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

In the Matter of the Accusation Against:

RHEEM SPECIALTY PHARMACY, LLC dba
RHEEM SPECIALTY PHARMACY, LLC;
JEFFREY M. MORGRIDGE and SAMIRA KHATAMI,
MEMBERS,
Original Pharmacy Permit No. PHY 51285;

and

SAMIRA KHATAMI,
Registered Pharmacist License No. RPH 60045,

Respondents.

Agency Case No. 7120

OAH No. 2022010622

DECISION AND ORDER

The attached Stipulated Surrender of Permit and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on November 2, 2022.

It is so ORDERED on October 3, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
CHAR SACHSON
Supervising Deputy Attorney General
GREGORY TUSS
Deputy Attorney General
State Bar No. 200659
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 510-3435
Facsimile: (415) 703-5480
Attorneys for Complainant

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

In the Matter of the Accusation Against: **RHEEM SPECIALTY PHARMACY, LLC** **dba Rheem Specialty Pharmacy, LLC** **Jeffrey M. Morgridge and Samira Khatami, Members** **346 Rheem Blvd, Ste. 109** **Moraga, CA 94556** **Original Pharmacy Permit No. PHY 51285** **SAMIRA KHATAMI** **5 Oak Knoll Ln** **Orinda, CA 94563** **Registered Pharmacist License No. RPH 60045,** Respondents.	Case No. 7120 OAH No. 2022010622 **STIPULATED SURRENDER OF PERMIT AND ORDER AS TO RESPONDENT RHEEM**

IT IS STIPULATED AND AGREED by and between the parties to these proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs. She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, and

Gregory Tuss, deputy attorney general.

2. Jeffrey M. Morgridge, a member of Rheem Specialty Pharmacy, LLC., dba Rheem Specialty Pharmacy LLC (Respondent Rheem), is represented in this proceeding by Jonathan C. Turner, whose address is 3620 American River Drive, Suite 120, Sacramento, CA 95864.

3. Samira Khatami (Respondent Khatami), a member of Respondent Rheem, is represented in this proceeding by John Bishop, whose address is 4100 Newport Place, Suite 670, Newport Beach, CA 92660.p, Esq., whose address is: 4100 Newport Place, Suite 670, Newport Beach, CA 92660.

4. On July 8, 2013, the Board issued Original Pharmacy Permit No. PHY 51285 to Respondent Rheem Specialty Pharmacy, LLC, dba Rheem Specialty Pharmacy, LLC, Jeffrey M. Morgridge and Samira Khatami, Members. This pharmacy permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7120, and it was cancelled on November 18, 2020.

JURISDICTION

5. Accusation No. 7120 was filed before the Board and is currently pending against Respondent Rheem. The accusation and all other statutorily required documents were properly served on Respondent Rheem on August 2, 2021. Respondent Rheem filed its notice of defense contesting the accusation. A copy of Accusation No. 7120 is attached as exhibit 1 and incorporated by reference.

ADVISEMENT AND WAIVERS

6. Respondent Rheem has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7120. Respondent Rheem also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of Permit and Order as to Respondent Rheem.

7. Respondent Rheem is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the accusation, the right to confront and cross-examine the witnesses against it, the right to present evidence and to testify on its own behalf, the right to the issuance of subpoenas to compel the attendance of witnesses and the production of

documents, the right to reconsideration and court review of an adverse decision, and all other rights accorded by the Administrative Procedure Act and other applicable laws.

8. Respondent Rheem voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent Rheem understands that the charges and allegations in Accusation No. 7120, if proven at a hearing, constitute cause for imposing discipline upon its pharmacy permit.

10. For the purpose of resolving the accusation without the expense and uncertainty of further proceedings, Respondent Rheem agrees that at a hearing Complainant could establish a factual basis for the charges in the accusation and that those charges constitute cause for discipline. Respondent Rheem gives up its right to contest that cause for discipline exists based on those charges.

11. Respondent Rheem understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of its pharmacy permit without further process.

RESERVATION

12. The admissions made by Respondent Rheem are only for the purposes of this stipulated surrender and the accusation against Respondent Rheem's permit, and shall not be admissible in any other criminal, civil, or administrative proceeding, including any other proceedings in which the Board of Pharmacy, Department of Consumer Affairs, or any other licensing agency is involved.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board. Respondent Rheem understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender without notice to or participation by Respondent Rheem or its counsel. By signing the stipulation, Respondent Rheem understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its decision and order, this Stipulated Surrender of Permit and Order as to Respondent Rheem shall

be of no force or effect except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

14. The parties understand and agree that portable document format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures, shall have the same force and effect as the originals.

15. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of Permit and Order as to Respondent Rheem may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

16. In consideration of these admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS ORDERED that Original Pharmacy Permit No. PHY 51285 issued to Respondent Rheem Specialty Pharmacy, LLC, dba Rheem Specialty Pharmacy, LLC, Jeffrey M. Morgridge and Samira Khatami, Members, is surrendered and accepted by the Board.

1. Respondent Rheem understands and agrees that for purposes of Business and Professions Code section 4307 this surrender shall be construed the same as revocation.

2. The surrender of Respondent Rheem's pharmacy permit and the acceptance of the surrendered permit by the Board shall constitute the imposition of discipline against Respondent Rheem. This stipulation constitutes a record of the discipline and shall become a part of Respondent Rheem's license history with the Board.

3. Respondent Rheem shall lose all rights and privileges as a pharmacy in California as of the effective date of the Board's decision and order.

4. Respondent Rheem shall relinquish the premises wall license and renewal license to the board within 10 days of the effective date of this decision.

5. If Respondent Rheem ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent Rheem must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 7120 shall be deemed to be true, correct and admitted by Respondent Rheem when the Board determines whether to grant or deny the application or petition.

6. Respondent Rheem shall pay the agency its costs of investigation and enforcement in the amount of $8,000.00 prior to issuance of a new or reinstated license. Respondents Rheem and Khatami are jointly and severally liable for these costs.

7. If Respondent Rheem should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation, No. 7120 shall be deemed to be true, correct, and admitted by Respondent Rheem for the purpose of any statement of issues or any other proceeding seeking to deny or restrict licensure.

8. Respondent Rheem shall, within 10 days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed and approved by the board of all controlled substances and dangerous drugs and/or dangerous devices. Respondent Rheem shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the board. Respondent Rheem shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

9. Respondent Rheem shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by at minimum providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent Rheem shall provide a copy of the written notice to the board. For the purposes of this provision, 'ongoing patients' means

those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding 60 days.

ACCEPTANCE

I have carefully read this Stipulated Surrender of Permit and Order as to Respondent Rheem and have fully discussed it with my attorney, Jonathan Turner. I understand the stipulation and the effect it will have on Respondent Rheem's pharmacy permit. I enter into this Stipulated Surrender of Permit and Order as to Respondent Rheem voluntarily, knowingly, and intelligently, and agree to be bound by the decision and order of the Board of Pharmacy.

DATED: _____

_____
JEFFREY M. MORGRIDGE, MEMBER
RHEEM SPECIALTY PHARMACY, LLC.,
DBA RHEEM SPECIALTY PHARMACY
LLC
Respondent Rheem

I have read and fully discussed with Jeffrey M. Morgridge, a member of Respondent Rheem, the terms and conditions and other matters contained in this Stipulated Surrender of Permit and Order as to Respondent Rheem. I approve its form and content.

DATED: _____

_____
JONATHAN TURNER
Attorney for Jeffrey M. Morgridge,
Member of Respondent Rheem

///

those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding 60 days.

ACCEPTANCE

I have carefully read this Stipulated Surrender of Permit and Order as to Respondent Rheem and have fully discussed it with my attorney, Jonathan Turner. I understand the stipulation and the effect it will have on Respondent Rheem's pharmacy permit. I enter into this Stipulated Surrender of Permit and Order as to Respondent Rheem voluntarily, knowingly, and intelligently, and agree to be bound by the decision and order of the Board of Pharmacy.

DATED: 06/24/2022

JEFFREY M. MORGRIDGE, MEMBER
RHEEM SPECIALTY PHARMACY, LLC.,
DBA RHEEM SPECIALTY PHARMACY LLC
Respondent Rheem

I have read and fully discussed with Jeffrey M. Morgridge, a member of Respondent Rheem, the terms and conditions and other matters contained in this Stipulated Surrender of Permit and Order as to Respondent Rheem. I approve its form and content.

DATED: 6/24/2022

JONATHAN TURNER
Attorney for Jeffrey M. Morgridge, Member of Respondent Rheem

///

I have carefully read this Stipulated Surrender of Permit and Order as to Respondent Rheem and have fully discussed it with my attorney, John Bishop. I understand the stipulation and the effect it will have on Respondent Rheem's pharmacy permit. I enter into this Stipulated Surrender of Permit and Order as to Respondent Rheem voluntarily, knowingly, and intelligently, and agree to be bound by the decision and order of the Board of Pharmacy.

DATED: 8/1/2022

DocuSigned by:
Samira Khatami
C63109CD2CE649A...

SAMIRA KHATAMI, MEMBER
RHEEM SPECIALTY PHARMACY, LLC., DBA RHEEM SPECIALTY PHARMACY LLC
Respondent Rheem

I have read and fully discussed with Samira Khatami, a member of Respondent Rheem, the terms and conditions and other matters contained in this Stipulated Surrender of Permit and Order as to Respondent Rheem. I approve its form and content.

DATED: 8/2/2022

DocuSigned by:
John Bishop
A01FB7D05FC1485...

JOHN BISHOP
Attorney for Samira Khatami, Member of Respondent Rheem

ENDORSEMENT

This Stipulated Surrender of Permit and Order as to Respondent Rheem is submitted for consideration by the Board of Pharmacy, Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
CHAR SACHSON
Supervising Deputy Attorney General

GREGORY TUSS
Deputy Attorney General
Attorneys for Complainant

SF2021400526
43107945.docx

I have carefully read this Stipulated Surrender of Permit and Order as to Respondent Rheem and have fully discussed it with my attorney, John Bishop. I understand the stipulation and the effect it will have on Respondent Rheem's pharmacy permit. I enter into this Stipulated Surrender of Permit and Order as to Respondent Rheem voluntarily, knowingly, and intelligently, and agree to be bound by the decision and order of the Board of Pharmacy.

DATED: _____

SAMIRA KHATAMI, MEMBER
RHEEM SPECIALTY PHARMACY, LLC., DBA RHEEM SPECIALTY PHARMACY LLC
Respondent Rheem

I have read and fully discussed with Samira Khatami, a member of Respondent Rheem, the terms and conditions and other matters contained in this Stipulated Surrender of Permit and Order as to Respondent Rheem. I approve its form and content.

DATED: _____

JOHN BISHOP
Attorney for Samira Khatami, Member of Respondent Rheem

ENDORSEMENT

This Stipulated Surrender of Permit and Order as to Respondent Rheem is submitted for consideration by the Board of Pharmacy, Department of Consumer Affairs.

DATED: 8-5-22

Respectfully submitted,

ROB BONTA
Attorney General of California
CHAR SACHSON
Supervising Deputy Attorney General

GREGORY TUSS
Deputy Attorney General
Attorneys for Complainant

SF2021400526
43107945.docx

Exhibit 1

Accusation No. 7120

ROB BONTA
Attorney General of California
CHAR SACHSON
Supervising Deputy Attorney General
JONATHAN D. COOPER
Deputy Attorney General
State Bar No. 141461
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 510-3433
Facsimile: (415) 703-5480
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **RHEEM SPECIALTY PHARMACY, LLC** **dba Rheem Specialty Pharmacy, LLC** **Jeffrey M. Morgridge and Samira Khatami, Members** **346 Rheem Blvd, Ste. 109** **Moraga, CA 94556** **Original Pharmacy Permit No. PHY 51285** **And** **SAMIRA KHATAMI** **5 Oak Knoll Ln** **Orinda, CA 94563** **Registered Pharmacist License No. RPH 60045** Respondents.	Case No. 7120 **ACCUSATION**

PARTIES

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

2. On or about July 8, 2013, the Board issued Original Pharmacy Permit Number PHY

51285 to Rheem Specialty Pharmacy, LLC, dba Rheem Specialty Pharmacy, LLC, Jeffrey M. Morgridge and Samira Khatami, Members (hereinafter "Respondent Rheem"). The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein. It was cancelled on November 18, 2020.

3. On or about September 13, 2007, the Board issued Original Pharmacist License Number RPH 60045 to Samira Khatami (hereinafter "Respondent Khatami"). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2022, unless renewed. Respondent Khatami served as Pharmacist-in-Charge for Respondent Rheem since July 8, 2013.

JURISDICTION

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

5. Section **4011** of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section **4300(a)** of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section **4300.1** of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY AND REGULATORY PROVISIONS

Business and Professions Code:

8. Section **4059** of the Code, in pertinent part, prohibits furnishing of any dangerous drug or dangerous device except upon the prescription of an authorized prescriber.

9. Section **4081** of the Code states, in pertinent part:

(a) All records of manufacture and of sale, acquisition, 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, 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, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

. . .

10. Section **4105** of the Code requires, in pertinent part, that unless a waiver is granted by the board, all records and other documentation of the acquisition and disposition of dangerous drugs and devices by any entity licensed by the board be retained on the licensed premises, in a readily retrievable form, for three years from the date of making.

11. Section **4113(c)** of the Code states:

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.

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

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been 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.

. . .

(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.

. . .

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

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

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

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

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

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

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

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or

any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308 , may refer to a pharmacist or to any other person who serves in such 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.

15. Section **4332** of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

California Code of Regulations:

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

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

. . .

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

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

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

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

18. California Code of Regulations, title 16, section **1735.2** states, in pertinent part:

. . .

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30

days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

. . .

19. California Code of Regulations, title 16, section **1735.3** states, in pertinent part:

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

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

. . .

20. California Code of Regulations, title 16, section **1735.5** states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

. . .

21. California Code of Regulations, title 16, section **1735.7** states:

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

///

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

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

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

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

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

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

Controlled Substances/Dangerous Drugs:

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

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

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

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

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

25. California Health and Safety Code section **11153** states:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

(b) Any person who knowingly violates this section shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars ($20,000), or by both that fine and imprisonment.

(c) No provision of the amendments to this section enacted during the second year of the 1981-82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.

COST RECOVERY

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

PHARMACY LAW VIOLATIONS

27. On or about October 29, 2020, a Pharmacy Board Inspector inspected Respondent Rheem. The inspection revealed numerous violations of standards applicable to pharmacies, as follows:

a. Self-Assessment of Pharmacy: Respondent Rheem and Respondent Khatami (hereinafter "Respondents") failed to comply with California Code of Regulations, title 16, section 1715, subsections (a) and (d), which require pharmacies to complete and keep on file self-assessments of the pharmacies' compliance with federal and state pharmacy law.

b. Self-Assessment Regarding Compounding Limitations and Requirements: Respondents failed to comply with California Code of Regulations, title 16, section 1735.2, subsection (k), which requires compounding pharmacies to complete and keep on file self-assessments of the pharmacies' compliance with federal and state pharmacy law.

c. Compounding Log: Respondents failed to comply with California Code of Regulations, title 16, section 1735.3, subsection (a)(2)(J), which requires compounding pharmacies to maintain a compounding log documenting quality reviews and required post-compounding process and procedures.

d. Compounding Policies and Procedures: Respondents failed to comply with California Code of Regulations, title 16, section 1735.5, subsection (b), which requires compounding pharmacies to maintain written policies and procedures for compounding and to update them on an annual basis. On the date of the inspection, the compounding policies and procedures had not been updated or reviewed since 2014.

e. Compounding Quality Assurance: Respondents failed to comply with California Code of Regulations, title 16, section 1735.8, which requires compounding pharmacies to maintain a written quality assurance plan designed to monitor and ensure the integrity, potency, quality and strength of compounded drug preparations. On the date of the inspection, Respondents failed to show that they had completed end product testing to ensure the potency and labeled strength on any compounded drug product.

f. Training of Compounding Staff: Respondents failed to comply with California Code of Regulations, title 16, section 1735.7, which requires compounding pharmacies to train, evaluate and assess the ongoing competency of pharmacy staff, and to maintain documentation of compliance with these requirements. On the date of the inspection, Respondents failed to show that they had complied with these requirements.

g. Fraudulent Conduct: Respondents engaged in unprofessional conduct, in violation of Code section 4301, subsection (f), by engaging in fraudulent acts. Between November 1, 2018 and October 29, 2020, Respondents filled fraudulent prescriptions for foot bath treatments. The prescriptions were purportedly issued by medical practitioners. The practitioners, however, did not in actuality issue or authorize the prescriptions. Respondents billed for prescriptions that were never written and/or were never filled.

h. Failure to Maintain Current Inventory: Respondents failed to comply with Code section 4081, subsection (a), and California Code of Regulations, title 16, section 1718, which require pharmacies to maintain a current inventory of manufacture, sale, acquisition and disposition of dangerous drugs and devices. A two-year audit from November 1, 2018 to October 29, 2020 revealed substantial overages of vancomycin, clindamycin and ketoconazole. In other words, the audit revealed that Respondents had dispensed more of these drugs than Respondents had purchased.

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Pharmacy Laws)

28. Respondents are each and severally subject to discipline under Code sections 4113, subsection (c), 4301, subsections (j) and (o), and, by reference to section(s) 4081, 4105 and/or 4332 of the Code, for violating laws regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, as set forth above in paragraph 27 and its subsections.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct -- Fraud)

29. Respondents are each and severally subject to discipline under section 4301(f) of the Code and under Code section 4113, subsection (c), in that Respondents committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption, as set forth above in paragraph 27 and its subsections.

///

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

30. Respondents are each and severally subject to discipline under section 4301 of the Code and under Code section 4113, subsection (c), in that Respondents committed acts of unprofessional conduct, as set forth above in paragraph 27 and its subsections.

FOURTH CAUSE FOR DISCIPLINE

(Pharmacist's Failure to Exercise Education, Training and Experience)

31. Respondent Khatami is subject to discipline under section 4306.5 of the Code in that she inappropriately exercised her education, training or experience as a pharmacist, as set forth above in paragraph 27 and its subsections.

OTHER MATTERS

32. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Original Permit Number PHY 51285 issued to Respondent Rheem, then Respondent Rheem shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51285 is placed on probation or until Pharmacy Permit Number PHY 51285 is reinstated if it is revoked.

33. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 60045, issued to Respondent Khatami, then Respondent Khatami shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 60045 is placed on probation or until Pharmacist License Number RPH 60045 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Permit Number PHY 51285 issued to Respondent Rheem;

2. Revoking or suspending Pharmacist License Number RPH 60045, issued to Respondent Khatami;

3. Prohibiting Respondents Rheem and Khatami from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51285 is placed on probation or until Pharmacy Permit Number PHY 51285 is reinstated if Pharmacy Permit Number PHY 51285 is revoked;

4. Prohibiting Respondent Khatami from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 60045 is placed on probation or until Pharmacist License Number RPH 60045 is reinstated if Pharmacist License Number RPH 60045 is revoked;

5. Ordering Respondents to jointly and severally be responsible to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 7/29/2021

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant