondent's Exhibit B. These records contained medical and/or personal information primarily in the form of pharmacy records obtained from respondent during complainant's investigation, and other pharmacy records submitted by respondent in defense of the Accusation. The parties sought to protect these documents from disclosure to protect patient privacy and confidentiality, and asserted that the documents were so voluminous as to make redaction unduly burdensome. In *NBC Subsidiary (KNBC-TV), Inc. v. Superior Court* (1999) 20 Cal.4th 1178, the California Supreme Court set forth the findings that both the trial and appellate courts must expressly make to seal a record. Courts must find that (1) there is an overriding interest

supporting sealing records; (2) there is a substantial probability that the interest will be prejudiced absent sealing; (3) the proposed sealing is narrowly tailored to serve the overriding interest; and (4) there is no less restrictive means of achieving the overriding interest. (*Ibid* at 1217-1218.) The parties met their burden to demonstrate that there was no less restrictive means of achieving the interest supporting sealing the records, which in this case is patient privacy. The documents are so voluminous that appropriate redactions to preserve patient privacy could not be made within a reasonable time, and the numerous redactions required would so deface the materials that they would lose their probative value. Complainant's and respondent's request to seal these records was granted. Thus, complainant's Exhibit 6 and respondent's Exhibit B shall be placed under seal following the use of the documents in preparation of the Proposed Decision. These exhibits shall remain under seal and shall not be opened except by order of the Office of Administrative Hearings or by a reviewing court.

The record was held open for respondent to provide additional evidence by November 22, 2016. Respondent timely submitted an inspection report, corrective action documentation, and award of accreditation from United Compounding Management (UCM) to Roxsan Pharmacy dated July 21, 2016. These documents were marked collectively as respondent's Exhibit L. Complainant was given until November 29, 2016, to lodge any objections, but complainant did not object. Exhibit L was received in evidence, the record was closed and the matter was submitted on November 29, 2016.

FACTUAL FINDINGS

Jurisdiction

1. Complainant filed the Accusation in her official capacity. Respondent timely filed a notice of defense.

2. The Board issued Pharmacist License Number RPH 68252 to respondent on October 5, 2012. The license will expire on December 31, 2017, unless renewed.

Stipulation to Undisputed Facts

3. On November 9, 2016, the parties executed a written Stipulation Re Undisputed Facts for Hearing (stipulation) in which respondent admitted to the truth and accuracy, and further admitted to culpability as alleged, regarding the Seventh, Eighth, Ninth, Tenth, and Eleventh Causes for Discipline contained in the Accusation. (Exhibit 4.) Those causes for discipline directly referenced an underlying "Statement of Facts" that preceded the causes for discipline in the Accusation. Thus, by assenting to the stipulation, respondent also did not dispute the facts alleged in paragraphs 2, 4, and 57 through 144 of the "Statement of Facts."

The underlying factual basis and causes for discipline state as follows:[1]

57. The Board received the first complaint on June 9, 2011. In substance, the complainant alleged that on February 21, 2011, Roxsan Pharmacy substituted an inappropriate device for injecting a drug marketed under the name "Omnitrope." Omnitrope is indicated for growth hormone deficiency and has an off-label use of improving female fertility. The Board investigated the complaint and conducted an inspection of Roxsan Pharmacy on June 23, 2011. The relevant findings are alleged in Section A, below.

58. The second consumer complaint came to the Board on July 27, 2011. The complainant alleged that Roxsan Pharmacy dispensed Domperidone to nursing mothers to enhance breast milk production. Domperidone is approved in some countries for gastrointestinal disorders. The United States Food and Drug Administration, the federal agency responsible for reviewing new drug applications, has not approved Domperidone for any purpose in this country and has banned the drug's importation and interstate transfer except for research purposes. The Board inspected Roxsan Pharmacy on September 15, 2011. The relevant findings are alleged in Section B, below.

59. The Board received the third consumer complaint on February 21, 2013. The complainant alleged that Roxsan Pharmacy sold dangerous drugs and controlled substances to Louisiana residents without being licensed in that state, as Louisiana law requires. The Board inspected Roxsan Pharmacy on June 4, 2013. The relevant findings are alleged in Section C, below.

60. The fourth consumer complaint came to the Board on September 24, 2013. The complainant alleged that Roxsan Pharmacy dispensed prescriptions to consumers in Connecticut without being licensed in that state, as Connecticut law requires. The Board inspected Roxsan Pharmacy on November 5, 2013. The relevant findings are alleged in Section D, below.

61. The Board learned of the fifth complaint on September 25, 2013. The Arkansas State Board of Pharmacy alleged that Roxsan Pharmacy dispensed prescriptions to consumers in

[1] All stipulated facts are numbered and set forth verbatim as they appear in the Accusation.

Arkansas without being licensed in that state, as Arkansas law requires. The Board inspected Roxsan Pharmacy on November 5, 2013. The relevant findings are alleged in Section E, below.

62. The sixth consumer complaint came from the California State Health and Human Services Agency, Department of Health Care Services ("Department of Health Care Services"). The Board received the complaint on September 27, 2013. The Department alleged that Roxsan Pharmacy did not maintain original prescription records for certain dispensed drugs. The Board investigated the complaint and inspected the pharmacy on November 5, 2013. The relevant findings are alleged in Section F, below.

63. The seventh consumer complaint came to the Board on December 2, 2013. The complainant alleged that Roxsan Pharmacy dispensed the wrong dose of Leuprolide. The Board investigated the complaint. The relevant findings are alleged in Section G, below.

64. The Board received the eighth consumer complaint on April 16, 2014. The complainant alleged that Roxsan Pharmacy dispensed dangerous drugs to consumers in Florida and Maryland without being licensed in those states. The Board investigated the complaint. The relevant findings are alleged in Section H, below.

65. The final consumer complaint reached the Board on August 11, 2014. The Board launched an investigation, during the course of which it was revealed that Roxsan Pharmacy had applied an incorrect expiration date to a Progesterone prescription. The relevant findings are alleged in Section I, below.

A. <u>Omnitrope Complaint and Pharmacy Inspection on June 23, 2011</u>

66. On December 9, 2010, a San Francisco-based fertility doctor prescribed Omnitrope (somatropin) 5mg per 1.5ml to one of her patients. Omnitrope is a recombinant human growth hormone indicated for the treatment of adult onset or childhood onset growth hormone deficiency. It is dispensed in cartridges holding doses of 5mg per 1.5ml or 10mg per 1.5ml. The cartridges are designed by the manufacturer, Sandoz, to be used with its own dispensing pens, Pen 5 and Pen 10. Each pen is

specific to the prescribed dose—Pen 5 for 5mg prescriptions and Pen 10 for 10mg prescriptions. Sandoz supplies the pens to patients free of charge upon the prescriber's request. In Omnitrope's published drug information, Sandoz warns against using non-proprietary devices to dispense the medication, stating that Omnitrope cartridges "must be used with the corresponding OMNITROPE® Pen 5 and Pen 10 delivery system, respectively."

67. The Follistim Pen is a dispensing device made by Merck. It is designed to inject precise doses of Merck's Follistim AQ (follitropin beta) drug. Follistim AQ is a gonadotropin that stimulates reproductive processes in women. Follistim AQ is indicated for the induction of ovulation and pregnancy and development of multiple follicles for patients in assisted reproductive programs. Merck sells the drug in cartridges dosed in international units (IU). Follistim AQ is available in strengths of 175 IU per 0.210ml, 350 IU per 0.420ml, 650 IU per 0.780ml, and 975 IU per 1.170ml. Merck's patient information guide advises patients not to "mix any other medicines into the cartridge" and directs patients to "[u]se [the] "Follistim AQ Cartridge only with the Follistim Pen."

68. On February 21, 2011, Roxsan Pharmacy received a faxed prescription for Omnitrope. Pharmacist J.A. (not a party to this action) dispensed the Omnitrope cartridge (5mg per 1.5ml) that day and substituted a Follistim Pen for the Omnitrope Pen 5. Roxsan Pharmacy and the dispensing pharmacist did not instruct the patient on how to convert milliliters (Omnitrope Pen) into international units (Follistim Pen) or otherwise provide adequate use instructions.

69. The patient was unable to use the Follistim pen dispensed by Roxsan Pharmacy and obtained the Omnitrope Pen 5 from her fertility clinic. Roxsan Pharmacy never replaced the Follistim pen with a suitable dispensing device.

70. On June 9, 2011, the patient's partner filed a complaint with the Board over the substitution of the Follistim pen. On June 23, 2011, a Board inspector conducted a complaint inspection of Roxsan Pharmacy at its Beverly Hills location. The inspector documented the following relevant facts:

1. A Pharmacist Falsified a Prescription Record

71. As part of the inspection into the Omnitrope consumer complaint, the inspector asked for all pharmacy records related to the dispensing of the patient's Omnitrope prescription. The dispensing pharmacist, J.A., produced records that showed the prescription was written on December 9, 2010 for "Omnitrope Pen 5 (5mg/1.5ml)" in a quantity of five with one authorized refill. The prescription was typed and contained instructions to "dispense as written." The words "Foll Pen #1 per MD" appeared, handwritten, on the right side of the prescription. The dispensing pharmacist told the inspector that the physician verbally authorized the substitution.

72. The inspector noticed that the handwritten portion of the order, which purported to reflect the physician's order for the substitution, was wet. To test her belief, she ran her finger across the ink. The order smeared. The dispensing pharmacist admitted that she wrote the order for the substitution during the inspection.

73. By letter dated July 6, 2011, the prescribing doctor denied having authorized the Follistim Pen's substitution.

2. Pharmacist-in-Charge Shahla Melamed Falsified the DEA Biennial Controlled Substance Inventory

74. Later in the inspection, the Board inspector requested the pharmacy's federal Drug Enforcement Administration biennial controlled substance inventory. Pharmacist K.B. (not a party to this action) produced a spiral notebook containing handwritten controlled substance counts. The dates of the inventories were June 7, 2007, May 6, 2009 and June 1, 2011. For the biennial periods ending in 2007 and 2009, the inventories included Schedule II through V controlled substances. For the period ending in 2011, the inventory recorded only Schedule II controlled substances; missing were drug counts for Schedule III through V controlled substances.

75. At some point during the inspection, Respondent Shahla Melamed, the Pharmacist-in-Charge, arrived at the pharmacy. The Board inspector asked her for the pharmacy's self assessment and DEA inventory. Respondent Shahla Melamed produced the same spiral notebook as before. The inspector noticed that within the 2009 inventory, the header had

been changed to include the date of June 1, 2011 for Scheduled drugs not listed in the 2011 inventory. The Board inspector asked Respondent Shahla Melamed if she added the 2011 date to the 2009 inventory. After first denying the charge, Respondent Shahla Melamed admitted adding "6/1/11" to the 2009 controlled substance inventory. The modification gave the appearance that Roxsan Pharmacy maintained a count of Schedule III through V controlled substances for the biennial reporting period ending in 2011.

3. Roxsan Pharmacy Did Not Perform End-Product Sterility and Pyrogen Testing on Sterile Injectable Products or Keep Temperature Records

76. While evaluating the pharmacy's sterile compounding practice, the Board inspector discovered that Roxsan Pharmacy compounded injectable alprostadil alcohol solution on March 30, 2011 and June 2, 2011, and also prepared mitomycin injectable solution on February 14, 2011. Roxsan Pharmacy did not conduct end-product sterility and pyrogen testing on either solution to ensure safe use. Nor did the pharmacy maintain temperature records for the freezer used to store these and other sterile injectable solutions.

4. Roxsan Pharmacy Did Not Verify All Pharmacy Technician Work, Did Not Ensure that Each Pharmacy Technician Was Wearing Identification, and Maintained 17 Expired Ingredients in Active Compounding Stock

77. In addition to having deficient practices concerning sterile injectable products, Roxsan Pharmacy comingled 17 expired compounding ingredients with active compounding stock and permitted two of its pharmacy technicians to be present in the compounding area without wearing identification badges. The Board inspector found 14 medication bubble cards prepared by pharmacy technicians that did not contain a pharmacist's initials indicating that a pharmacist had verified the technician's work.

B. <u>Domperidone Complaint and Inspection on September 15, 2011</u>

78. On July 28, 2011, the Board received a complaint alleging that Roxsan Pharmacy dispensed Domperidone. Domperidone is a galactagogue, meaning it increases breast

milk production in lactating women. The drug is not approved in the United States for any purpose although it is approved in other countries for the treatment of gastrointestinal disorders. The FDA bans the importation and interstate transportation of finished products and bulk compounding ingredients containing Domperidone except for use in research and development.

79. On September 15, 2011, Board inspectors conducted a complaint inspection at Roxsan Pharmacy. They discovered compounded Domperidone in the pharmacy's inventory. The pharmacy possessed 100 10mg capsules, 200 20mg capsules, 200 30mg capsules and 100 40mg capsules of the drug. The pharmacy dispensed 452 prescriptions containing Domperidone in these various strengths between approximately August 4, 2005 and September 2, 2011.

80. Under its authority to embargo misbranded drugs, the Board seized the pharmacy's stock of Domperidone. (Bus. & Prof. Code, § 4084.)

C. Louisiana Complaint and Pharmacy Inspection on June 4, 2013

81. On February 21, 2013, the Louisiana Board of Pharmacy complained to the Board that Roxsan Pharmacy was soliciting business from Louisiana physicians and selling dangerous drugs and controlled substances in that state without proper licensure.

82. On June 4, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge. He admitted to the inspector that Roxsan Pharmacy dispensed and shipped dangerous drugs to patients in Louisiana without being licensed in that state.

83. From July 31, 2012 to June 6, 2013, Roxsan Pharmacy dispensed 22 original prescriptions and two refills to patients residing in Louisiana. All but one of the prescriptions contained ketamine, a Schedule III controlled substance.

84. The inspection further revealed that Roxsan Pharmacy established incorrect beyond-use dates for eight batch compounded drug products. In each case, the compounded drug product's expiration date exceeded the expiration date of one of its ingredients. Respondent Shahla Melamed verified the

products in question and Roxsan Pharmacy dispensed prescriptions from the stale batches.

D. Connecticut Complaint and Pharmacy Inspection on November 5, 2013

85. On September 24, 2013, a Connecticut consumer complained to the Board that Roxsan Pharmacy was dispensing prescriptions to consumers in Connecticut without being licensed in that state.

86. On November 5, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge.

87. From May 21, 2012 to June 14, 2013, Roxsan Pharmacy dispensed 230 prescriptions to patients residing in Connecticut. During this period, Respondent Roxsan Pharmacy was not licensed in the state of Connecticut.

E. Arkansas Complaint and Pharmacy Inspection on November 5, 2013

88. On September 25, 2013, the Arkansas Board of Pharmacy complained to the Board that Roxsan Pharmacy was dispensing prescriptions to consumers in Arkansas without proper licensure.

89. On November 5, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge. He admitted that Respondent Roxsan Pharmacy shipped prescriptions into Arkansas without being licensed in that state.

90. From January 7, 2013 to June 11, 2013, Roxsan Pharmacy dispensed 16 original prescriptions to patients residing in Arkansas. During this period, Respondent Roxsan Pharmacy was not licensed in the state of Arkansas.

F. Department of Health Care Services Complaint and Pharmacy Inspection on November 5, 2013

91. Responding to a complaint from the Department of Health Care Services, the Board inspected Roxsan Pharmacy on November 5, 2013. On March 28, 2014, the Board inspector

asked for original prescription records for 41 prescriptions dispensed between June 1 and December 31, 2012. Roxsan Pharmacy produced six original dispensing records but did not have records for the remaining 35 prescriptions.

G. Leuprolide Complaint

92. On December 2, 2013, a patient filed a complaint with the Board after Roxsan Pharmacy filled her prescription in the wrong strength. In early 2014, the Board inspected Roxsan Pharmacy. The inspector documented the following relevant facts:

1. Variation from Leuprolide Prescription

93. On December 18, 2012, an Orange County-based fertility doctor prescribed Leuprolide acetate 40mcg/0.2ml to one of her patients undergoing in vitro fertilization ("IVF"). During an IVF cycle, different medications are used to control the menstrual cycle of the patient to allow for optimal stimulation of the ovaries. The physician directed the patient to use Leuprolide for ten to twelve days.

94. On December 18, 2012, Roxsan Pharmacy received a faxed prescription for diluted Leuprolide. Two days later, a pharmacist who is not a party to this action dispensed *full-strength* Leuprolide 1mg/0.2ml. The dispensed drug was not diluted as the prescription required.

95. The patient injected the dispensed medication each day for nine days before she consulted her fertility doctor, who discovered the pharmacy's error. The physician ended the IVF cycle because she believed that the incorrect dosage of Leuprolide had compromised the patient's treatment.

2. Roxsan Pharmacy Did Not Perform End-Product Sterility and Pyrogen Testing on Sterile Injectable Products

96. While evaluating the pharmacy's sterile compounding practice, the Board inspector discovered that from November 2012 to February 2013, Roxsan Pharmacy compounded twenty products from non-sterile sources. The compounded products were Cyanocobalmin and several batches of (separately) Leuprolide and Hyaluronidase. Roxsan Pharmacy failed to conduct pyrogen testing on all 20 products. It also failed to

conduct end-product sterility testing on 19 of the selfsame products. The one product that Roxsan Pharmacy *did* test for sterility was Leuprolide; however, the pharmacy failed to quarantine the product while it awaited test results.

97. On November 7, 14 and 19, 2012 and again on January 11, 2013, the pharmacy compounded bacteriostatic water (benzyl alcohol 0.9% injection) for use in sterile injectable solutions. The pharmacy prepared the bacteriostatic water with sodium chloride granules, a non-sterile ingredient. Roxsan Pharmacy did not conduct end-product sterility or pyrogen testing on the bacteriostatic water to ensure its sterility. It used the untested water to create injectable compounds that were sold and dispensed as sterile. Roxsan Pharmacy did not test any of the final compounds made from this untested bacteriostatic water.

98. From November 1, 2012, to March 22, 2013, Roxsan Pharmacy dispensed 474 compounded prescriptions made from non-sterile ingredients without subjecting the final product to end-product sterility and pyrogen testing.

H. Florida and Maryland Complaints

99. Roxsan Pharmacy dispensed 6,048 prescriptions for dangerous drugs to Florida residents from approximately January 10, 2012 to March 21, 2013. Of that number, 1,949 prescriptions contained ketamine, a Schedule III controlled substance. Roxsan Pharmacy also dispensed 3,516 prescriptions for dangerous drugs to Maryland residents from approximately February 9, 2012 to June 26, 2013. Of that number, 1,745 contained ketamine. Roxsan Pharmacy did not have a license in Florida or Maryland when it dispensed these prescriptions.

I. Progesterone Complaint

100. On August 11, 2014, a California consumer complained to the Board about a prescription of Progesterone 200 mg Gelatin Troche. On January 5, 2015, a Board inspector requested the master formula for the drug. From this she learned that Roxsan Pharmacy labeled the prescription with a beyond-use date greater than what the master formula supported. Roxsan Pharmacy did not conduct stability studies to justify its extended expiration date.

[¶ . . . ¶]

SEVENTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)
(As to Respondents Roxsan Pharmacy and Farbod Melamed)

114. Respondents Roxsan Pharmacy and Farbod Melamed are subject to discipline under section[2] 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, as follows:

115. **Regulation 1716**: Regulation[3] 1716 prohibits deviation from the requirements of a prescription except upon the prior consent of the prescriber or in accordance with section 4073 of the Code. Section 4073 allows a pharmacist to select a generic drug that boasts the same effectiveness as the brand name drug subject to the prescriber's order not to substitute. On December 18, 2012, Respondent Roxsan Pharmacy dispensed full-strength Leuprolide 1mg/0.2ml instead of the prescribed Leuprolide acetate 40mcg/0.2ml. Respondent Roxsan Pharmacy deviated from the requirements of the patient's prescription without prior prescriber consent and in violation of section 4073. Respondent Farbod Melamed was the Pharmacist-in-Charge at the time of the conduct in question and had the responsibility under Code sections 4036.5 and 4113, subdivision (c), to ensure that the dispensed medication conformed to the patient's prescription. Complainant realleges paragraphs 63, 92–95.

116. **Regulation 1735.2, subd. (h)**: Regulation 1735.2, subdivision (h), states that 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 cannot 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

---

[2] The Accusation uses the terms "section" and "Code" to refer to the Business and Professions Code.

[3] The Accusation uses the term "Regulation" to refer to the California Code of Regulations, title 16.

packaging. Respondent Roxsan Pharmacy compounded the following drug products and labeled each with an expiration date in excess of the expiration date of one of its ingredients. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Farbod Melamed had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that each compounded drug product contained a correct beyond-use date. Complainant realleges paragraphs 59, 65, 81–84, and 100.

Date Compounded	**Drug**	**Ingredient or Compound with Expiration Date that is Less Than the Beyond-Use Date**	**Beyond-Use Date on Label**
1/7/2013	Cream with: Hydroquinone cream 2% Kojic acid 2% Triamcinolone 2% Retinoic acid (tretinoin) 0.025%	4/6/2013 Hydroquinone cream 2%	5/7/2013
1/10/2013	Cream with: Hydroquinone cream 4% Kojic acid 4% Triamcinolone 4% Retinoic acid (tretinoin) 0.05%	3/12/2013 Hydroquinone cream 4%	5/10/2013
2/21/2013	Hydroquinone cream 8%	7/19/2013 Sodium metabisulfite	8/20/2013
2/21/2013	Hydroquinone cream 10%	7/19/2013 Sodium metabisulfite	8/20/2013
5/17/2013	Hydroquinone cream 2%	7/19/2013 Sodium metabisulfite	11/13/2013
5/20/2013	Hydroquinone cream 5%	7/19/2013 Sodium metabisulfite	11/16/2013
5/28/2013	Hydroquinone cream 5% with Salicylic acid 5% solution	11/24/2013	

Date Compounded	Drug	Ingredient or Compound with Expiration Date that is Less Than the Beyond-Use Date	Beyond-Use Date on Label
7/1/2014	Progesterone 200 mg Gelatin Troche (PCCA Special Micronized)	9/29/2014 Compound (Progesterone 200 mg Gelatin Troche [PCCA Special Micronized])	12/28/2014

117. **Section 4342**: Section 4342 empowers the Board to act to prevent the sale of pharmaceutical preparations and drugs that fail to conform to the standard and tests as to quality and strength. Inspections on June 4, 2013 and October 10, 2014 revealed that Respondent Roxsan Pharmacy compounded eight drug products and labeled them with expiration dates that exceeded the expiration dates of their ingredients, as more particularly set forth in paragraph 116, *supra*. Respondent Farbod Melamed was the Pharmacist-in-Charge at the time of the acts in question and had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that pharmaceutical preparations and drugs dispensed by the pharmacy conformed to the standard and tests as to quality and strength. Complainant realleges paragraphs 59, 65, 81–84, 100, and 116.

EIGHTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)
(As to All Respondents)

118. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, as follows:

A. Respondents Illegally Shipped Drugs Into Other States Without a License

119. **Section 4059.5, subdivision (e)**, prohibits the transfer, sale or delivery of dangerous drugs and devices to persons

outside California unless the transfer, sale or delivery complies with California law, federal law, and the law of the state into which the dangerous drug or device is delivered. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed violated Code section 4059.5, subdivision (e), by selling dangerous drugs in other states in contravention of the laws of those states and in violation of the laws of this State.

1. Louisiana Drug Sales

120. From approximately September 28, 2012 to June 6, 2013, Respondent Roxsan Pharmacy dispensed 22 prescriptions for dangerous drugs and two refills to patients in the state of Louisiana without proper licensure. Twenty-one of the twenty-two prescriptions contained ketamine, a Schedule III controlled substance.

121. Respondent Roxsan Pharmacy dispensed four of the aforementioned prescriptions from September 28, 2012 through December 2, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 18 prescriptions were dispensed between December 3, 2012 and June 6, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

122. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Louisiana complied with the Pharmacy Law, federal law and the Louisiana Pharmacy Practice Act. Complainant realleges paragraphs 59 and 81–84.

2. Connecticut Drug Sales

123. From approximately May 21, 2012 to June 14, 2013, Respondent Roxsan Pharmacy dispensed 230 prescriptions for dangerous drugs to patients in the state of Connecticut without proper licensure.

124. Respondent Roxsan Pharmacy dispensed 128 of the aforementioned prescriptions between May 21, 2012 and December 2, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 102 prescriptions were dispensed between December 3, 2012 and

June 14, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

125. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Connecticut complied with the Pharmacy Law, federal law and the Connecticut Pharmacy Practice Act. Complainant realleges paragraphs 60 and 85–87.

3. Florida Drug Sales

126. From approximately January 10, 2012 to March 21, 2013, Respondent Roxsan Pharmacy dispensed 6,048 prescriptions for dangerous drugs to patients in the state of Florida without proper licensure.

127. Respondent Roxsan Pharmacy dispensed 4,604 of the aforementioned prescriptions between January 10, 2012 and December 1, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 1,444 prescriptions were dispensed between December 3, 2012 and March 21, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

128. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Florida complied with the Pharmacy Law, federal law and the Florida Pharmacy Act. Complainant realleges paragraphs 64 and 99.

4. Maryland Drug Sales

129. From approximately February 9, 2012 to June 26, 2013, Respondent Roxsan Pharmacy dispensed 3,516 prescriptions for dangerous drugs to patients in the state of Maryland without proper licensure.

130. Respondent Roxsan Pharmacy dispensed 1,152 of the aforementioned prescriptions between February 9, 2012 and December 1, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 2,364

prescriptions were dispensed between December 3, 2012 and June 26, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

131. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Maryland complied with the Pharmacy Law, federal law and the laws of Maryland. Complainant realleges paragraphs 64 and 99.

5. Respondent Shahla Melamed Knew About the Out-of-State Drug Sales

132. When Respondent Farbod Melamed became the Pharmacist-in-Charge, Respondent Shahla Melamed remained the pharmacy's President, Chief Executive Officer and Secretary. As a corporate officer, she had knowledge that Roxsan Pharmacy dispensed dangerous drugs to residents of Connecticut, Florida, Louisiana and Maryland without being licensed in those states, even after she ceased being the Pharmacist-in-Charge. Complainant realleges paragraphs 59–60, 81–87, 99, and 118–131.

B. Respondents Failed to Test Sterile Injectable Medication

133. **Regulation 1751, subdivision (c)**, requires a compounding pharmacy to perform end-product testing for sterility and pyrogens (bacterial toxins) whenever it compounds sterile injectable drug products from one or more non-sterile ingredients. The regulation requires the pharmacy to quarantine injectable drug products until end-product testing confirms the drugs' sterility and acceptable levels of pyrogens.

134. Respondent Roxsan Pharmacy prepared sterile injectable drug products from non-sterile sources without subjecting the final product to testing. Specifically, from October 2012, to February, 2013, Roxsan Pharmacy compounded twenty products (Cyanocobalmin, Leuprolide, and Hyaluronidase) prepared from non-sterile sources without testing them. The pharmacy also prepared bacteriostatic water on November 7, 14, and 19, 2012, and again on January 11, 2013, using non-sterile sources without testing it. The

bacteriostatic water was then used to create other injectable compounds but these compounds were not tested for sterility.

135. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that sterile injectable products compounded from non-sterile ingredients were quarantined until end-product testing confirmed their sterility and acceptable levels of pyrogens. Complainant realleges paragraphs 2–4, 63, and 92–98.

C. **Respondents Failed to Keep Records of Sale and Disposition of Dangerous Drugs**

136. **Sections 4081, subdivision (a), and 4105**, require a pharmacy to maintain all records of sale, acquisition, receipt, shipment, or disposition of dangerous drugs for three years from the date of making. The records must be open to inspection during the pharmacy's business hours. On March 28, 2014, the Board requested original prescription records for 41 prescriptions dispensed between June 1 and December 31, 2012. Roxsan Pharmacy produced six original dispensing records but did not produce records for the remaining 35 prescriptions. Respondents failed to keep and maintain records of sale, acquisition, receipt, shipment and disposition for those 35 prescriptions, all of which were dangerous drugs.

137. Respondent Roxsan Pharmacy dispensed 33 of the undocumented prescriptions prior to December 3, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining two undocumented prescriptions were dispensed on December 17 and 26, 2012, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

138. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to maintain all records of sale, acquisition, receipt, shipment and disposition of dangerous drugs. Complainant realleges paragraphs 62 and 91.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)
(As to Respondents Roxsan Pharmacy and Farbod Melamed)

139. Respondents Roxsan Pharmacy and Farbod Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, in particular Code section 4059.5, subdivision (e).

140. **Section 4059.5, subdivision (e)**, prohibits the transfer, sale or delivery of dangerous drugs and devices to persons outside of California unless the transfer, sale or delivery complies with California law, federal law, and the law of the state into which the dangerous drug or device is delivered. Respondents Roxsan Pharmacy and Farbod Melamed violated Code section 4059.5, subdivision (e) by dispensing medications to patients in the state of Arkansas in contravention of California and Arkansas law.

141. From approximately January 7, 2013 to June 11, 2013, Respondent Roxsan Pharmacy dispensed 16 prescriptions to patients in the state of Arkansas without proper licensure.

142. During that time period, Respondent Farbod Melamed was the Pharmacist-in-Charge and had a duty to ensure that every prescription dispensed and sold in Arkansas complied with the Pharmacy Law, federal law and Arkansas law. Complainant realleges paragraphs 61, 88–90.

143. Respondent Shahla Melamed, as Roxsan Pharmacy's President, Chief Executive Officer and Secretary, had knowledge of the out-of-state drug sales. Complainant realleges paragraph 132.

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of State and Federal Statutes Regulating Controlled Substances and Dangerous Drugs)
(As to All Respondents)

144. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (j), for violating statutes of this State and other

states regulating controlled substances and dangerous drugs. Complainant realleges paragraphs 57–143.

ELEVENTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct—Conduct Which Would Warrant Denial of an Application)
(As to All Respondents)

145. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (p), for engaging in conduct that would have warranted denial of a license. Complainant realleges paragraphs 57–144.

Mitigation and Rehabilitation

4. Respondent is Shahla Melamed's nephew. She hired him at Roxsan when he was a new, inexperienced pharmacist in October 2012, the month he became licensed. She wanted to hire him as the pharmacist in charge (PIC) immediately, but he felt uncomfortable due to his complete lack of experience. But she persisted, and in December 2012, she made him the PIC. When Shahla Melamed hired respondent, she represented that the business was in complete compliance with all pharmacy regulations and laws. She paid respondent a salary with no further financial incentives. At that time, Roxsan was licensed in several other states and Shahla Melamed had an "Infertility Specialty Department" that supplied infertility drugs out of state. Shahla Melamed had plans to expand Roxsan's infertility drug business in other states. As a new pharmacist, respondent was unaware that Shahla Melamed was misleading him and was unaware of any non-compliance by Roxsan.

5. In late 2013, the Board inspected Roxsan, and respondent was required to respond to the Board's inspection report. He reviewed every detail of the report and learned, for the first time, that Roxsan had shipped drugs to several states without licensure in those states to provide drugs. Respondent created a "Do Not Send" list and sent multiple directives to Roxsan staff informing them to which states Roxsan could not send drugs. (Exhibit A.) Respondent also reviewed Roxsan's "Licensing Requirements" procedures and protocols with its staff to ensure no future violations occurred. However, he later learned that Shahla Melamed was instructing staff to continue sending unauthorized medications to other states without a proper license and without his knowledge. The staff would fill out blank FedEx shipping forms, then submit them directly to the shipper with the drugs. This way, the illegal shipment would not appear on the Roxsan patient manifest. Respondent provided multiple examples of this secret procedure, which he described to the Board's inspector, at the administrative hearing. (Exhibit B, pp. 1-3, 6-14.) Respondent was also unaware of the improper sterile compounding procedures Shahla Melamed and another staff pharmacist, C.B.,[4] performed until the Board informed him they were improper. He developed a

[4] Because C.B. was not charged in the Accusation, she is not identified here to protect her privacy.

protocol for quarantine, storage and release of compounded products (Exhibit F), but he had no knowledge of Shahla Melamed's or C.B.'s failures to follow these protocols.

6. When respondent discovered the extent of Shahla Melamed's deception and pharmacy violations, he removed himself as Roxsan's PIC. His father's family considered her actions a profound betrayal, and they have severed all ties to her.

7. From January 2015 through October 2016, respondent completed 34 continuing pharmacy education courses totaling 103.5 hours of instruction. In April of 2016, he completed a pharmacy sterile compounding course that required 34 hours of home study and six hours of observational practice and instruction. (Exhibit I.)

8. Joseph M. Redman is the chief executive officer and president of Parallax Health Sciences, Incorporated (Parallax), Roxsan's current owner. Mr. Redman testified that Parallax purchased Roxsan after Shahla Melamed committed the misconduct alleged in the Accusation and fired her in November 2015 for insubordination when that misconduct became known. Before Parallax fired her, they paid a private investigation firm to perform an investigation of Roxsan, which established evidence that she had intentionally violated multiple state and federal pharmacy and drug laws. Since Parallax purchased the pharmacy, Mr. Redman has worked with the Board and the Attorney General's office to ensure full compliance with all state and federal pharmacy laws and regulations. Mr. Redman views respondent in an entirely different light than Shahla Melamed. He believes respondent is an ethical, professional, highly capable pharmacist with excellent leadership abilities. He interviewed Roxsan staff and found that among them, respondent was universally held in high regard. Due to the Accusation, respondent has asked not to be the PIC at Roxsan, and Mr. Redman honored respondent's request, but he believes respondent is fully capable of dealing with compliance issues. To ensure current pharmacy compliance, Mr. Redman hired a pharmacy-compliance expert, Tanaz Kohan, to engage Roxsan in a lengthy certification process through the United Compounding Management Credentialing and Accreditation Program (UCAP). On July 21, 2016, Roxsan completed the UCAP and was awarded accreditation. The accreditation process involved a lengthy application, education and inspection process, after which UCAP generated a 54-page report of Roxsan's compliance results and verifications. (Exhibit L.) Mr. Redman provided a letter attesting to the substance of his testimony and extolling respondent's good character. (Exhibit G.)

9(a). Tiffany Marshall has been a licensed pharmacy technician at Roxsan since 2000 and was working at the pharmacy when the allegations in the Accusation occurred. She testified credibly that Shahla Melamed diverted out of state drug shipments from respondent's attention by instructing staff to hand-carry the packages to FedEx and fill in shipping labels on blank forms, while not listing Roxsan as the shipper. When respondent became aware of the violations that were occurring, Shahla Melamed instructed staff not to follow his directives. Shahla Melamed was the pharmacy's "dictator" and constantly reminded them that she would fire them if they failed to heed her instructions. To Ms. Marshall's knowledge, respondent was unaware of the violations alleged in the Accusation when they occurred, and he played no part in Shahla Melamed's misconduct. Ms. Marshall

and Roxsan's staff look up to respondent as a professional, highly ethical pharmacist and a leader. Ms. Marshall provided a letter attesting to these facts. (Exhibit E.)

9(b). Marcia C. Limbo, a pharmacy staff employee at Roxsan since 2000, submitted a sworn declaration reiterating the process Shahla Melamed used to divert out of state drug shipments from respondent's attention that Tiffany Marshall described in her testimony. Shahla Melamed made it clear that although respondent was the PIC, she was the owner, and she would fire anyone who did not follow her orders. Shahla Melamed persisted in manipulating the staff in this manner until the day the pharmacy was sold and the new owners fired her.

10. Tanaz Kohan, a licensed pharmacist, testified that he is the current Compliance Officer at Roxsan. He trains staff, writes protocols, and ensures that all laws and regulations are followed. Mr. Redman hired him in May 2015, at which time Mr. Kohan was introduced to respondent. Mr. Kohan believes respondent is a highly knowledgeable, highly ethical, professional pharmacist and "key player" in Roxsan's day-to-day operations. Mr. Kohan is aware of the allegations in the Accusation. He has seen no evidence that respondent knowingly or directly engaged in wrongdoing as the PIC at Roxsan, and he feels respondent is a "scapegoat" as a result of Shahla Melamed's many violations while respondent was PIC. Since Mr. Kohan's employment, Roxsan has engaged in a Verified Pharmacy Program conducted by the National Association of Pharmacy Boards (NAPB), whose findings go to Focus Script, a national accreditation agency. Roxsan passed the NAPB inspection process in every respect and earned its accreditation. Mr. Kohan provided a letter attesting to these facts. (Exhibit H.)

11. Calli Bucci, the Chief Financial Officer of Roxsan since its new ownership purchased the pharmacy in 2015, wrote a letter describing respondent as a trustworthy, dedicated, hardworking professional who has exhibited high standards and morals in the workplace. Ms. Bucci was aware of the allegations against respondent. (Exhibit H.)

12. Three pharmacists, a physician, and an attorney who know respondent professionally and personally submitted letters endorsing his good character high standards, dedication, professionalism and ethics. (Exhibit J.)

13. Respondent presented as a humble, respectful, appropriately remorseful witness. He understood that as the PIC at Roxsan when the violations occurred, he was responsible for those violations. He denied that he was ever aware of, or took part in, any of the violations of pharmacy law that were later attributed to him as PIC.

Additional Evidence

14. The sum of the evidence established that respondent was the unwitting victim of Shahla Melamed's extensive misconduct while respondent was the PIC at Roxsan. Complainant did not contest this aspect of the evidence at the administrative hearing, and established no direct evidence attributing wrongful acts to respondent. Regarding the

allegations of out-of-state sales of drugs in violation of state and/or federal laws, Complainant alleged that only Shahla Melamed, but not respondent, had knowledge of out-of-state drug sales.

Costs

15. Deputy Attorney General (DAG) Antonio Lopez, Jr., who conducted the hearing, submitted a certified declaration of costs showing the Attorney General's office billed his costs to the Board in the amount of $3,485. However, DAG Lopez was the third attorney assigned to this matter, following DAG Matthew King and DAG Thomas Rinaldi, whose collective billings totaled $5,227.50. DAG Lopez's billings reflected extensive work toward preparing the matter for hearing, and those were reasonable costs. But some of DAG Lopez's costs were duplicative of the costs incurred by DAGs King and Rinaldi, solely due to the case being reassigned. While the other two DAGs' billed time may be reasonable, it is not reasonable to pass those costs onto respondent. In addition, Attorney General support staff billed the Board $294.50 in reasonable costs. Therefore, combining DAG Lopez's and support staff's costs, the Attorney General incurred a total of $3,779.50 in reasonable costs.

16. The Board submitted certified declarations establishing its costs of investigation of this matter as totaling $31,200.75. Those costs are reasonable.

17. Combining the Attorney General's and Board's totals as set forth above, Complainant incurred reasonable costs totaling $34,980.25. These costs will be analyzed further below.

LEGAL CONCLUSIONS

1. The practice of pharmacy, like the practice of medicine, is a profession. *Vermont & 110th Medical Arts Pharmacy v. Board of Pharmacy* (1981) 125 Cal.App.3d 19, 25. The standard of proof in an administrative disciplinary action seeking the suspension or revocation of a professional license is "clear and convincing evidence." *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856. The key element of "clear and convincing evidence" is that it must establish a high probability of the existence of the disputed fact, greater than proof by a preponderance of the evidence. Evidence of a charge is clear and convincing so long as there is a "high probability" that the charge is true. *People v. Mabini* (2001) 92 Cal.App.4th 654, 662.

2. Cause exists to discipline respondent's pharmacist license number RPH 68252 under Business and Professions Code section 4301, subdivision (o), for committing unprofessional conduct by violating or assisting in or abetting the violation of state law governing pharmacy, to wit: California Code of Regulations, title 16 (Regulation), section 1716, by dispensing prescriptions which deviated from the requirements of a prescription; Regulation section 1735.2, subdivision (h), by providing compounded drug products beyond their expiration dates; and Regulation 4352, by compounding drug products and labeling them with

expiration dates that exceeded the expiration dates of their ingredients. (Factual Finding 3, subparagraphs 59, 63, 65, 81-84, 92-95, 100 and 116.)

3. Cause exists to discipline respondent's pharmacist license number RPH 68252 under Business and Professions Code section 4301, subdivision (o), for committing unprofessional conduct by violating or assisting in or abetting the violation of state law governing pharmacy, to wit: Regulation section 4059.5, subdivision (e), by transferring, selling or delivering dangerous drugs and devices to persons outside California in contravention of the laws of the states of Louisiana, Connecticut, Florida, Maryland, and Arkansas; Regulation 1751, by failing to test sterile injectable medications to confirm the drugs' sterility, preparing sterile injectable drugs from non-sterile sources without final-product testing, and ensuring compounded sterile injectable products were quarantined until end-product testing confirmed their sterility and acceptable levels of pyrogens; and Regulation section 4081, subdivision (a), by failing to maintain records of sale, acquisition, receipt, shipment or disposition of two dangerous drug prescriptions providing compounded drug products beyond their expiration dates, dispensing two undocumented prescriptions (Factual Finding 3, subparagraphs 59, 60, 62, 63, 81-87, 88-98, 99, and 118-131.)

4. Cause exists to discipline respondent's pharmacist license number RPH 68252 under Business and Professions Code section 4301, subdivision (j), for committing unprofessional conduct by violating statutes of California and other states regulating controlled substances and dangerous drugs, as set forth in Factual Finding 3, subparagraphs 57-144.

5. Cause exists to discipline respondent's pharmacist license number RPH 68252 under Business and Professions Code section 4301, subdivision (p), for committing unprofessional conduct by engaging in conduct that would have warranted denial of a license, as set forth in Factual Finding 3, subparagraphs 57-144, and Legal Conclusions 2-4.

Analysis to Determine Penalty

6(a). The Board's Disciplinary Guidelines state that in determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the following applicable factors should be considered (each factor is numbered from the Guidelines, with a corresponding analysis):

> 1. Actual or potential harm to the public. No actual harm to the public was alleged. The potential harm to the public is that minimum pharmacy standards were not met regarding drug compounding and testing for prescriptions to be used by patients. The illegal sending of prescriptions out-of-state, by its nature, is in contravention of California's and other states' laws, and results in the provision of drugs outside of legal regulation.
>
> 2. Actual or potential harm to any consumer. No actual harm to a consumer was alleged. The potential harm to consumers is that unregulated prescriptions may be incorrect, and drugs

compounded in a manner below standard could be harmful or dangerous.

3. Prior disciplinary record, including level of compliance with disciplinary order(s). Respondent has no prior disciplinary record.

4. Prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s). Respondent has none.

5. Number and/or variety of current violations. The number of violations is high. However, respondent was not directly involved with, or aware of, those violations.

6. Nature and severity of the act(s), offense(s) or crime(s) under consideration. By virtue of his role as PIC, respondent was responsible for ensuring that Roxsan's preparation and delivery of prescriptions was in compliance with all laws and regulations governing pharmacy practice. He failed to recognize that the pharmacy's then owner, Shahla Melamed, was acting in flagrant violation of those laws and regulations.

7. Aggravating evidence. The evidence did not give rise to aggravating circumstances.

8. Mitigating evidence. Several witnesses and letter-writers attested to respondent's good character and his victimization by Shahla Melamed.

9. Rehabilitation evidence. Respondent cooperated with the Board's investigation and took responsibility for his misconduct. Respondent took multiple continuing education courses. He also instituted several practices and procedures to better control the preparation, tracking and processing of prescriptions at Roxsan.

[¶ . . . ¶]

13. Time passed since the act(s) or offense(s). The misconduct occurred between two and four years ago.

14. Whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct. To some degree respondent's conduct was negligent in that he was responsible for ensuring the legitimacy and correctness of the

> prescriptions the pharmacy was filling, yet he is mostly being held accountable for conduct committed by Shahla Melamed, who has surrendered her pharmacist license.
>
> 15. Financial benefit to the respondent from the misconduct. No evidence was presented regarding the potential or actual financial benefit to respondent, except that he was paid a salary with no financial incentives.

6(b). Considering all of these factors, respondent committed serious misconduct due to the volume of violations that were established. Respondent's culpability was attenuated, however, by his insight into Shahla Melamed's misconduct, his willingness to take responsibility as the then PIC of Roxsan, his cooperation with the Board, and his efforts to rehabilitate himself and the newly-owned Roxsan's pharmacy practices. It was also undisputed by complainant that Shahla Melamed was the primary source of misconduct, whereas respondent was later held accountable due to his status as PIC. By multiple credible accounts, respondent was a victim of Shahla Melamed's manipulation of both him and other staff at Roxsan. In sum, respondent appears to be a good candidate for probation. The following order will best achieve the purpose of public protection.

Costs Award

7. A licensee found to have violated a licensing act may be ordered to pay reasonable costs of investigation and prosecution. (Bus. & Prof. Code § 125.3.) The California Supreme Court in *Zuckerman v. State Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, 45, instructs that the following factors should be considered when determining the reasonableness of costs sought pursuant to regulations such as section 125.3 regarding the recovery of prehearing investigation and enforcement costs.

> The Board must exercise its discretion to reduce or eliminate cost awards in a manner that will ensure that regulation . . . does not deter . . . [licensees] with potentially meritorious claims or defenses from exercising their right to a hearing. Thus, the Board must not assess the full costs of investigation and prosecution when to do so will unfairly penalize a . . . [licensee] who has committed some misconduct, but who has used the hearing process to obtain dismissal of other charges or a reduction in the severity of the discipline imposed. The Board must consider the . . . [licensee's] "subjective good faith belief in the merits of his or her position" [Citation.] and whether the . . . [licensee] has raised a "colorable challenge" to the proposed discipline. [Citation.] Furthermore, as in the cost recoupment schemes in which the government seeks to recover from criminal defendants the cost of their state-provided legal representation [Citation], the Board must determine that the . . .

> [licensee] will be financially able to make later payments. Finally, the Board may not assess the full costs of investigation and prosecution when it has conducted a disproportionately large investigation to prove that a . . . [licensee] engaged in relatively innocuous misconduct.

8. As set forth in Factual Findings 15 through 17, the Board incurred investigation and prosecution costs in amounts totaling $34, 980.25 in connection with the Accusation. In light of the fact that complainant did not prevail on several alleged causes for discipline, an apportionment of costs must be considered.

9. Section 125.3 is silent on the apportionment-of-costs issue. Nonetheless, civil cases addressing a prevailing party's recovery of attorney fees where apportionment is not covered by statutory or contractual clause are instructive. In *Reynolds Metals Co. v. Alperson* (1979) 25 Cal.3d 124, where a party prevailing on both a contract containing a fee clause and on a tort theory precluding fee recovery, the fees were allocated between the two causes of action. In *Slavin v. Fink* (1994) 25 Cal.App.4th 722, a similar allocation occurred where, as in this case, a party prevailed on some, but not all, of its claims.

10. The board was not successful in establishing all of its alleged causes for subjecting respondent to administrative discipline. These unsuccessful claims against respondent required work, with attendant costs, that overlapped with the work performed and costs incurred on the otherwise successful claim. Without more specific evidence to determine a precise apportionment, the costs of investigation and prosecution shall be apportioned equally between complainant's unsuccessful and successful claims alleged in each cause for discipline of the Accusation presented in this matter.

11. Cause for discipline was established in connection with the Seventh through Eleventh Causes for Discipline but not in connection with the First through Sixth Causes for Discipline. Complainant's investigation and prosecution cost of $34,980.25 is divided equally among the eleven causes alleged for discipline. Therefore, $3,180.03 is allocated to each of the five successful causes of discipline established.

12. Under *Zuckerman*, supra, a determination must be made regarding respondent's financial ability to make future cost award payments. Respondent submitted no evidence that he lacks the financial ability to pay costs. Under these circumstances, respondent shall pay complainant's costs of investigation and prosecution in an amount totaling $15,900.15.

ORDER

Pharmacist License number RPH 68252, issued to respondent Farbod Melamed, is hereby revoked. However, the revocation is stayed and respondent is placed on probation for three years upon the following terms and conditions:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations. Respondent shall report any of the following occurrences to the board, in writing, within 72 hours of such occurrence: an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws; a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment; a conviction of any crime; discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's registered pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance. Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of his efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, only where applicable, respondent shall notify all present and prospective employers of the decision in case number 5455 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within 30 days of the effective date of this decision, and within 15 days of respondent undertaking any new employment, in that event only respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5455, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent should work for or become employed by or through a pharmacy employment service, he must notify her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 5455 in advance of respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within 30 days of the effective date of this decision, and within 15 days of respondent undertaking any new employment by or through a pharmacy employment service, in that event respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number 5455 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns

During the period of probation, respondent shall not supervise any intern pharmacist. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $15,900.15. It is within the board's discretion to establish a reasonable monthly or quarterly repayment plan with respondent.

There shall be no deviation from the repayment schedule the board establishes absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve him of his responsibility to reimburse the board its costs of investigation and prosecution.

9. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of Licenses

Respondent shall, at all times while on probation, maintain active, current licenses with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within 10 days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for 3 years from the effective

date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within 10 days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within 10 days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 120 hours per calendar month in California, respondent must notify the board in writing within 10 days of the cessation of practice, and must further notify the board in writing within 10 days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding 48 months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 120 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 120 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. Violation of Probation

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondents, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other

action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Pharmacy Self-Assessment Mechanism

Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.

Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.

Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.

16. No New Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation licensed by the board in addition to, or other than, Roxsan Pharmacy. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

17. Separate File of Records (For pharmacist owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

18. Report of Controlled Substances (For pharmacist owners and pharmacists-in-charge)

Respondent shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than 10 days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

19. Ethics Course

Within 60 calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

20. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

DATED: January 3, 2017

DocuSigned by:
John E. DeCure
17FD47F60F0543E...

JOHN E. DeCURE
Administrative Law Judge
Office of Administrative Hearings

KAMALA D. HARRIS
Attorney General of California
LINDA L. SUN
Supervising Deputy Attorney General
MATTHEW A. KING
Deputy Attorney General
State Bar No. 265691
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
matthew.king@doj.ca.gov
(213) 897-7446

Attorneys for Complainant

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

In the Matter of the Accusation Against: **ROXSAN PHARMACY, INC.; FARBOD MELAMED, Pharmacist-in-Charge, SHAHLA KEYVANFAR MELAMED, CEO, President, Secretary** 465 N. Roxbury Dr. Beverly Hills, CA 90210 **Pharmacy Permit No. PHY 38297,** **SHAHLA KEYVANFAR MELAMED** 465 N. Roxbury Dr. Beverly Hills, CA 90210 **Pharmacist License No. RPH 42096,** And **FARBOD MELAMED** 411 North Palm Dr. #11 Beverly Hills, CA 90210 **Pharmacist License No. RPH 68252** Respondents.	Case No. 5455 **A C C U S A T I O N** [Gov. Code, § 11503.]

///

///

///

///

Complainant alleges:

PARTIES

1. Complainant Virginia K. Herold brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, an agency within the Department of Consumer Affairs.

2. On November 3, 1992, the Board issued Pharmacy Permit Number PHY 38297 to Shahla Keyvanfar Melamed to do business as Rox San Pharmacy. On September 30, 2003, the license holder changed its name to Roxsan Pharmacy, Inc. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on November 1, 2015 unless it is renewed.

3. On August 19, 1988, the Board issued Pharmacist License Number RPH 42096 to Shahla Keyvanfar Melamed. Said license was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2016 unless it is renewed. Respondent Shahla Melamed was the Pharmacist-in-Charge of Roxsan Pharmacy, formerly known as Rox San Pharmacy, from November 3, 1992 through December 2, 2012. She is and has been the President, Secretary and Chief Executive Officer of Roxsan Pharmacy since August 5, 2003.

4. On October 5, 2012, the Board issued Pharmacist License Number RPH 68252 to Farbod Melamed. Said license was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2015 unless it is renewed. Respondent Farbod Melamed has been the Pharmacist-in-Charge of Roxsan Pharmacy since December 3, 2012. Respondent Farbod Melamed disassociated as the Pharmacist-in-Charge on January 20, 2015.

///

///

///

///

///

///

///

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code and all regulatory references are to title 16 of the California Code of Regulations unless otherwise indicated.

6. Section 4300 relevantly states that the Board has authority to suspend or revoke any license issued under the Pharmacy Law, and that the proceedings to suspend or revoke a license must be conducted according to the Administrative Procedure Act (Gov. Code, §§ 11500, *et seq.*).

7. Section 4300.1 of the Code provides the Board with continuing jurisdiction over a license regardless of the license's expiration, cancellation, forfeiture, retirement, surrender or suspension.

STATUTORY PROVISIONS

8. Section 4036.5 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.

9. Section 4059.5 relevantly 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.

10. Section 4081 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.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

11. Section 4105 states:

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

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

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

(d) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

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

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

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is

subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

12. Section 4113, subdivision (c) states:

(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.

13. Section 4156 states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

14. Section 4150 relevantly states:

A pharmacy corporation means a corporation that is authorized to render professional services, as defined in Section 13401 of the Corporations Code, so long as that corporation and its shareholders, officers, directors, and employees rendering professional services who are pharmacists are in compliance with the Moscone-Knox Professional Corporation Act, this article, and all other statutes and regulations now or hereafter enacted or adopted pertaining to the corporation and the conduct of its affairs.

15. Section 4301 relevantly 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.

...

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

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board…

16. Section 4302 states:

The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

17. Section 4306 states:

It shall constitute unprofessional conduct and a violation of this chapter for any person licensed under this chapter to violate, attempt to violate, directly or indirectly, or assist in or abet the violation of, or conspire to violate, any provision or term of this article, the Moscone-Knox Professional Corporation Act, or any regulations duly adopted under those laws.

18. Section 4306.5 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.

19. Section 4307 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.

20. Section 4324 relevantly states:

(a) Every person who...falsely makes, alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail for not more than one year.

21. Section 4342 relevantly 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).

22. Section 111400 of the Sherman Food, Drug, and Cosmetic Law (Health & Saf. Code, §§ 109875, *et seq.*) defines a misbranded drug or device as one that "is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

///

///

///

///

REGULATORY PROVISIONS

23. Regulation 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

24. Regulation 1735 states:

(a) 'Compounding' means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances

(b) 'Compounding' does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.

(c) 'Compounding' does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

25. Regulation 1735.2 relevantly states:

(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…

26. Regulation 1751 relevantly states:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

...

(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

27. Regulation 1751.1 relevantly states:

(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

(b) In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:

…

(2) Refrigerator and freezer temperatures.

…

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

28. Regulation 1751.7 relevantly states:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

…

(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

…

///

///

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

29. Regulation 1770 states:

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

30. Regulation 1793.7 relevantly states:

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

...

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician...

ARKANSAS PHARMACY LAW

31. At all times relevant to the charges brought herein, Arkansas Administrative Code, title 070, division 00, rule 4, section 04-04-0001 stated, in pertinent part:

Out of State pharmacies shall comply with the following qualifications to be, and remain, licensed in Arkansas by the Board.

(a)(1) The pharmacy holds a current license in good standing in the state(s) in which it is located.

(2) Each pharmacist dispensing drugs into Arkansas shall be licensed as a pharmacist in Arkansas or in the state where he practices if that state has standards of licensure at least equivalent to those of Arkansas.

...

(c) The out of state pharmacy shall apply for licensure and renewal on forms provided by the Board. The Board may require such information as reasonably necessary to carry out the provisions of A.C.A. § 17-92-401, including, without limitation, the name, address and position of each officer and director of a corporation or of the owners if the pharmacy is not a corporation.

Provided, however, the Board may grant an exemption from licensing under A.C.A. § 17-92-401 upon application by any non-resident pharmacy which confines its dispensing activity to isolated transactions...

...

(e) The pharmacy shall maintain records of drugs dispensed to Arkansas addresses in such a manner so as to be readily retrievable upon request. These records shall be made available for inspection by the Board or by Arkansas law enforcement authorities.

(f) The pharmacy shall timely respond to any request for information from the Board or law enforcement authorities.

(g) The pharmacy shall maintain an incoming toll free telephone number for use by Arkansas customers to be answered by a pharmacist with access to patient records. This service shall be available a minimum of 40 hours a week, six days per week during normal business hours. This telephone number plus others available for use shall be printed on each container of drugs dispensed into Arkansas. The toll free number shall have sufficient extensions to provide reasonable access to incoming callers.

...

(i) The facilities and records of the pharmacy shall be subject to inspection by the Board: provided, however, the Board may accept in lieu thereof satisfactory inspection reports by the licensing entity using similar standards of the state where the pharmacy is located.

(j) Each out of state pharmacy doing business in Arkansas by dispensing and delivering or causing to be delivered prescription drugs to Arkansas consumers shall designate a resident agent in Arkansas for service of process.

(k) Each out of state pharmacy doing business in Arkansas shall comply with Board of Pharmacy regulation 09-00-0001 (Patient Information, Drug Use Evaluation, and Patient Counseling).

...

The responsibility to ensure compliance with this regulation rests both with the Arkansas pharmacist in charge and with the pharmacy owner if they are not the same.

CONNECTICUT PHARMACY LAW

32. At all times relevant to the charges brought herein, section 20-601 of the Connecticut Pharmacy Practice Act stated in pertinent part:

The department shall collect the following nonrefundable fees:

...

(12) The fee for issuance of a nonresident pharmacy certificate of registration is seven hundred fifty dollars.

(13) The fee for renewal of a nonresident pharmacy certificate of registration is one hundred ninety dollars...

33. Section 20-605 of the Connecticut Pharmacy Practice Act states:

No individual may engage in the practice of pharmacy unless the individual holds a current license or temporary permit to practice pharmacy issued by the department.

34. At all times relevant to the charges brought herein, section 20-627 of the Connecticut Pharmacy Practice Act stated:[1]

> (a) As used in sections 20-627 to 20-630, inclusive, "nonresident pharmacy" means any pharmacy located outside this state which ships, mails or delivers, in any manner, legend devices or legend drugs into this state pursuant to a prescription order.
>
> (b) A nonresident pharmacy shall be registered with the department, upon approval of the commission, and shall:
>
> (1) Disclose annually in a report to the commission the location, names and titles of all principal corporate officers, if applicable, and all pharmacists who are dispensing drugs or devices to residents of this state. A nonresident pharmacy shall file an additional report within thirty days after any change of office, corporate officer or pharmacist.
>
> (2) Submit a statement that the nonresident pharmacy complies with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as comply with all requests for information made by the commission pursuant to this section.
>
> (3) Maintain at all times, a valid unexpired license, permit or registration to conduct such pharmacy in compliance with the laws of the state in which the nonresident pharmacy is located.
>
> (4) Before receiving a certificate of registration from the department, submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located.
>
> (c) A nonresident pharmacy shall, during its regular hours of operation, but not less than six days per week, and for a minimum of forty hours per week, provide a toll-free telephone number to facilitate communication between patients in this state and a pharmacist at such nonresident pharmacy who has access to the patient's records. Such toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

35. At all times relevant to the charges brought herein, section 20-628 of the Connecticut Pharmacy Practice Act stated:

> No nonresident pharmacy shall engage in the business of shipping, mailing or delivering legend devices or legend drugs in this state unless such nonresident pharmacy has been issued a certificate of registration by the commission and has paid the fee for issuance or renewal of such certificate of registration required in section 20-601. Applications for a certificate of registration as a nonresident pharmacy shall be made on a form furnished by the commission. The commission may require such information as it deems reasonably necessary to carry out the purpose of this section.

///

///

[1] Amended by 2014 Conn. Legis. Serv. P.A. 14-224 (H.B. 5262) (WEST)

FLORIDA PHARMACY LAW

36. At all times relevant to the charges brought herein, section 465.0156 of the Florida Pharmacy Act stated:

> (1) Any pharmacy which is located outside this state and which ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state shall be considered a nonresident pharmacy, shall be registered with the board, shall provide pharmacy services at a high level of protection and competence, and shall disclose to the board the following specific information:
>
> (a) That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed;
>
> (b) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to residents of this state. This disclosure shall be made within 30 days after any change of location, corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to residents of this state;
>
> (c) That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to the residents of this state;
>
> (d) That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed; and
>
> (e) That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs.
>
> (2) Applications for nonresident pharmacy registration under this section shall be made on a form furnished by the board. The board may require such information as the board deems reasonably necessary to carry out the purposes of this section. The board may grant an exemption from the registration requirements of this section to any nonresident pharmacy which confines its dispensing activity to isolated transactions. The board may define by rule the term isolated transactions.
>
> (3) The registration fee and the biennial renewal fee shall be the fee specified in s. 465.022.
>
> (4) The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.0158, s. 465.017(2), or s. 465.025, or with any requirement of this section in accordance with this chapter.

(5) In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with this chapter for conduct which causes or could cause serious bodily or psychological injury to a human or serious bodily injury to a nonhuman animal in this state.

(6) A nonresident pharmacy is subject to s. 456.0635.

(7) It is unlawful for any nonresident pharmacy which is not registered pursuant to this section to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

(8) This section does not apply to Internet pharmacies required to be permitted under s. 465.0197.

(9) Notwithstanding s. 465.003(10), for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

LOUISIANA PHARMACY LAW

37. At all times relevant to the charges brought herein, section 1201 of the Louisiana Pharmacy Practice Act stated:

A. Except as otherwise provided in this Chapter, it shall be unlawful for any individual to engage in the practice of pharmacy unless currently licensed or registered to practice under the provisions of this Chapter.

B. Licensed practitioners authorized under the laws of this state to compound drugs and to dispense drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, and all other requirements for the dispensing of drugs applicable to pharmacists.

C. It shall be unlawful for any individual to assist in the practice of pharmacy unless currently registered or certified by the board.

38. At all times relevant to the charges brought herein, section 1221 of the Louisiana Pharmacy Practice Act stated:

A. No person shall open, establish, operate, or maintain a pharmacy located within this state unless the pharmacy is issued a permit by the board.

B. No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy located out-of-state unless the pharmacy is issued a permit by the board.

C. No permit to operate a pharmacy shall be granted or renewed unless evidence satisfactory to the board ensures that a pharmacist in the state where the permit is issued and pharmacy is located will be on duty during normal hours as administratively defined.

39. At all times relevant to the charges brought herein, section 1232 of the Louisiana Pharmacy Practice Act stated:

> A. A pharmacy located outside this state which does business in this state within the meaning of this Chapter shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit".
>
> B. A nonresident pharmacy granted a nonresident pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers, as well as the owner's managing officer and pharmacist-in-charge. A report containing this information shall be made to the board on an annual basis and within thirty business days after any change of office, corporate officer, or within ten business days of the departure of the prior owner's managing officer or pharmacist-in-charge.
>
> C. The nonresident pharmacy shall maintain at all times authorization to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to seeking a permit from the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located, as well as any other state pharmacy licensing agency or any agent thereof, and any inspection reports produced by the federal Food and Drug Administration or the federal Drug Enforcement Administration. Thereafter, the nonresident pharmacy granted a permit shall submit to the board a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the state in which it is located, or by any other state pharmacy licensing agency, or any agent thereof, or by the federal Food and Drug Administration or the federal Drug Enforcement Administration. In addition to or in lieu of an inspection by the regulatory or licensing body of the state in which it is a resident, or any agent thereof, the nonresident pharmacy shall be subject to an inspection by the board. When the board conducts an inspection of a nonresident pharmacy, the board shall recover its expenses from the nonresident pharmacy in addition to the applicable permit fee authorized by this Chapter.
>
> D. A nonresident pharmacy granted a nonresident pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.
>
> E. Records for all prescriptions and products delivered into the state shall be readily retrievable from the other prescription records of the nonresident pharmacy and shall be in compliance with all federal laws and with regulations as may be required by this state.

40. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2301, entitled "Purpose," stated:

> A. Out-of-State Pharmacies shall comply with the provisions of this Chapter in order to be and remain permitted to operate in Louisiana as an out-of-state pharmacy.

///

///

B. This Chapter applies to any place physically located outside the state of Louisiana that provides services in the state of Louisiana where prescription drugs are dispensed and/or pharmacy care is provided to residents of the state of Louisiana. This includes, but is not limited to, pharmacies providing goods and services via U.S. mail carrier, commercial carrier, the Internet, and/or directly to Louisiana residents.

41. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2303, entitled "Out-of-State Pharmacy Requirements," stated:

A. The out-of-state pharmacy shall hold a current pharmacy permit in good standing in the state(s) in which it is located and/or practicing pharmacy.

B. Each pharmacist dispensing drugs into Louisiana shall be licensed as a pharmacist in good standing in the state(s) where he practices.

C. Every out-of-state pharmacy doing business in Louisiana by dispensing and delivering prescription drugs and devices to Louisiana residents shall designate a resident agent and a registered office in Louisiana for the service of process.

42. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2305, entitled "Out-of-State Pharmacy Permit Requirements," stated:

A. The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board. The board may require such information as reasonably necessary to carry out the provisions of R.S. 37:1232, including, without limitation, the name, address, and position of each officer and director of a corporation or of the owners, if the pharmacy is not a corporation.

B. The out-of-state pharmacy shall pay an annual permit fee as defined in R.S. 37:1184.

43. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2307, entitled "Pharmacist-in-Charge," relevantly stated:

A. Designation. A pharmacist licensed by the Louisiana Board of Pharmacy shall be named in the application as the pharmacy's pharmacist-in-charge for the Louisiana permit and shall be responsible for the pharmacy permit's compliance.

B. The pharmacist-in-charge shall have an active and current license in the state in which the pharmacy is located, and further, shall not have any restrictions that prohibit the position of pharmacist-in-charge.

C. Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription

department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

44. At all times relevant to the charges brought herein, Louisiana Administrative Code, title 46, section 2309, entitled "Applicable Laws and Regulations," stated:

> A. Louisiana pharmacy laws and regulations shall be applicable to regulate the practice of pharmacy for that portion of the out-of-state pharmacy's Louisiana pharmacy practice or operation.

MARYLAND PHARMACY LAW

45. At all times relevant to the charges brought herein, section 12-401 of the Maryland Health Occupations Code stated:

> **Permit required**
> (a) A person shall hold a pharmacy permit issued by the Board before the person may establish or operate a pharmacy in this State.
>
> **Multiple permits**
> (b) A separate pharmacy permit is required for each pharmacy that a person establishes or operates.

46. At all times relevant to the charges brought herein, section 12-402 of the Maryland Health Occupations Code stated:

> To qualify for a pharmacy permit, an applicant shall satisfy the Board that the pharmacy for which the application is made will be operated in accordance with the standards specified in § 12-403 of this subtitle.

47. At all times relevant to the charges brought herein, section 12-403 of the Maryland Health Occupations Code relevantly stated:

> **Laws or regulations of state in which located**
> (b) This section does not require a nonresident pharmacy to violate the laws or regulations of the state in which it is located.
>
> **Pharmacy permit requirements**
> (c) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
>
> (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;
>
> (2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;
>
> (3) Shall ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation;

(4) Shall be supervised by a licensed pharmacist who is responsible for the operations of the pharmacy at all times the pharmacy is in operation;

...

(17) With regard to a prescription drug that is delivered in this State by the United States mail, a common carrier, or a delivery service and is not personally hand delivered directly to a patient or to the agent of the patient at the residence of the patient or at another location designated by the patient, shall:

(i) Provide a general written notice in each shipment of a prescription drug that alerts a consumer that, under certain circumstances, a medication's effectiveness may be affected by exposure to extremes of heat, cold, or humidity; and

(ii) Provide a specific written notice in each shipment of a prescription drug that provides a consumer with a toll-free or local consumer access telephone number accessible during regular hours of operation, which is designed to respond to consumer questions pertaining to medications;

...

Licensed pharmacist on staff

(e) A nonresident pharmacy shall:

(1) Hold a pharmacy permit issued by the Board; and

(2) Have a pharmacist on staff who is:

(i) Licensed by the Board; and

(ii) Designated as the pharmacist responsible for providing pharmaceutical services to patients in the State.

Application and fee for pharmacy permit

(f)(1) In order to obtain a pharmacy permit from the Board, a nonresident pharmacy shall:

(i) Submit an application to the Board on the form that the Board requires;

(ii) Pay to the Board an application fee set by the Board;

(iii) Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located; and

(iv) On the required permit application, identify the name and current address of an agent located in this State officially designated to accept service of process.

(2) A nonresident pharmacy shall report a change in the name or address of the resident agent in writing to the Board 30 days prior to the change.

Compliance with home state laws

(g) Notwithstanding subsection (b) of this section, a nonresident pharmacy shall:

(1) Comply with the requirements of subsection (c)(2), (7) through (12), and (19) of this section when:

(i) Dispensing prescription drugs or prescription devices to a patient in this State; or

(ii) Otherwise engaging in the practice of pharmacy in this State;

(2) On an annual basis and within 30 days after a change of office, corporate officer, or pharmacist, disclose to the Board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescriptions for drugs or devices to persons in this State;

(3) Comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is located and all requests for information made by the Board pursuant to this section;

(4) Maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which it is located;

(5) Maintain its records of prescription drugs or devices dispensed to patients in this State so that the records are readily retrievable;

(6) During its regular hours of operation, but not less than 6 days a week, and for a minimum of 40 hours per week, provide toll-free telephone service to facilitate communication between patients in this State and a pharmacist or an individual who:

(i) Has access to the patient's prescription records; and

(ii) Is required to refer patients in the State to the responsible pharmacist licensed in the State, as appropriate;

(7) Disclose its toll-free telephone number on a label affixed to each container of drugs or devices;

(8) Comply with the laws of this State relating to the confidentiality of prescription records if there are no laws relating to the confidentiality of prescription records in the state in which the nonresident pharmacy is located; and

(9) Comply with the requirements of subsection (c)(17) and (20) of this section.

///

///

COST RECOVERY

48. 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.

DRUG CLASSIFICATIONS

49. Cyanocobalmin, commonly known as vitamin B12, is a dangerous drug when in the form of an injectable solution. (Bus. & Prof. Code, § 4022.)

50. Follistim AQ is a brand name for follitropin beta, a follicle-stimulating hormone indicated primarily for female infertility and ovarian failure. Follitropin beta is a dangerous drug. (Bus. & Prof. Code, § 4022.)

51. Hylenex and Wylase are brand names for hyaluronidase, a genetically designed protein that aids in the absorption of injected medications. Hyaluronidase is a dangerous drug. (Bus. & Prof. Code, § 4022.)

52. Ketamine is a Schedule III controlled substance and dangerous drug. (Bus. & Prof. Code, § 4022; Health & Saf. Code, § 11056, subd. (g).) It functions as an anesthetic and analgesic.

53. Lupron is the brand name for leuprolide, a dangerous drug that reduces testosterone in men and estrogen in women. (Bus. & Prof. Code, § 4022.)

54. Omnitrope is the brand name for somatropin, a dangerous drug indicated for growth failure in children and adults and for treatment of HIV-related Lipodystrophy. Somatropin has an off-label use of improving female fertility. (Bus. & Prof. Code, § 4022.)

55. Progesterone is a dangerous drug and naturally occurring hormone in women that regulates ovulation and menstruation. (Bus. & Prof. Code, § 4022.)

///

///

///

///

STATEMENT OF FACTS

56. This Accusation alleges causes for discipline stemming from nine consumer complaints.

57. The Board received the first complaint on June 9, 2011. In substance, the complainant alleged that on February 21, 2011, Roxsan Pharmacy substituted an inappropriate device for injecting a drug marketed under the name "Omnitrope." Omnitrope is indicated for growth hormone deficiency and has an off-label use of improving female fertility. The Board investigated the complaint and conducted an inspection of Roxsan Pharmacy on June 23, 2011. The relevant findings are alleged in Section A, below.

58. The second consumer complaint came to the Board on July 27, 2011. The complainant alleged that Roxsan Pharmacy dispensed Domperidone to nursing mothers to enhance breast milk production. Domperidone is approved in some countries for gastrointestinal disorders. The United States Food and Drug Administration, the federal agency responsible for reviewing new drug applications, has not approved Domperidone for any purpose in this country and has banned the drug's importation and interstate transfer except for research purposes. The Board inspected Roxsan Pharmacy on September 15, 2011. The relevant findings are alleged in Section B, below.

59. The Board received the third consumer complaint on February 21, 2013. The complainant alleged that Roxsan Pharmacy sold dangerous drugs and controlled substances to Louisiana residents without being licensed in that state, as Louisiana law requires. The Board inspected Roxsan Pharmacy on June 4, 2013. The relevant findings are alleged in Section C, below.

60. The fourth consumer complaint came to the Board on September 24, 2013. The complainant alleged that Roxsan Pharmacy dispensed prescriptions to consumers in Connecticut without being licensed in that state, as Connecticut law requires. The Board inspected Roxsan Pharmacy on November 5, 2013. The relevant findings are alleged in Section D, below.

61. The Board learned of the fifth complaint on September 25, 2013. The Arkansas State Board of Pharmacy alleged that Roxsan Pharmacy dispensed prescriptions to consumers in

Arkansas without being licensed in that state, as Arkansas law requires. The Board inspected Roxsan Pharmacy on November 5, 2013. The relevant findings are alleged in Section E, below.

62. The sixth consumer complaint came from the California State Health and Human Services Agency, Department of Health Care Services ("Department of Health Care Services"). The Board received the complaint on September 27, 2013. The Department alleged that Roxsan Pharmacy did not maintain original prescription records for certain dispensed drugs. The Board investigated the complaint and inspected the pharmacy on November 5, 2013. The relevant findings are alleged in Section F, below.

63. The seventh consumer complaint came to the Board on December 2, 2013. The complainant alleged that Roxsan Pharmacy dispensed the wrong dose of Leuprolide. The Board investigated the complaint. The relevant findings are alleged in Section G, below.

64. The Board received the eighth consumer complaint on April 16, 2014. The complainant alleged that Roxsan Pharmacy dispensed dangerous drugs to consumers in Florida and Maryland without being licensed in those states. The Board investigated the complaint. The relevant findings are alleged in Section H, below.

65. The final consumer complaint reached the Board on August 11, 2014. The Board launched an investigation, during the course of which it was revealed that Roxsan Pharmacy had applied an incorrect expiration date to a Progesterone prescription. The relevant findings are alleged in Section I, below.

A. <u>Omnitrope Complaint and Pharmacy Inspection on June 23, 2011</u>

66. On December 9, 2010, a San Francisco-based fertility doctor prescribed Omnitrope (somatropin) 5mg per 1.5ml to one of her patients. Omnitrope is a recombinant human growth hormone indicated for the treatment of adult onset or childhood onset growth hormone deficiency. It is dispensed in cartridges holding doses of 5mg per 1.5ml or 10mg per 1.5ml. The cartridges are designed by the manufacturer, Sandoz, to be used with its own dispensing pens, Pen 5 and Pen 10. Each pen is specific to the prescribed dose—Pen 5 for 5mg prescriptions and Pen 10 for 10mg prescriptions. Sandoz supplies the pens to patients free of charge upon the prescriber's request. In Omnitrope's published drug information, Sandoz warns against using

non-proprietary devices to dispense the medication, stating that Omnitrope cartridges "must be used with the corresponding OMNITROPE® Pen 5 and Pen 10 delivery system, respectively."

67. The Follistim Pen is a dispensing device made by Merck. It is designed to inject precise doses of Merck's Follistim AQ (follitropin beta) drug. Follistim AQ is a gonadotropin that stimulates reproductive processes in women. Follistim AQ is indicated for the induction of ovulation and pregnancy and development of multiple follicles for patients in assisted reproductive programs. Merck sells the drug in cartridges dosed in international units (IU). Follistim AQ is available in strengths of 175 IU per 0.210ml, 350 IU per 0.420ml, 650 IU per 0.780ml, and 975 IU per 1.170ml. Merck's patient information guide advises patients not to "mix any other medicines into the cartridge" and directs patients to "[u]se [the] "Follistim AQ Cartridge only with the Follistim Pen."

68. On February 21, 2011, Roxsan Pharmacy received a faxed prescription for Omnitrope. Pharmacist J.A. (not a party to this action) dispensed the Omnitrope cartridge (5mg per 1.5ml) that day and substituted a Follistim Pen for the Omnitrope Pen 5. Roxsan Pharmacy and the dispensing pharmacist did not instruct the patient on how to convert milliliters (Omnitrope Pen) into international units (Follistim Pen) or otherwise provide adequate use instructions.

69. The patient was unable to use the Follistim pen dispensed by Roxsan Pharmacy and obtained the Omnitrope Pen 5 from her fertility clinic. Roxsan Pharmacy never replaced the Follistim pen with a suitable dispensing device.

70. On June 9, 2011, the patient's partner filed a complaint with the Board over the substitution of the Follistim pen. On June 23, 2011, a Board inspector conducted a complaint inspection of Roxsan Pharmacy at its Beverly Hills location. The inspector documented the following relevant facts:

1. A Pharmacist Falsified a Prescription Record

71. As part of the inspection into the Omnitrope consumer complaint, the inspector asked for all pharmacy records related to the dispensing of the patient's Omnitrope prescription. The dispensing pharmacist, J.A., produced records that showed the prescription was written on

December 9, 2010 for "Omnitrope Pen 5 (5mg/1.5ml)" in a quantity of five with one authorized refill. The prescription was typed and contained instructions to "dispense as written." The words "Foll Pen #1 per MD" appeared, handwritten, on the right side of the prescription. The dispensing pharmacist told the inspector that the physician verbally authorized the substitution.

72. The inspector noticed that the handwritten portion of the order, which purported to reflect the physician's order for the substitution, was wet. To test her belief, she ran her finger across the ink. The order smeared. The dispensing pharmacist admitted that she wrote the order for the substitution during the inspection.

73. By letter dated July 6, 2011, the prescribing doctor denied having authorized the Follistim Pen's substitution.

2. Pharmacist-in-Charge Shahla Melamed Falsified the DEA Biennial Controlled Substance Inventory

74. Later in the inspection, the Board inspector requested the pharmacy's federal Drug Enforcement Administration biennial controlled substance inventory. Pharmacist K.B. (not a party to this action) produced a spiral notebook containing handwritten controlled substance counts. The dates of the inventories were June 7, 2007, May 6, 2009 and June 1, 2011. For the biennial periods ending in 2007 and 2009, the inventories included Schedule II through V controlled substances. For the period ending in 2011, the inventory recorded only Schedule II controlled substances; missing were drug counts for Schedule III through V controlled substances.

75. At some point during the inspection, Respondent Shahla Melamed, the Pharmacist-in-Charge, arrived at the pharmacy. The Board inspector asked her for the pharmacy's self assessment and DEA inventory. Respondent Shahla Melamed produced the same spiral notebook as before. The inspector noticed that within the 2009 inventory, the header had been changed to include the date of June 1, 2011 for Scheduled drugs not listed in the 2011 inventory. The Board inspector asked Respondent Shahla Melamed if she added the 2011 date to the 2009 inventory. After first denying the charge, Respondent Shahla Melamed admitted adding "6/1/11" to the 2009 controlled substance inventory. The modification gave the appearance that Roxsan Pharmacy

maintained a count of Schedule III through V controlled substances for the biennial reporting period ending in 2011.

3. Roxsan Pharmacy Did Not Perform End-Product Sterility and Pyrogen Testing on Sterile Injectable Products or Keep Temperature Records

76. While evaluating the pharmacy's sterile compounding practice, the Board inspector discovered that Roxsan Pharmacy compounded injectable alprostadil alcohol solution on March 30, 2011 and June 2, 2011, and also prepared mitomycin injectable solution on February 14, 2011. Roxsan Pharmacy did not conduct end-product sterility and pyrogen testing on either solution to ensure safe use. Nor did the pharmacy maintain temperature records for the freezer used to store these and other sterile injectable solutions.

4. Roxsan Pharmacy Did Not Verify All Pharmacy Technician Work, Did Not Ensure that Each Pharmacy Technician Was Wearing Identification, and Maintained 17 Expired Ingredients in Active Compounding Stock

77. In addition to having deficient practices concerning sterile injectable products, Roxsan Pharmacy comingled 17 expired compounding ingredients with active compounding stock and permitted two of its pharmacy technicians to be present in the compounding area without wearing identification badges. The Board inspector found 14 medication bubble cards prepared by pharmacy technicians that did not contain a pharmacist's initials indicating that a pharmacist had verified the technician's work.

B. <u>Domperidone Complaint and Inspection on September 15, 2011</u>

78. On July 28, 2011, the Board received a complaint alleging that Roxsan Pharmacy dispensed Domperidone. Domperidone is a galactagogue, meaning it increases breast milk production in lactating women. The drug is not approved in the United States for any purpose although it is approved in other countries for the treatment of gastrointestinal disorders. The FDA bans the importation and interstate transportation of finished products and bulk compounding ingredients containing Domperidone except for use in research and development.

79. On September 15, 2011, Board inspectors conducted a complaint inspection at Roxsan Pharmacy. They discovered compounded Domperidone in the pharmacy's inventory. The

pharmacy possessed 100 10mg capsules, 200 20mg capsules, 200 30mg capsules and 100 40mg capsules of the drug. The pharmacy dispensed 452 prescriptions containing Domperidone in these various strengths between approximately August 4, 2005 and September 2, 2011.

80. Under its authority to embargo misbranded drugs, the Board seized the pharmacy's stock of Domperidone. (Bus. & Prof. Code, § 4084.)

C. Louisiana Complaint and Pharmacy Inspection on June 4, 2013

81. On February 21, 2013, the Louisiana Board of Pharmacy complained to the Board that Roxsan Pharmacy was soliciting business from Louisiana physicians and selling dangerous drugs and controlled substances in that state without proper licensure.

82. On June 4, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge. He admitted to the inspector that Roxsan pharmacy dispensed and shipped dangerous drugs to patients in Louisiana without being licensed in that state.

83. From July 31, 2012 to June 6, 2013, Roxsan Pharmacy dispensed 22 original prescriptions and two refills to patients residing in Louisiana. All but one of the prescriptions contained ketamine, a Schedule III controlled substance.

84. The inspection further revealed that Roxsan Pharmacy established incorrect beyond-use dates for eight batch compounded drug products. In each case, the compounded drug product's expiration date exceeded the expiration date of one of its ingredients. Respondent Shahla Melamed verified the products in question and Roxsan Pharmacy dispensed prescriptions from the stale batches.

D. Connecticut Complaint and Pharmacy Inspection on November 5, 2013

85. On September 24, 2013, a Connecticut consumer complained to the Board that Roxsan Pharmacy was dispensing prescriptions to consumers in Connecticut without being licensed in that state.

86. On November 5, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge.

///

87. From May 21, 2012 to June 14, 2013, Roxsan Pharmacy dispensed 230 prescriptions to patients residing in Connecticut. During this period, Respondent Roxsan Pharmacy was not licensed in the state of Connecticut.

E. Arkansas Complaint and Pharmacy Inspection on November 5, 2013

88. On September 25, 2013, the Arkansas Board of Pharmacy complained to the Board that Roxsan Pharmacy was dispensing prescriptions to consumers in Arkansas without proper licensure.

89. On November 5, 2013, the Board inspected Roxsan Pharmacy. Respondent Farbod Melamed was the acting Pharmacist-in-Charge. He admitted that Respondent Roxsan Pharmacy shipped prescriptions into Arkansas without being licensed in that state.

90. From January 7, 2013 to June 11, 2013, Roxsan Pharmacy dispensed 16 original prescriptions to patients residing in Arkansas. During this period, Respondent Roxsan Pharmacy was not licensed in the state of Arkansas.

F. Department of Health Care Services Complaint and Pharmacy Inspection on November 5, 2013

91. Responding to a complaint from the Department of Health Care Services, the Board inspected Roxsan Pharmacy on November 5, 2013. On March 28, 2014, the Board inspector asked for original prescription records for 41 prescriptions dispensed between June 1 and December 31, 2012. Roxsan Pharmacy produced six original dispensing records but did not have records for the remaining 35 prescriptions.

G. Leuprolide Complaint

92. On December 2, 2013, a patient filed a complaint with the Board after Roxsan Pharmacy filled her prescription in the wrong strength. In early 2014, the Board inspected Roxsan Pharmacy. The inspector documented the following relevant facts:

1. Variation from Leuprolide Prescription

93. On December 18, 2012, an Orange County-based fertility doctor prescribed Leuprolide acetate 40mcg/0.2ml to one of her patients undergoing in vitro fertilization ("IVF"). During an IVF cycle, different medications are used to control the menstrual cycle of the patient

to allow for optimal stimulation of the ovaries. The physician directed the patient to use Leuprolide for ten to twelve days.

94. On December 18, 2012, Roxsan Pharmacy received a faxed prescription for diluted Leuprolide. Two days later, a pharmacist who is not a party to this action dispensed *full-strength* Leuprolide 1mg/0.2ml. The dispensed drug was not diluted as the prescription required.

95. The patient injected the dispensed medication each day for nine days before she consulted her fertility doctor, who discovered the pharmacy's error. The physician ended the IVF cycle because she believed that the incorrect dosage of Leuprolide had compromised the patient's treatment.

2. Roxsan Pharmacy Did Not Perform End-Product Sterility and Pyrogen Testing on Sterile Injectable Products

96. While evaluating the pharmacy's sterile compounding practice, the Board inspector discovered that from November 2012 to February 2013, Roxsan Pharmacy compounded twenty products from non-sterile sources. The compounded products were Cyanocobalmin and several batches of (separately) Leuprolide and Hyaluronidase. Roxsan Pharmacy failed to conduct pyrogen testing on all 20 products. It also failed to conduct end-product sterility testing on 19 of the selfsame products. The one product that Roxsan Pharmacy *did* test for sterility was Leuprolide; however, the pharmacy failed to quarantine the product while it awaited test results.

97. On November 7, 14 and 19, 2012 and again on January 11, 2013, the pharmacy compounded bacteriostatic water (benzyl alcohol 0.9% injection) for use in sterile injectable solutions. The pharmacy prepared the bacteriostatic water with sodium chloride granules, a non-sterile ingredient. Roxsan Pharmacy did not conduct end-product sterility or pyrogen testing on the bacteriostatic water to ensure its sterility. It used the untested water to create injectable compounds that were sold and dispensed as sterile. Roxsan Pharmacy did not test any of the final compounds made from this untested bacteriostatic water.

98. From November 1, 2012, to March 22, 2013, Roxsan Pharmacy dispensed 474 compounded prescriptions made from non-sterile ingredients without subjecting the final product to end-product sterility and pyrogen testing.

H. **Florida and Maryland Complaints**

99. Roxsan Pharmacy dispensed 6,048 prescriptions for dangerous drugs to Florida residents from approximately January 10, 2012 to March 21, 2013. Of that number, 1,949 prescriptions contained ketamine, a Schedule III controlled substance. Roxsan Pharmacy also dispensed 3,516 prescriptions for dangerous drugs to Maryland residents from approximately February 9, 2012 to June 26, 2013. Of that number, 1,745 contained ketamine. Roxsan Pharmacy did not have a license in Florida or Maryland when it dispensed these prescriptions.

I. **Progesterone Complaint**

100. On August 11, 2014, a California consumer complained to the Board about a prescription of Progesterone 200 mg Gelatin Troche. On January 5, 2015, a Board inspector requested the master formula for the drug. From this she learned that Roxsan Pharmacy labeled the prescription with a beyond-use date greater than what the master formula supported. Roxsan Pharmacy did not conduct stability studies to justify its extended expiration date.

///

///

///

///

///

///

///

///

///

///

///

///

///

///

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Falsification of Pharmacy Records)

(As to Respondents Roxsan Pharmacy and Shahla Melamed)

101. Respondents Roxsan Pharmacy and Shahla Melamed are subject to discipline under section 4301, subdivision (g), for knowingly making or signing a document that falsely represents the existence or nonexistence of a state of facts. On June 23, 2011, Respondent Shahla Melamed knowingly falsified a DEA biennial controlled substance inventory during an inspection of the pharmacy. Complainant realleges paragraphs 57, 66–70 and 74–75.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Falsification of Pharmacy Records)

(As to Respondent Roxsan Pharmacy)

102. Respondent Roxsan Pharmacy is subject to discipline under section 4301, subdivision (g), in that on June 23, 2011, one of its pharmacists knowingly falsified a prescription for Omnitrope 5mg/1.5ml. Complainant realleges paragraphs 57 and 66–73.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Subverting a Board Investigation)

(As to Respondents Roxsan Pharmacy and Shahla Melamed)

103. Respondents Roxsan Pharmacy and Shahla Melamed are subject to discipline under section 4301, subdivision (q), for attempting to subvert an investigation of the Board on June 23, 2011. Complainant realleges paragraphs 57, 66–75 and 101–102.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Dishonesty, Fraud or Deceit)

(As to Respondents Roxsan Pharmacy and Shahla Melamed)

104. Respondents Roxsan Pharmacy and Shahla Melamed are subject to discipline under section 4301, subdivision (f), for committing an act on June 23, 2011 involving dishonesty, fraud, deceit or corruption. Complainant realleges paragraphs 57, 66–75 and 101–103.

///

///

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to Respondent Roxsan Pharmacy)

105. Respondent Roxsan Pharmacy is subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate a state law governing pharmacy. In particular, Respondent Roxsan Pharmacy violated Code section 4324, which section makes it a crime to falsely make or alter a prescription. On June 23, 2011, a pharmacist employed by Respondent Roxsan Pharmacy knowingly falsified a pharmacy record during an inspection of the pharmacy. The pharmacist wrote an unauthorized device substitution (Follistim Pen) on a prescription for Omnitrope 5mg/1.5ml. Complainant realleges paragraphs 57, 66–73 and 102–104.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to Respondents Roxsan Pharmacy and Shahla Melamed)

106. Respondents Roxsan Pharmacy and Shahla Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, as follows:

107. **Section 4342**: Section 4342 empowers the Board to act to prevent the sale of pharmaceutical preparations and drugs that fail to conform to the standard and tests as to quality and strength. On June 23, 2011, a Board inspection revealed that Roxsan Pharmacy stored 17 expired ingredients in its active compounding stock, as set forth in the table below. Respondent Shahla Melamed was the Pharmacist-in-Charge at the time of the acts in question and, under Code sections 4036.5 and 4113, subdivision (c), she had the responsibility of ensuring that pharmaceutical preparations and drugs dispensed by the pharmacy conformed to the standard and tests as to quality and strength. Complainant realleges paragraphs 57 and 77.

///

///

Drug	Expiration Date	Days Expired at Time of Inspection
Sorbitol	5/2/2008	Three years, 52 days
Sorbitan Monooleate	10/10/2008	Two years, 256 days
Potassium Azelaoyl	11/19/2008	Two years, 216 days
Versabase Foam	2/26/2010	One year, 117 days
Sardine Flavor	3/1/2010	One year, 114 days
Kaolin	4/30/2010	One year, 54 days
Rapeseed Oil	6/1/2010	One year, 22 days
PCCA[2] Vanpen	10/13/2010	253 days
Cocamide DEA	10/14/2010	252 days
Dow Corning 1501 Fluid	10/17/2010	249 days
Versabase Shampoo	11/6/2010	229 days
Gelatin	11/19/2010	216 days
Arginine	11/23/2010	212 days
PCCA[2] Anhydrous Lipoderm	1/27/2011	147 days
Ascorbyl Palmitate	2/11/2011	132 days
PCCA[2] Natapres	3/26/2011	89 days
Panthenol	4/30/2011	54 days

108. **Health and Safety Code section 111400**: Health and Safety Code section 111400 defines as "misbranded" any drug that is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in its labeling. From approximately August 4, 2005 to September 2, 2011, Respondent Roxsan Pharmacy compounded and dispensed 452 misbranded prescriptions containing Domperidone. Domperidone is not approved for any purpose in the United States and no safe dosage has been established. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Shahla Melamed was responsible, under

[2] Professional Compounding Centers of America

Code sections 4036.5 and 4113, subdivision (c), for preventing the sale of a drug dangerous to human health. Complainant realleges paragraphs 58, 78–80.

109. **Regulation 1716**: Regulation 1716 prohibits deviation from the requirements of a prescription except upon the prior consent of the prescriber or in accordance with section 4073 of the Code. Section 4073 allows a pharmacist to select a generic drug that boasts the same effectiveness as the brand name drug subject to the prescriber's order not to substitute. On February 21, 2011, Respondent Roxsan Pharmacy dispensed a Follistim Pen for injecting Omnitrope 5mg per 1.5ml and failed to provide appropriate use instructions. The Follistim Pen is not designed for Omnitrope injectable medication and cannot be substituted for the Omnitrope Pen 5. Respondent Roxsan Pharmacy deviated from the requirements of the patient's prescription without prior prescriber consent and in violation of section 4073. Respondent Shahla Melamed was the Pharmacist-in-Charge at the time of the conduct in question and had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that the dispensed medication conformed to the patient's prescription. Complainant realleges paragraphs 57 and 66–70.

110. **Regulation 1751.1, subd. (b)**: Regulation 1751.1, subdivision (b), requires pharmacies to maintain temperature records for all refrigerators and freezers in which sterile compounded products are stored. An inspection on June 23, 2011 revealed that Respondent Roxsan Pharmacy did not maintain temperature records for the freezer it used to store sterile injectable products. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Shahla Melamed was responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that adequate temperature readings of the freezer were recorded and maintained for inspection. Complainant realleges paragraphs 57 and 76.

111. **Regulation 1751.7, subd. (c)**: Regulation 1751.7, subdivision (c), requires a compounding pharmacy to perform end-product testing for sterility and pyrogens (bacterial toxins) whenever it compounds sterile injectable drug products from one or more non-sterile ingredients. The regulation requires the pharmacy to quarantine injectable drug products until end-product testing confirms their sterility and acceptable levels of pyrogens. Respondent Roxsan Pharmacy prepared sterile injectable drug products from non-sterile sources without subjecting

the final product to testing. Specifically, on February 14, 2011, Respondent Roxsan Pharmacy prepared mitomycin 0.2% injection solution without testing it. The pharmacy also prepared but failed to test alprostadil alcohol injection solution on March 30 and June 2, 2011. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Shahla Melamed had a duty, under Code sections 4036.5 and 4113, subdivision (c), to ensure that sterile injectable products compounded from non-sterile ingredients were quarantined until end-product testing confirmed their sterility and acceptable levels of pyrogens. Complainant realleges paragraphs 57 and 76.

112. **Regulation 1793.7, subd. (a)**: Regulation 1793.7, subdivision (a), requires a pharmacist to verify every function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals. The verification must be documented in writing by the verifying pharmacist on the prescription label. Respondents Roxsan Pharmacy and Shahla Melamed failed to verify 14 bubble packs of medication that were prepared by a pharmacy technician. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Shahla Melamed was responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that each bubble pack prepared by a pharmacy technician was verified by a pharmacist. The prescriptions and dates of preparation for which no written verification of technician work appeared on the prescription label are set forth in the table below. Complainant realleges paragraphs 57 and 77.

Date	Rx. No.	Drug	No. of Cards Per Rx.
2/1/2011	1238102	Atenolol 25mg	1
3/1/2011	1238102	Atenolol 25mg	1
4/1/2011	1238102	Atenolol 25mg	1
4/7/2011	1284869	Actos 30mg	1
4/11/2011	1285308	Simvastatin 20mg	1

(*cont'd...*)

Date	Rx. No.	Drug	No. of Cards Per Rx.
4/12/2011	1285427	Metoclopramide 5mg	3
4/12/2011	1285430	Omeprazole 20mg	1
4/12/2011	1285435	Hydralazine 10mg	2
4/19/2011	1285431	Isosorbide 30mg	1
4/19/2011	1285437	Aggrenox	1
5/1/2011	1238102	Atenolol 25mg	1

113. **Regulation 1793.7, subd. (c)**: Regulation 1793.7, subdivision (c), requires a pharmacy technician to wear identification that clearly identifies him as a pharmacy technician. During an inspection on June 23, 2011, two pharmacy technicians were not wearing identification clearly identifying them as pharmacy technicians. Respondent Shahla Melamed was the Pharmacist-in-Charge at the time of the act in question and was responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that pharmacy technicians were wearing proper identification. Complainant realleges paragraphs 57 and 77.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to Respondents Roxsan Pharmacy and Farbod Melamed)

114. Respondents Roxsan Pharmacy and Farbod Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, as follows:

115. **Regulation 1716**: Regulation 1716 prohibits deviation from the requirements of a prescription except upon the prior consent of the prescriber or in accordance with section 4073 of the Code. Section 4073 allows a pharmacist to select a generic drug that boasts the same effectiveness as the brand name drug subject to the prescriber's order not to substitute. On December 18, 2012, Respondent Roxsan Pharmacy dispensed full-strength Leuprolide 1mg/0.2ml instead of the prescribed Leuprolide acetate 40mcg/0.2ml. Respondent Roxsan Pharmacy

deviated from the requirements of the patient's prescription without prior prescriber consent and in violation of section 4073. Respondent Farbod Melamed was the Pharmacist-in-Charge at the time of the conduct in question and had the responsibility under Code sections 4036.5 and 4113, subdivision (c), to ensure that the dispensed medication conformed to the patient's prescription. Complainant realleges paragraphs 63, 92–95.

116. **Regulation 1735.2, subd. (h)**: Regulation 1735.2, subdivision (h), states that 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 cannot 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. Respondent Roxsan Pharmacy compounded the following drug products and labeled each with an expiration date in excess of the expiration date of one of its ingredients. As the Pharmacist-in-Charge at the time of the acts in question, Respondent Farbod Melamed had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that each compounded drug product contained a correct beyond-use date. Complainant realleges paragraphs 59, 65, 81–84, and 100.

Date Compounded	**Drug**	**Ingredient or Compound with Expiration Date that is Less Than the Beyond-Use Date**	**Beyond-Use Date on Label**
1/7/2013	Cream with: Hydroquinone cream 2% Kojic acid 2% Triamcinolone 2% Retinoic acid (tretinoin) 0.025%	4/6/2013 Hydroquinone cream 2%	5/7/2013

(*cont'd...*)

Date Compounded	Drug	Ingredient or Compound with Expiration Date that is Less Than the Beyond-Use Date	Beyond-Use Date on Label
1/10/2013	Cream with: Hydroquinone cream 4% Kojic acid 4% Triamcinolone 4% Retinoic acid (tretinoin) 0.05%	3/12/2013 Hydroquinone cream 4%	5/10/2013
2/21/2013	Hydroquinone cream 8%	7/19/2013 Sodium metabisulfite	8/20/2013
2/21/2013	Hydroquinone cream 10%	7/19/2013 Sodium metabisulfite	8/20/2013
5/17/2013	Hydroquinone cream 2%	7/19/2013 Sodium metabisulfite	11/13/2013
5/20/2013	Hydroquinone cream 5%	7/19/2013 Sodium metabisulfite	11/16/2013
5/28/2013	Hydroquinone cream 5% with Salicylic acid 5% solution	7/19/2013 Sodium metabisulfite	11/24/2013
7/1/2014	Progesterone 200 mg Gelatin Troche (PCCA Special Micronized)	9/29/2014 Compound (Progesterone 200 mg Gelatin Troche [PCCA Special Micronized])	12/28/2014

117. **Section 4342**: Section 4342 empowers the Board to act to prevent the sale of pharmaceutical preparations and drugs that fail to conform to the standard and tests as to quality and strength. Inspections on June 4, 2013 and October 10, 2014 revealed that Respondent Roxsan Pharmacy compounded eight drug products and labeled them with expiration dates that exceeded the expiration dates of their ingredients, as more particularly set forth in paragraph 116, *supra*. Respondent Farbod Melamed was the Pharmacist-in-Charge at the time of the acts in question and had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that pharmaceutical preparations and drugs dispensed by the pharmacy conformed to the standard and tests as to quality and strength. Complainant realleges paragraphs 59, 65, 81–84, 100, and 116.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to All Respondents)

118. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, as follows:

A. Respondents Illegally Shipped Drugs Into Other States Without a License

119. **Section 4059.5, subdivision (e),** prohibits the transfer, sale or delivery of dangerous drugs and devices to persons outside California unless the transfer, sale or delivery complies with California law, federal law, and the law of the state into which the dangerous drug or device is delivered. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed violated Code section 4059.5, subdivision (e), by selling dangerous drugs in other states in contravention of the laws of those states and in violation of the laws of this State.

1. Louisiana Drug Sales

120. From approximately September 28, 2012 to June 6, 2013, Respondent Roxsan Pharmacy dispensed 22 prescriptions for dangerous drugs and two refills to patients in the state of Louisiana without proper licensure. Twenty-one of the twenty-two prescriptions contained ketamine, a Schedule III controlled substance.

121. Respondent Roxsan Pharmacy dispensed four of the aforementioned prescriptions from September 28, 2012 through December 2, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 18 prescriptions were dispensed between December 3, 2012 and June 6, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

///

///

///

///

122. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Louisiana complied with the Pharmacy Law, federal law and the Louisiana Pharmacy Practice Act. Complainant realleges paragraphs 59 and 81–84.

2. Connecticut Drug Sales

123. From approximately May 21, 2012 to June 14, 2013, Respondent Roxsan Pharmacy dispensed 230 prescriptions for dangerous drugs to patients in the state of Connecticut without proper licensure.

124. Respondent Roxsan Pharmacy dispensed 128 of the aforementioned prescriptions between May 21, 2012 and December 2, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 102 prescriptions were dispensed between December 3, 2012 and June 14, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

125. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Connecticut complied with the Pharmacy Law, federal law and the Connecticut Pharmacy Practice Act. Complainant realleges paragraphs 60 and 85–87.

3. Florida Drug Sales

126. From approximately January 10, 2012 to March 21, 2013, Respondent Roxsan Pharmacy dispensed 6,048 prescriptions for dangerous drugs to patients in the state of Florida without proper licensure.

127. Respondent Roxsan Pharmacy dispensed 4,604 of the aforementioned prescriptions between January 10, 2012 and December 1, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 1,444 prescriptions were dispensed between December 3, 2012 and March 21, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

128. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Florida complied with the Pharmacy Law, federal law and the Florida Pharmacy Act. Complainant realleges paragraphs 64 and 99.

4. Maryland Drug Sales

129. From approximately February 9, 2012 to June 26, 2013, Respondent Roxsan Pharmacy dispensed 3,516 prescriptions for dangerous drugs to patients in the state of Maryland without proper licensure.

130. Respondent Roxsan Pharmacy dispensed 1,152 of the aforementioned prescriptions between February 9, 2012 and December 1, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining 2,364 prescriptions were dispensed between December 3, 2012 and June 26, 2013, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

131. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that every prescription dispensed and sold in Maryland complied with the Pharmacy Law, federal law and the laws of Maryland. Complainant realleges paragraphs 64 and 99.

5. Respondent Shahla Melamed Knew About the Out-of-State Drug Sales

132. When Respondent Farbod Melamed became the Pharmacist-in-Charge, Respondent Shahla Melamed remained the pharmacy's President, Chief Executive Officer and Secretary. As a corporate officer, she had knowledge that Roxsan Pharmacy dispensed dangerous drugs to residents of Connecticut, Florida, Louisiana and Maryland without being licensed in those states, even after she ceased being the Pharmacist-in-Charge. Complainant realleges paragraphs 59–60, 81–87, 99, and 118–131.

///

///

B. **Respondents Failed to Test Sterile Injectable Medication**

133. **Regulation 1751, subdivision (c)**, requires a compounding pharmacy to perform end-product testing for sterility and pyrogens (bacterial toxins) whenever it compounds sterile injectable drug products from one or more non-sterile ingredients. The regulation requires the pharmacy to quarantine injectable drug products until end-product testing confirms the drugs' sterility and acceptable levels of pyrogens.

134. Respondent Roxsan Pharmacy prepared sterile injectable drug products from non-sterile sources without subjecting the final product to testing. Specifically, from October 2012, to February, 2013, Roxsan Pharmacy compounded twenty products (Cyanocobalmin, Leuprolide, and Hyaluronidase) prepared from non-sterile sources without testing them. The pharmacy also prepared bacteriostatic water on November 7, 14, and 19, 2012, and again on January 11, 2013, using non-sterile sources without testing it. The bacteriostatic water was then used to create other injectable compounds but these compounds were not tested for sterility.

135. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to ensure that sterile injectable products compounded from non-sterile ingredients were quarantined until end-product testing confirmed their sterility and acceptable levels of pyrogens. Complainant realleges paragraphs 2–4, 63, and 92–98.

C. **Respondents Failed to Keep Records of Sale and Disposition of Dangerous Drugs**

136. **Sections 4081, subdivision (a), and 4105**, require a pharmacy to maintain all records of sale, acquisition, receipt, shipment, or disposition of dangerous drugs for three years from the date of making. The records must be open to inspection during the pharmacy's business hours. On March 28, 2014, the Board requested original prescription records for 41 prescriptions dispensed between June 1 and December 31, 2012. Roxsan Pharmacy produced six original dispensing records but did not produce records for the remaining 35 prescriptions. Respondents failed to keep and maintain records of sale, acquisition, receipt, shipment and disposition for those 35 prescriptions, all of which were dangerous drugs.

///

137. Respondent Roxsan Pharmacy dispensed 33 of the undocumented prescriptions prior to December 3, 2012, during which time Respondent Shahla Melamed was the Pharmacist-in-Charge. The remaining two undocumented prescriptions were dispensed on December 17 and 26, 2012, during which time Respondent Farbod Melamed was the Pharmacist-in-Charge.

138. Under Code sections 4036.5 and 4113, subdivision (c), Respondents Shahla Melamed and Farbod Melamed had a duty, during the respective times in which each pharmacist served as the Pharmacist-in-Charge, to maintain all records of sale, acquisition, receipt, shipment and disposition of dangerous drugs. Complainant realleges paragraphs 62 and 91.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Pharmacy Law and Regulations)

(As to Respondents Roxsan Pharmacy and Farbod Melamed)

139. Respondents Roxsan Pharmacy and Farbod Melamed are subject to discipline under section 4301, subdivision (o), for violating, or assisting in or abetting the violation of or conspiring to violate provisions of the Pharmacy Law and state laws and regulations governing pharmacy, in particular Code section 4059.5, subdivision (e).

140. **Section 4059.5, subdivision (e)**, prohibits the transfer, sale or delivery of dangerous drugs and devices to persons outside of California unless the transfer, sale or delivery complies with California law, federal law, and the law of the state into which the dangerous drug or device is delivered. Respondents Roxsan Pharmacy and Farbod Melamed violated Code section 4059.5, subdivision (e) by dispensing medications to patients in the state of Arkansas in contravention of California and Arkansas law.

141. From approximately January 7, 2013 to June 11, 2013, Respondent Roxsan Pharmacy dispensed 16 prescriptions to patients in the state of Arkansas without proper licensure.

142. During that time period, Respondent Farbod Melamed was the Pharmacist-in-Charge and had a duty to ensure that every prescription dispensed and sold in Arkansas complied with the Pharmacy Law, federal law and Arkansas law. Complainant realleges paragraphs 61, 88–90.

///

///

143. Respondent Shahla Melamed, as Roxsan Pharmacy's President, Chief Executive Officer and Secretary, had knowledge of the out-of-state drug sales. Complainant realleges paragraph 132.

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of State and Federal Statutes Regulating Controlled Substances and Dangerous Drugs)

(As to All Respondents)

144. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (j), for violating statutes of this State and other states regulating controlled substances and dangerous drugs. Complainant realleges paragraphs 57–143.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Conduct Which Would Warrant Denial of an Application)

(As to All Respondents)

145. Respondents Roxsan Pharmacy, Shahla Melamed and Farbod Melamed are subject to discipline under section 4301, subdivision (p), for engaging in conduct that would have warranted denial of a license. Complainant realleges paragraphs 57–144.

///

///

///

///

///

///

///

///

///

///

///

///

DISCIPLINARY CONSIDERATIONS

Complainant alleges as a disciplinary consideration the following prior violations:

Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Code Fed. Regs., tit. 21, § 1304.04 (f)	Failure to maintain separate inventories and records of controlled substances	Roxsan Pharmacy CI 2007 35352 (6/5/08) PIC Shahla Melamed CI 2007 36251 (6/5/08)
Code Fed. Regs., tit. 21, § 1304.11 (c)	Failure to maintain complete inventory of controlled substances	Roxsan Pharmacy CI 2001 22642 (3/3/03) CI 2004 27776 (10/26/04) PIC Shahla Melamed CI 2001 22642 (3/3/03) CI 2004 27776 (10/26/04)
Code, § 4052 (a)	Scope of practice	Roxsan Pharmacy CI 2002 24424 (9/8/03)
Code, § 4059	Furnishing dangerous drug or device other than upon the prescription of a person authorized to prescribe dangerous drugs and devices	Roxsan Pharmacy CI 2002 24424 (9/8/03) PIC Shahla Melamed CI 2002 24424 (9/8/03)
Code, § 4076	Failure to dispense prescription in a container that meets the requirements of state and federal law and is correctly labeled	Roxsan Pharmacy CI 2001 22642 (3/3/03) PIC Shahla Melamed CI 2001 22642 (3/3/03)

(*cont'd...*)

Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Code, § 4076 (a) Code, § 4076 (a)(11)(A)	Mislabeling of physical description of the dispensed medication	Roxsan Pharmacy CI 2007 35352 (6/5/08) CI 2007 36248 (10/1/09) CI 2009 41104 (6/4/10) PIC Shahla Melamed CI 2007 36251 (6/5/08) CI 2009 41471 (10/1/09) CI 2009 44011 (6/24/10)
Code, § 4077 (d)	Failure of pharmacist to affix warning label on products containing dimethyl sulfoxide	Roxsan Pharmacy CI 2007 36248 (10/1/09) PIC Shahla Melamed CI 2009 41471 (10/1/09)
Code, § 4081 (a)	Failure of pharmacy to maintain a current inventory of dangerous drugs and to have that inventory available for inspection	Roxsan Pharmacy CI 2004 27776 (10/26/04) CI 2007 35352 (6/5/08) PIC Shahla Melamed CI 2004 27776 (10/26/04) CI 2007 36251 (6/5/08)
Code, § 4104 (a)	Failure to 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 ability to practice the profession or is discovered to have engaged in the theft, diversion or self-use of dangerous drugs	Roxsan Pharmacy CI 2007 35352 (6/5/08) PIC Shahla Melamed CI 2007 36251 (6/5/08)

(*cont'd...*)

Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Code, § 4115 (g)	Failure of pharmacist to supervise pharmacy technician in reviewing work completed during pharmacist's temporary absence	Roxsan Pharmacy CI 2001 22642 (3/3/03) PIC Shahla Melamed CI 2007 36251 (6/5/08)
Code, § 4125 (a) Regulation 1711 (e)	Failure of pharmacy to complete and maintain quality assurance review following medication error	Roxsan Pharmacy CI 2002 24424 (9/8/03) CI 2009 41104 (6/4/10) PIC Shahla Melamed CI 2002 24424 (9/8/03) CI 2009 44011 (6/24/10)
Code, § 4342 Regulation 1716.2 (a)(3)	Failure to ensure pharmaceutical preparations and drugs dispensed by the pharmacy conform to the standard and tests as to quality and strength	Roxsan Pharmacy CI 2001 22642 (3/3/03) CI 2002 24424 (9/8/03) CI 2004 27776 (10/26/04) CI 2007 35352 (6/5/08) CI 2007 36248 (10/1/09) CI 2009 41104 (6/24/10) PIC Shahla Melamed CI 2001 22642 (3/3/03) CI 2002 24424 (9/8/03) CI 2004 27775 (10/26/04) CI 2007 36251 (6/5/08) CI 2009 41471 (10/1/09) CI 2009 44011 (6/24/10)
Regulation 1707.3	Failure of pharmacist to review patient's drug therapy and medication record before dispensing prescription	Roxsan Pharmacy CI 2009 41104 (6/4/10) PIC Shahla Melamed CI 2009 44011 (6/24/10)

(cont'd...)

Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Regulation 1714 (c)	Failure to maintain pharmacy and fixtures and equipment in clean and orderly condition	Roxsan Pharmacy CI 2001 22642 (3/3/03) PIC Shahla Melamed CI 2001 22642 (3/3/03)
Regulation 1715 (a)	Failure of pharmacy to maintain current pharmacy self-assessment form	Roxsan Pharmacy CI 2007 35352 (6/5/08) PIC Shahla Melamed CI 2007 36251 (6/5/08)
Regulation 1716.2 (a)(4)	Failure of pharmacy to maintain records that include the signature or initials of the pharmacists performing the compounding	Roxsan Pharmacy CI 2004 27776 (10/26/04) CI 2007 35352 (6/5/08) CI 2009 41104 (6/24/10) PIC Shahla Melamed CI 2004 27776 (10/26/04) CI 2007 36251 (6/5/08) CI 2009 44011 (6/24/10)
Regulation 1718	Failure to maintain complete inventory of all dangerous drugs	Roxsan Pharmacy CI 2001 22642 (3/3/03) PIC Shahla Melamed CI 2007 36251 (6/5/08)
Regulation 1761 (a) Regulation 1716	Variation from prescription	Roxsan Pharmacy CI 2004 27776 (10/26/04) CI 2007 35352 (6/5/08) CI 2009 41104 (6/4/10) PIC Shahla Melamed CI 2004 27776 (10/26/04) CI 2007 36251 (6/5/08) CI 2009 44011 (6/24/10)

(cont'd...)

Section Violated	Offense	Cited Person, Citation Number and Date of Issuance
Regulation 1793.7	Failure to have policies and procedures and a job description for pharmacy technicians in place in the pharmacy	Roxsan Pharmacy CI 2004 27776 (10/26/04) PIC Shahla Melamed CI 2004 27776 (10/26/04)
Regulation 1793.7 (a)	Failure of pharmacist to verify and document work of pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals	Roxsan Pharmacy CI 2004 27776 (10/26/04) CI 2009 41104 (6/24/10) PIC Shahla Melamed CI 2004 27776 (10/26/04) CI 2009 44011 (6/24/10)
Regulation 1793.7 (a), (c), (d)	Pharmacy technician not wearing identification	Roxsan Pharmacy CI 2007 35352 (6/5/08) CI 2007 36248 (10/1/09) PIC Shahla Melamed CI 2007 36251 (6/5/08) CI 2009 41471 (10/1/09)

///

///

///

///

///

///

///

///

///

///

///

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 38297, issued to Roxsan Pharmacy, Inc. with Shahla Keyvanfar Melamed as its CEO and President;

2. Revoking or suspending Pharmacist License Number RPH 42096, issued to Shahla Keyvanfar Melamed;

3. Revoking or suspending Pharmacist License Number RPH 68252, issued to Farbod Melamed;

4. Prohibiting Shahla Keyvanfar Melamed from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee during the period in which discipline is imposed on Pharmacy Permit Number PHY 38297, issued to Roxsan Pharmacy, Inc. with Shahla Keyvanfar Melamed as its CEO and President.

5. Ordering Roxsan Pharmacy, Inc., Shahla Keyvanfar Melamed and Farbod Melamed to pay the reasonable costs of the investigation and enforcement of this case pursuant to Business and Professions Code section 125.3; and

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

DATED: April 15, 2015

Virginia Herold

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