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

In the Matter of the Third Amended Accusation Against:

WHITE HOUSE PHARMACY INC.,
DBA SAN JOSE COMPOUNDING PHARMACY;
PATRICK JOSEPH D'ANGELO, OWNER,
Pharmacy Permit No. PHY 54957; and

JOHN T. SORCI
Pharmacist License No. RPH 45060; and

MARA TIBAYAN RASE,
Pharmacist License No. RPH 75062; and

SHIVAN ACHARYA,
Pharmacist License No. RPH 76346,

Respondents.

Agency Case No. 6802

OAH No. 2021030542

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval 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 September 28, 2022.

It is so ORDERED on August 29, 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
JOSHUA D. JOHNSON
Deputy Attorney General
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San Francisco, CA 94102-7004
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **WHITE HOUSE PHARMACY INC., DBA SAN JOSE COMPOUNDING PHARMACY; PATRICK JOSEPH D'ANGELO, OWNER** **2453 Forest Ave.** **San Jose, CA 95128** **Pharmacy Permit No. PHY 54957** **JOHN T. SORCI** **15048 Bel Estos Dr.** **San Jose, CA 95124** **Pharmacist License No. RPH 45060** **MARA TIBAYAN RASE** **25577 Salerno Way** **Yorba Linda, CA 92887** **Pharmacist License No. RPH 75062** **SHIVAN ACHARYA** **1600 Green Hills Rd., #101** **Scotts Valley, CA 95066** **Pharmacist License No. RPH 76346** Respondents.	Case No. 6802 OAH No. 2021030542 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL AS TO SHIVAN ACHARYA** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). 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, by Joshua D. Johnson, Deputy Attorney General.

2. Respondent Shivan Acharya (Respondent Acharya) is represented in this proceeding by attorney Natalia Mazina, whose address is: Mazina Law, 100 Pine Street, Suite 1250, San Francisco, CA 94111.

JURISDICTION

3. On or about March 29, 2017, the Board of Pharmacy issued Pharmacist License Number RPH 76346 to Respondent Acharya. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2022, unless renewed.

4. Accusation No. 6802, as amended, was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent Acharya. The Third Amended Accusation and all other statutorily required documents were properly served on Respondent on April 13, 2022. Respondent timely filed his Notice of Defense contesting the Accusation. A copy of Third Amended Accusation No. 6802 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6802, as amended. Respondent Acharya has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent Acharya is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by

counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his 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 California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

8. Respondent Acharya understands and agrees that the charges and allegations in Accusation No. 6802, as amended, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License.

9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent Acharya agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent Acharya hereby gives up his right to contest those charges.

10. Respondent Acharya agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent Acharya understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent Acharya or his counsel. By signing the stipulation, Respondent Acharya understands and agrees that he may not withdraw his 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, the Stipulated Settlement and Disciplinary Order for Public Reproval 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.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval 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 Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 76346 issued to Respondent Shivan Acharya shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6802, as amended, attached as exhibit A.

Ethics Course. Within sixty (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 that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year from the effective date of the Decision, to successfully complete it before the end of the second year from the effective date of the Decision, or to timely submit proof of completion to the board or its designee, shall be considered a violation of this Stipulated Settlement and Disciplinary Order for Public Reproval.

Cost Recovery. No later than one year from the effective date of the Decision, Respondent Acharya shall pay $3,000 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent Acharya fails to pay the Board costs as ordered, Respondent Acharya shall not be allowed to renew his Pharmacist License until Respondent Acharya pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 6802, as amended, this stipulated settlement is contingent upon Respondent Acharya's full compliance with all conditions of this Order. If Respondent Acharya fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent Acharya's Pharmacist License No. RPH 76346.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

SHIVAN ACHARYA
Respondent Acharya

I have read and fully discussed with Respondent Shivan Acharya the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

NATALIA MAZINA
Attorney for Respondent Shivan Acharya

Cost Recovery. No later than one year from the effective date of the Decision, Respondent Acharya shall pay $3,000 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code Section 125.3. If Respondent Acharya fails to pay the Board costs as ordered, Respondent Acharya shall not be allowed to renew his Pharmacist License until Respondent Acharya pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in Accusation No. 6802, as amended, this stipulated settlement is contingent upon Respondent Acharya's full compliance with all conditions of this Order. If Respondent Acharya fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent Acharya's Pharmacist License No. RPH 76346.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: July 18, 2022

SHIVAN ACHARYA
Respondent Acharya

I have read and fully discussed with Respondent Shivan Acharya the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: July 18, 2022

NATALIA MAZINA
Attorney for Respondent Shivan Acharya

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

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

JOSHUA D. JOHNSON
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: July 15, 2022

Respectfully submitted,

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

JOSHUA D. JOHNSON
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Third Amended Accusation No. 6802

ROB BONTA
Attorney General of California
CHAR SACHSON
Supervising Deputy Attorney General
JOSHUA D. JOHNSON
Deputy Attorney General
State Bar No. 244774
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E-mail: Joshua.Johnson@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
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In the Matter of the Accusation Against**:** **WHITE HOUSE PHARMACY INC., DBA SAN JOSE COMPOUNDING PHARMACY; PATRICK JOSEPH D'ANGELO, OWNER** **2453 Forest Ave.** **San Jose, CA 95128** **Pharmacy Permit No. PHY 54957** **JOHN T. SORCI** **15048 Bel Estos Dr.** **San Jose, CA 95124** **Pharmacist License No. RPH 45060** **MARA TIBAYAN RASE** **25577 Salerno Way** **Yorba Linda, CA 92887** **Pharmacist License No. RPH 75062** **SHIVAN ACHARYA** **1055 Town and Country Rd #527** **Orange, CA 92868** **Pharmacist License No. RPH 76346**	Case No. 6802 **THIRD AMENDED ACCUSATION**

GARY EDWARD MARTIN
PO Box 946
Redwood City, CA 94064

Pharmacist License No. RPH 24981

Respondents.

PARTIES

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

2. On or about September 30, 2016, the Board of Pharmacy issued Pharmacy Permit Number PHY 54957 to White House Pharmacy Inc., doing business as San Jose Compounding Pharmacy; Patrick Joseph D'Angelo Chief Financial Officer, President, Secretary, Treasurer and sole shareholder (Respondent San Jose Compounding Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2022, unless renewed.

3. On or about March 5, 1992, the Board of Pharmacy issued Pharmacist License Number RPH 45060 to Respondent John T. Sorci (Respondent Sorci). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2024, unless renewed. Respondent Sorci is and has served as Pharmacist-in-Charge for Respondent San Jose Compounding Pharmacy since or about March 2, 2018.

4. On or about September 27, 2016, the Board of Pharmacy issued Pharmacist License Number RPH 75062 to Respondent Mara Tibayan Rase (Respondent Rase). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2022, unless renewed. Respondent Rase has served as Pharmacist-in-Charge for Respondent San Jose Compounding Pharmacy from about March 1, 2017 to March 1, 2018.

5. On or about March 29, 2017, the Board of Pharmacy issued Pharmacist License Number RPH 76346 to Respondent Shivan Acharya (Respondent Acharya). The Pharmacist

License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2022, unless renewed.

6. On or about April 17, 1967, the Board of Pharmacy issued Pharmacist License Number RPH 24981 to Respondent Gary Edward Martin (Respondent Martin). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2022, unless renewed. Respondent Martin has served as Pharmacist-in-Charge for Respondent San Jose Compounding Pharmacy from about September 30, 2016 to November 28, 2016.

JURISDICTION

7. This Third Amended 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.

8. 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.].

9. Section 4300, subdivision (a), of the Code states that "(a) Every license issued may be suspended or revoked."

10. Section 4300.1 of the Code states:

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

STATUTORY PROVISIONS

11. Section 4036 of the Code states:

> "Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.

12. Section 4058 of the Code states:

Every person holding a license issued under this chapter to operate a premises shall display the original license and current renewal license upon the licensed premises in a place where it may be clearly read by the public.

13. Section 4059.5, subdivision (e) of the Code states:

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

14. Section 4113, subdivision (c) of the Code 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.

15. Section 4116, subdivision (a) of the Code states:

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

16. Section 4123 of the Code states:

Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. That information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

17. Section 4301 of the Code states:

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

…

(b) Incompetence.

(c) Gross negligence.

…

(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.

…

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

…

18. 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.

…

19. 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.

20. Section 4322 of the Code states:

Any person who attempts to secure or secures licensure for himself or herself or any other person under this chapter by making or causing to be made any false representations, or who fraudulently represents himself or herself to be registered, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine not exceeding five thousand dollars ($5,000), or by imprisonment not exceeding 50 days, or by both that fine and imprisonment.

21. Section 4342 of the Code states:

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

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

22. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

23. Health and Safety Code section 111295 states:

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

REGULATORY PROVISIONS

24. California Code of Regulations, title 16, section 1709 states:

(a) Each permit to operate a pharmacy shall show the name and address of the pharmacy, the form of ownership (individual, partnership or corporation) and the pharmacist-in-charge. Each pharmacy shall, in its initial application on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the Board within 30 days.

(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original permit was issued, shall require written notification to the board within 30 days.

(c) The following shall constitute a transfer of permit and require application for a change of ownership: any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license.

25. California Code of Regulations, title 16, section 1711 states:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication

error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

26. California Code of Regulations, title 16, section 1714, subdivision (c) states:

The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

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

…

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

…

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation,

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision; and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

(iv) the container in which it is packaged,

(v) the expected storage conditions, and

(vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

…

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

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

…

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

…

(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.

…

(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.

…

29. California Code of Regulations, title 16, section 1735.4, subdivision (a) states:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) - (c).

…

30. California Code of Regulations, title 16, section 1735.5 states:

(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.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

31. California Code of Regulations, title 16, section 1735.6 states:

…

(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.

…

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) (A) For sterile compounding, each BSC or CACI shall be externally exhausted.

(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted. For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency

particulate air (HEPA) filtration and to prevent their release into the work environment.

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

…

32. California Code of Regulations, title 16, section 1735.7, subdivision (a) 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.

33. 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.

34. California Code of Regulations, title 16, section 1793.1 states:

Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

(a) Receive a new prescription order orally from a prescriber or other person authorized by law.

(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(c) Identify, evaluate and interpret a prescription.

(d) Interpret the clinical data in a patient medication record system or patient chart.

(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.

(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(g) Perform all functions which require professional judgment.

35. California Code of Regulations, title 16, section 1793.3 states:

(a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization.

(b) A pharmacist may supervise the number of non-licensed personnel performing the duties specified in subdivision (a) that the pharmacist determines, in the exercise of his or her professional judgment, does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law.

…

COST RECOVERY

36. 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.

FIRST CAUSE FOR DISCIPLINE

(Duties of a Pharmacist – Respondents SJCP, Martin, and Sorci)

37. Respondent San Jose Compounding Pharmacy, Respondent Martin, and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1793.1, subdivisions (b), and/or (d) and/or (g), in that they violated statutes and/or

regulations regulating that only a licensed pharmacist may consult with a patient regarding a prescription, and/or interpret clinical data in a patient medication record system or patient chart, and/or supervise the packaging of drugs and check the packaging procedure and product upon completion. The circumstances are as follows:

(a) From approximately October 10, 2016 to October 20, 2016, while Respondent Martin was the PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy maintained dispensing records that showed Vishal Purohit, whose pharmacist license was revoked on July 29, 2016, as the dispensing "pharmacist" for sixty-four (64) prescription transactions including one controlled substance prescription when he was unlicensed and not authorized to perform the functions of a pharmacist.

(b) In or about 2021, while Respondent Sorci was PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy employed unlicensed Vishal Purohit as a "Compounding Formulation Specialist." Vishal Purohit consulted with patient JV numerous times regarding her compounded thyroid medications without the supervision of a pharmacist, and caused patient JV to believe he was the pharmacist. Respondent Sorci was unaware of the consultations and complaints patient JV made to Vishal Purohit regarding her medication that was compounded by Respondent San Jose Compounding Pharmacy.

SECOND CAUSE FOR DISCIPLINE

(Duties of a Pharmacist – Failure to Supervise – Respondent Sorci)

38. Respondent Sorci is subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1793.3, subdivision (b), in that he failed to properly supervise non-licensed personnel. The circumstances are as follows:

(a) In or about 2021, while Respondent Sorci was PIC, Respondent San Jose Compounding Pharmacy employed unlicensed Vishal Purohit as a "Compounding Formulation Specialist." Vishal Purohit consulted with patient JV numerous times regarding her compounded thyroid medications without the supervision of a pharmacist, and caused patient JV to believe he was the pharmacist. Respondent Sorci was unaware of the consultations and complaints patient

JV made to Vishal Purohit regarding her medication that was compounded by Respondent San Jose Compounding Pharmacy.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – False Representation re Unlicensed Employee – Respondents SJCP, Rase, and Sorci)

39. Respondent San Jose Compounding Pharmacy, Respondent Rase, and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (f), and/or 4322 in conjunction with Code section 4036, in that Respondents' conduct was unprofessional when Respondents made or caused to be made false representations regarding licensure of unlicensed individuals. The circumstances are as follows:

(a) In or about March 2017, Respondent San Jose Compounding Pharmacy and Respondent Rase allowed an unlicensed individual, Vishal Purohit, whose pharmacist license was revoked on or about July 29, 2016, to represent himself as a pharmacist for San Jose Compounding Pharmacy.

(b) In or about May 2017, Respondent San Jose Compounding Pharmacy and Respondent Rase allowed Priya Purohit, an unlicensed office manager, to represent herself as a pharmacist for San Jose Compounding Pharmacy. A payment dated on or about May 26, 2017, from the National Community Pharmacists Association showed the pharmacy's employee Priya Purohit, a non-licensed office manager, represented herself as a pharmacist. In or about 2021, Respondent San Jose Compounding Pharmacy and Respondent Sorci allowed an unlicensed individual, Vishal Purohit, whose pharmacist license was revoked on or about July 29, 2016, to represent himself as a "Compounding Formulation Specialist" for San Jose Compounding Pharmacy. Vishal Purohit consulted with patient JV numerous times regarding her compounded thyroid medications without the supervision of a pharmacist, and caused patient JV to believe he was the pharmacist.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – False Representation - Respondents SJCP and Sorci)

40. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to

disciplinary action under Code section 4301, subdivision (g), in that Respondents' conduct was unprofessional in that they knowingly made a document that falsely represented the existence or nonexistence of a state of facts. The circumstances are as follows:

(a) The Board requested a complete dispensing history for the period from February 1, 2018 through July 2, 2018. In response, Respondents provided an incomplete dispensing history that omitted fifteen prescriptions, including prescriptions: 146244, 146269, 146910, 143862, 147286, 141985, 147314, 147571, 147581, 147643, 147578, 147581, 147698, 146244, and 147700.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Pharmacist Acts or Omissions – Respondents Sorci and Rase)

41. Respondent Sorci and Respondent Rase are subject to disciplinary action under Code section 4301, subdivision (b) and/or (c), and/or Code section 4306.5, subdivision (a), in that their conduct was unprofessional, and/or that they inappropriately exercised their education, training and/or experience as a pharmacist. The circumstances are as follows:

(a) On or about February 14, 2018, while Respondent Rase was the PIC at San Jose Compounding Pharmacy, Respondent Rase failed to take accountability for the potential for a compounding error and failed to complete a quality assurance report when she was informed by consumers N. and D.W. (collectively NDW) of concerns related to a compound made by her pharmacy for prescription RX#143504.

(b) On or about July 2, 2018, while Respondent Sorci was the PIC at San Jose Compounding Pharmacy, Respondent Sorci instructed staff that garbing was not required if they were going in and out of the hazardous compounding room for less than five minutes, thereby potentially exposing staff to hazardous chemicals and allowing for cross-contamination to the general pharmacy area. As of October 5, 2021, Respondent Sorci maintained the same policy.

(c) On or about July 2, 2018, while Respondent Sorci was the PIC at San Jose Compounding Pharmacy, Respondent Sorci allowed staff to wear booties outside of the hazardous compounding room. Respondent Sorci allowed hair nets, beard covers and face masks to be reused for up to one week. Respondent Sorci allowed cleaning crews to clean the hazardous

compounding room without garbing if no compounding was taking place. Finally, Respondent Sorci instructed staff to wash hands first before garbing, rather than garbing first, while donning gloves last.

(d) On or about October 5, 2021, while Respondent Sorci was the PIC at San Jose Compounding Pharmacy, Respondent Sorci provided to the Inspector a list of hazardous drugs that did not include NIOSH Table 1, chemotherapy/anti-neoplastic, hazardous drugs which were compounded at San Jose Compounding Pharmacy. Chlorambucil and fluorouracil are listed in NIOSH Table 1. San Jose Compounding Pharmacy Policy and Procedure 7.010, section 7.11, states NIOSH Table 1 will be treated as hazardous. Between January 1, 2021 and October 5, 2021, San Jose Compounding Pharmacy compounded eleven drugs containing chlorambucil and one containing fluorouracil.

(e) On or about October 5, 2021, while Respondent Sorci was the PIC at San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy stored chemotherapy/ anti-neoplastic hazardous drugs, specifically, fluorouracil 2.5g/50ml and methotrexate 250mg/10ml injectable, on the main pharmacy shelving amongst non-hazardous drugs. In addition, fluorouracil topical solution 5% was located in the non-sterile, non-hazardous compounding room on a shelf. These items were not stored in the hazardous room as required by San Jose Compounding Pharmacy Policy and Procedure 7.010, section 8.0.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Adhere to Compounding Policies and Procedures – Respondents SJCP, Rase, and Sorci)

42. Respondent San Jose Compounding Pharmacy, Respondent Rase, and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.5, subdivisions (a) and (c)(1), (3), and/or (11), and section 1735.7, subdivision (a), in that they violated statutes and/or regulations regulating compounded drug preparation by failing to maintain written documentation regarding appropriate garbing to prevent cross-contamination with non-hazardous drugs, and to maintain policies and procedures for proper

garbing when compounding, and to inform staff of changes in the policies and procedures, and procedures for evaluating, maintaining, certifying, cleaning and disinfecting the hazardous compounding room. The circumstances are as follows:

(a) On or about February 14, 2018, while Respondent Rase was PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy failed to follow the policy and procedures for proper cleaning and garbing when engaged in compounding and specifically for hazardous compounding. A technician entered the hazardous room without proper garbing. Respondent Rase failed to demonstrate and follow the proper cleaning and garbing as per Respondent San Jose Compounding Pharmacy's policies and failed to observe and ensure proper technique from her compounding staff.

(b) On or about July 2, 2018, Respondent San Jose Compounding Pharmacy maintained written instructions indicating to staff that garbing was not required if they were going in and out of the hazardous compounding room for less than five minutes, thereby potentially exposing staff to hazardous chemicals and allowing for cross-contamination to the general pharmacy area. When in the compounding room for longer than five minutes, written policy was for staff to garb in a manner inconsistent with industry standards, including washing hands before donning shoe covers. Shoes and hair are considered dirty, and not washing hands after donning shoe covers and hair net could potentially contaminate the compounder's hands. Additionally, staff were allowed to wear booties outside of the hazardous compounding room, and hair nets, beard covers and face masks could be reused for up to one week. Cleaning crews were permitted to clean the hazardous compounding room without garbing if no compounding was taking place.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Proper Cleaning Instructions and Records for Compounding Room – Respondents SJCP, Rase, and Sorci)

43. Respondent San Jose Compounding Pharmacy, Respondent Rase, and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.6, subdivision (d) and/or California Code of Regulations, title 16, section 1735.5,

subdivisions (a) and (c)(4), in that they violated statutes and/or regulations regulating compounded drug preparation by failing to maintain effective written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. The circumstances are as follows:

(a) On or about February 14, 2018, while Respondent Rase was the PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy failed to maintain accurate cleaning records to ensure proper steps were being taken to prevent contamination from the hazardous compounding room. A technician acknowledged that records showed a cleaning was marked off even though it had not been performed and the pharmacy failed to follow their own policy and procedure for ensuring proper cleaning records of the facility.

(b) On or about July 2, 2018, while Respondent Sorci was the PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy maintained written instructions titled "Cleaning and Maintenance of the Non-Sterile Compounding Area," SOP Number 3.050, for the maintenance of the non-sterile hazardous compounding area that require staff, among other things, to use a cleaning solution of 70% isopropyl alcohol, and in certain areas, mixed with 2% acidified bleach solution, with an approved decontamination solution of 2% Liquinox. On or about September 4 through 14, 2018, the United States Food and Drug Administration (FDA), Department of Health and Human Services, inspected Respondent San Jose Compounding Pharmacy and found that Respondent San Jose Compounding Pharmacy produced highly potent drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination. Specially, Respondent San Jose Compounding Pharmacy's cleaning and decontamination solutions were not effective in deactivating hazardous drugs, or in removing highly potent residues. The FDA further found that Respondent San Jose Compounding Pharmacy's written procedure SOP Number 3.050 was not effective in deactivating hazardous drugs.

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EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Smooth Surface in Hazardous Compounding Room – Respondents SJCP, Rase, and Sorci)

44. Respondent San Jose Compounding Pharmacy, Respondent Rase, and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.6, subdivision (e)(4), in that they violated statutes and/or regulations regulating compounded drug preparation by failing to maintain all surfaces within the hazardous compounding room smooth, seamless, impervious, and non-shedding. The circumstances are as follows:

(a) On or about February 14, 2018, while Respondent Rase was PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy failed to use non-porous and non-shedding items in the hazardous compounding room to prevent contamination between products. Respondents had within the hazardous compounding room spatulas with wood handles – wood is a porous material. Plastic spatulas in the hazardous compounding room had visible degradation of the plastic, discoloration, and tears on them.

(b) On or about July 2, 2018, while Respondent Sorci was PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy performed hazardous, non-sterile compounding in a separate hazardous compounding room separated from the general pharmacy by Plexiglas that is held in place by Velcro. The Velcro surface was rough and observed to be disconnected in places, allowing for air transfer between rooms.

NINTH CAUSE FOR DISCIPLINE

(Failure to Certify Compounding Equipment – Respondents SJCP and Sorci)

45. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.6, subdivision (b) and/or California Code of Regulations, title 16, section 1735.5, subdivisions (a) and (c)(4), in that they violated statutes and/or regulations regulating compounded drug

preparation by failing to maintain and certify equipment used to compound drug preparations in accordance with manufacturers' specifications. The circumstances are as follows:

(a) On or about July 2, 2018, Respondent San Jose Compounding Pharmacy maintained a Laminar Air Flow Hood in the compounding room that had not been certified since October 31, 2016. Absent manufacturers' specifications, industry standard holds that hoods used for non-sterile compounding are certified annually. Respondent San Jose Compounding Pharmacy had no written policy for maintaining or certifying the Laminar Air Flow Hood.

TENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Pharmacy and Equipment in a Clean and Orderly Condition – Respondents SJCP and Sorci)

46. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1714, subdivision (c), in that they violated statutes and/or regulations regulating the practice of pharmacy, by failing to maintain pharmacy facilities, space, fixtures, and equipment in a clean and orderly condition. The circumstances are as follows:

(a) On or about July 2, 2018, Respondent San Jose Compounding Pharmacy had two filled trash bags placed on the floor in a back room that contained packaging material for reuse. Bags used for bagging prescriptions were stored in the bathroom directly in front of the toilet.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to List Instructions for Storage – Respondents SJCP and Sorci)

47. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.4, subdivision (a)(3), in that they violated statutes and/or regulations regulating compounded drug preparation, by failing to affix a container label and/or outer packaging label prior to dispensing that contained instructions for storage, handling, and administration. The circumstances are as follows:

(a) On or about June 20, 2018, Respondent San Jose Compounding Pharmacy dispensed prescription 147685 for benzocaine/lidocaine/tetracaine, the label for which failed to state proper instructions for storage.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Label Compound Drug Preparations – Respondents SJCP, Rase and Sorci)

48. Respondent San Jose Compounding Pharmacy, Respondent Rase, and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.4, subdivision (a)(5) in that they violated statutes and/or regulations regulating compounded drug preparation by failing to affix a container label and/or outer packaging label prior to dispensing that contained the date compounded, and/or to properly label prescriptions compounded by San Diego Optimum Compounding Pharmacy. The circumstances are as follows:

(a) On or about June 29, 2017, while Respondent Rase was PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy failed to properly label prescriptions compounded by San Diego Optimum Compounding Pharmacy. Respondent San Jose Compounding Pharmacy removed the original prescription compounding label from San Diego Optimum Compounding Pharmacy by discarding all the label information and replacing it with a San Jose Compounding Pharmacy label. Additionally, by discarding the original label, Respondent San Jose Compounding Pharmacy failed to retain all the relevant information provided on the label from the compounding pharmacy including the name of the compounding pharmacy, the original compounding date, the expiration date and initials of the pharmacist verifying the prescription from San Diego Optimum Compounding Pharmacy.

(a) On or about July 2, 2018, while Respondent Sorci was PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy had in its refrigerator two sterile injectable drugs, prescription numbers 147700 for Trimix and 146244 for alprostadil/bupivacaine, that were compounded offsite. The labels for the two sterile injectable drugs did not contain the date compounded.

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THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Document Measured Quantities of Ingredients – Respondents SJCP and Sorci)

49. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(E), in that they violated statutes and/or regulations regulating compounded drug preparation, by failing to maintain a compounding log that contained the quantity of each ingredient used in compounding the drug preparation. The circumstances are as follows:

(a) On or about July 2, 2018, Respondent San Jose Compounding Pharmacy's compounding log for the following lot orders did not contain the actual quantity of each ingredient used in compounding the drug preparation:

(1) 06182018#8596-01@21;

(2) 06182018#8596-01@22;

(3) 06182018#8596-01@23;

(4) 06182018#8596-01@24;

(5) 06182018#9445-01@20;

(6) 06282018#9445-01@19;

(7) 06122018#9445-01@20;

(8) 06152018#8397-02@6;

(9) 06272018#9445-01@23;

(10) 06192018#2992-02@36;

(11) 06202018#9445-01@3;

(12) 06202018#9445-01@5;

(13) 06262018#6415-01@21;

(14) 06222018#5291-01@18;

(15) 06142018#6556-01@11;

(16) 06152018#5714-01@19;

(17) 06132018#9480-01@26.

(b) On or about October 5, 2021, Respondent San Jose Compounding Pharmacy's compounding log for the following lot orders did not contain the actual quantity of each ingredient used in compounding the drug preparation:

(1) 04022021#-7499-04@2;

(2) 05192021#-8248-02@6.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Document Names of Manufacturers – Respondents SJCP and Sorci)

50. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F), in that they violated statutes and/or regulations regulating compounded drug preparation, by failing to maintain a compounding log that contained the manufacturer of each ingredient used in compounding the drug preparation. The circumstances are as follows:

(a) On or about July 2, 2018, Respondent San Jose Compounding Pharmacy's compounding log for the following lot orders did not contain the manufacturer of each ingredient used in compounding the drug preparation:

(1) 06182018#8596-01@21;

(2) 06182018#8596-01@22;

(3) 06182018#8596-01@23;

(4) 06182018#8596-02@24;

(5) 06182018#9445-01@20;

(6) 06282018#9445-01@19;

(7) 06122018#9445-01@20;

(8) 06272018#9445-01@23;

(9) 06192018#2992-02@36;

(10) 06202018#9445-01@3;

(11) 06202018#9445-01@4;

(12) 06202018#9445-01@5;

(13) 06262018#6415-01@21;

(14) 06222018#5291-01@18.

(b) On or about October 5, 2021, Respondent San Jose Compounding Pharmacy's compounding log for the following lot orders did not contain the manufacturer of each ingredient used in compounding the drug preparation:

(1) 08162021 #-600@7;

(2) 03312021#-8013-02@14;

(3) 06172021#-8013-02@22;

(4) 05252021#-8941-04@5;

(5) 06302021#-8941-03@11;

(6) 07272021#-8941-03@7;

(7) 09162021#-5312-06@1.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Document Correct Beyond Use Date – Respondents SJCP and Sorci)

51. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(H), in that they violated statutes and/or regulations regulating compounded drug preparation, by failing to maintain a compounding log that contained the beyond use date or beyond use date and time of the final compounded drug preparation. The circumstances are as follows:

(a) On or about October 5, 2021, Respondent San Jose Compounding Pharmacy's compounding log contained more than one beyond use date listed for the following lot orders:

(1) 04022021#-7499-04@2;

(2) 05202021#-9436-02@5.

SIXTEENTH CAUSE FOR DISCIPLINE

(Prevention of Sale of Expired Medications – Respondents SJCP and Sorci)

52. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to

disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination with Code section 4342, subdivision (a), in that they intended to sell pharmaceutical preparations and/or drugs that did 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, and/or that violated any provision of the Sherman Food, Drug, and Cosmetic Law. The Sherman Food, Drug, and Cosmetic Law prohibits the sale or offer for sale any drug or device that is adulterated. (Health & Saf. Code § 111295.) A drug or device is adulterated if it contains, in whole or in part, any filthy, putrid, or decomposed substance. (Health & Saf. Code § 111250.) The circumstances are as follows:

(a) On or about October 5, 2021, Respondent San Jose Compounding Pharmacy had in active stock, for sale, approximately nine expired over-the-counter drugs, dangerous drugs, and ingredients.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Assigned Expiration Date – Respondents SJCP and Sorci)

53. Respondent San Jose Compounding Pharmacy and Respondent Rase are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or section 4113, subdivision (c), of the Code, in combination with California Code of Regulations, title 16, section 1735.2, subdivision (i), in that they violated statutes and/or regulations regulating compounded drug preparation by assigning an expiration date to a compound drug preparation that was beyond the expiration date or beyond use date of one or more of the ingredients. The circumstances are as follows:

(a) On or about October 5, 2021, Respondent San Jose Compounding Pharmacy and Respondent Sorci assigned a beyond use date of December 15, 2021 to the prescription number 161374, consisting of 60 capsules, which was one day beyond the beyond use date of an ingredient used to compound the drug. Per hybrid master formulas/compounding records for lot #09162021 #-5312-06@1, one of the ingredients used to compound the drug was levothyroxine diluent 1:1000 powder, lot number 06172021#-8013-02@22, which had a beyond use date of December 14, 2021.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Display Original License – Respondents SJCP and Sorci)

54. Respondent San Jose Compounding Pharmacy and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or Code section 4113, subdivision (c), in combination Code section 4058, in that they failed to display the Respondent San Jose Compounding Pharmacy's original license and current renewal license upon the licensed premises in a place where it may be clearly read by the public. The circumstances are as follows:

(a) On or about October 5, 2021, only Respondent San Jose Compounding Pharmacy's current renewal pharmacy license was on display.

NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Prepare an Adequate Written Master Formula – Respondents SJCP, Sorci and Rase)

55. Respondent San Jose Compounding Pharmacy, Respondent Rase, and Respondent Sorci are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or section 4113, subdivision (c), of the Code, in combination with California Code of Regulations, title 16, section 1735.2, subdivision (e), in that they violated statutes and/or regulations regulating compounded drug preparation by failing to prepare an adequate written master formula including the necessary elements. The circumstances are as follows:

(a) On or about February 14, 2018, while Respondent Rase was PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy failed to have a master formula that outlined the quality review steps required at each step in the preparation of a compounded drug and a post-compounding process or procedure to verify the final product. The master formula record for consumers NDW cat's prescription RX#143504 did not show what the end product should look like or provide a document that confirmed the product made matched the quality assurance steps of the master formula.

(b) On or about October 5, 2021, while Respondent Sorci was PIC for San Jose Compounding Pharmacy, Respondent San Jose Compounding Pharmacy failed to prepare a written master formula document that includes at least the specific and essential compounding

steps used to prepare the drug. The following hybrid master formulas/compounding records for three lots of compounded dilution powders were used in approximately 10 prescriptions for approximately 755 compounded T4/T3 capsules contained incorrect specific and essential compounding steps:

(1) For levothyroxine 1:1000 dilution powder, lot: 03312021#-8013-02@14, used in compounding at least seven prescriptions, the steps did not list the correct ingredients, stated the incorrect amount of water and loss on drying, incorrect quantities of ingredients and incorrectly stated what to label the compounded product.

(2) For levothyroxine 1:1000 dilution powder, lot: 06172021#-8013-02@22, used in compounding at least three prescriptions, the steps did not list-the correct ingredients, stated the incorrect amount of water and loss on drying, incorrect quantities of ingredients, incorrectly stated what to label the compounded product and stated to store the compounded product in glass when in fact, it was being stored in plastic.

(3) For liothyronine 1:1000 dilution powder, lot: 03312021#-8013-01@16, used in compounding at least seven prescriptions, the steps did not list the correct ingredients.

TWENTIETH CAUSE FOR DISCIPLINE

(Out of State Order of Dangerous Drugs or Devices – Respondents SJCP and Rase)

56. Respondent San Jose Compounding Pharmacy and Respondent Rase are subject to disciplinary action under Code section 4059.5, subdivision (e), in that Respondents transferred, sold, or delivered to a person outside this state, a dangerous drug or device, in a manner not in compliance with the laws of California and of the United States and of the state or country to which the dangerous drugs or dangerous devices were transferred, sold, or delivered. The circumstances are as follows:

(a) From October 18, 2016 to February 28, 2017, Respondents shipped 15 prescriptions for dangerous drugs outside of California to patients in Oregon, Nevada, Arizona, and Michigan without proper licensure to ensure compliance with the laws of each state. At the time, Respondent Rase was the dispensing pharmacist while acting as the interim pharmacist-in-charge.

(b) From approximately March 1, 2017 to June 29, 2017, Respondents shipped 19 prescriptions for dangerous drugs outside of California to patients in Oregon, Nevada, Arizona, and Michigan without proper licensure to ensure compliance with the laws of each state.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Change in Ownership – Respondent SJCP)

57. Respondent San Jose Compounding Pharmacy is subject to disciplinary action under Code section 4301, subdivision (g), in combination with California Code of Regulations, title 16, section 1709, subdivisions (b) and (c), in that Respondent's conduct was unprofessional when it failed to notify the Board of a transfer in beneficial interest in a business entity licensed by the Board, and failed to apply for a change of ownership. The circumstances are as follows:

(a) On or about June 29, 2017 and through at least March 2018, Respondent San Jose Compounding Pharmacy made changes in the corporate officers and ownership during the pharmacy permit process and failed to notify the Board of the change. Board investigators informed Respondent San Jose Compounding Pharmacy of the violation and how to correct it on June 29, 2017, July 5, 2017, and July 20, 2017. Respondent San Jose Compounding Pharmacy failed to submit the change as requested until after March 2018.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Follow Quality Assurance Plan – Respondents SJCP and Rase)

58. Respondent San Jose Compounding Pharmacy and Respondent Rase are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or section 4113, subdivision (c), of the Code, in combination with California Code of Regulations, title 16, section 1735.8, subdivision (d), in that they violated statutes and/or regulations regulating compounding quality assurance by failing to follow 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. The circumstances are as follows:

(a) On or about October 20, 2017, Respondent San Jose Compounding Pharmacy filled a compounded prescription for replacement amlodipine 4.5 mg/ml (RX#143504) for consumers NDW to treat their cat's blood pressure. NDW observed that the medication that Respondent San

Jose Compounding Pharmacy provided had separated and turned cloudy with a dark chunk on the bottom. In addition, their cat's blood pressure did not improve.

(b) On or about February 14, 2018, Respondents failed to take action when they were notified of quality and potency issues with a compounded prescription RX#143504 from consumers NDW and failed to investigate other compounded products that may have been impacted due to a shared compounded ingredient.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Failure to Have a Quality Assurance Plan – Respondents SJCP and Rase)

59. Respondent San Jose Compounding Pharmacy and Respondent Rase are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or section 4113, subdivision (c), of the Code, in combination with California Code of Regulations, title 16, section 1711, subdivisions (c), (d), and (e), in that they violated statutes and/or regulations regulating quality assurance programs by failing to have a quality assurance policy and procedure for documenting medication error reporting, and/or for failing to communicate with the patient and prescriber regarding the medication error, and/or by failing to document the medication error, and/or for failing to investigate a complaint of potency and quality issues within two days of being notified of the complaint. The circumstances are as follows:

(a) On or about February 14, 2018, Respondents failed to have a quality assurance policy and procedure for documenting medication error reporting. Respondents failed to document their medication error in filling compounded RX#143504 for consumers NDW, and did not investigate the complaint from consumer NDW of potency and quality issues with their cat's compounded prescription.

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Appropriate Instruction for Recall of Dispensed Drug Preparation – Respondents SJCP and Rase)

60. Respondent San Jose Compounding Pharmacy and Respondent Rase are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or section 4113, subdivision (c), of the Code, in combination with California Code of Regulations, title 16, section

1735.5, subdivisions (a) and (c)(2), that they violated statutes and/or regulations regulating compounded drug preparation by failing to maintain effective written documentation regarding recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The circumstances are as follows:

(a) On or about February 14, 2018, Respondents failed to initiate a recall of prescriptions that were suspected to have been compounded with a product used in multiple preparations when it received a complaint from consumers NWD alleging the prescription RX#143504 was ineffective and the preparation had quality issues.

TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Annually Update and Review Compounding Policies and Procedures – Respondents SJCP and Rase)

61. Respondent San Jose Compounding Pharmacy and Respondent Rase are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or section 4113, subdivision (c), of the Code, in combination with California Code of Regulations, title 16, section 1735.5, subdivision (b), in that they violated statutes and/or regulations regulating compounded drug preparation by failing to document, review, and update when changes are made, the compounding policies and procedures on a yearly basis. The circumstances are as follows:

(a) On or about February 14, 2018, it was discovered that Respondents failed to update the compounding policy and procedures annually, and failed to review the changes with the compounding staff.

TWENTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Negative Pressure in Compounding Room – Respondents SJCP and Rase)

62. Respondent San Jose Compounding Pharmacy and Respondent Rase are subject to disciplinary action under Code section 4301, subdivision (j) and/or (o), and/or section 4113, subdivision (c), of the Code, in combination with California Code of Regulations, title 16, section 1735.6, subdivision (e)(2), in that they violated statutes and/or regulations regulating

compounding facilities and equipment by failing to maintain a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces. The circumstances are as follows:

(a) On or about February 14, 2018, Respondents failed to maintain the negative pressure required for the hazardous compounding room.

(b) On or about June 29, 2017, the negative pressurization of the hazardous compounding room was found to be off.

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Subverting Investigation – Respondents SJCP, Rase, and Acharya)

63. Respondent San Jose Compounding Pharmacy, Respondent Rase, and Respondent Acharya are subject to disciplinary action under Code section 4301, subdivision (q), in conjunction with Code section 4116, subdivision (a), in that Respondents' conduct was unprofessional when they engaged in conduct that subverted or attempted to subvert an investigation of the Board. The circumstances are as follows:

(a) On or about June 29, 2017, Board investigators performed an inspection of Respondent San Jose Compounding Pharmacy. At the start of the inspection, Vishal Purohit, whose pharmacist license was revoked on July 29, 2016, fled out the back door of the pharmacy with a lab coat in hand. Respondent Acharya was present with Vishal Purohit in the pharmacy and Respondent Acharya was responsible for him. When Board investigators asked what Vishal Purohit was doing in the back of the pharmacy, Respondent Acharya feigned ignorance of Vishal Purohit and disavowed responsibility for the activities of Vishal Purohit in the pharmacy. During the inspection, Board investigators discovered a document titled "HOT LIST" instructing staff to obstruct any Board inspections and to obstruct access to the storage area of the pharmacy and instructing staff to answer investigators' questions only with yes or no answers.

OTHER MATTERS

64. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 54957 issued to Respondent San Jose Compounding Pharmacy, then any person 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 which received this discipline or denial, 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 leading to discipline or denial, 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 54957 is placed on probation or until Pharmacy Permit Number PHY 54957 is reinstated if it is revoked.

65. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 45060 issued to Respondent Sorci, Respondent Sorci 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 45060 is placed on probation or until Pharmacist License Number RPH 45060 is reinstated if it is revoked.

66. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 75062 issued to Respondent Rase, Respondent Rase 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 75062 is placed on probation or until Pharmacist License Number RPH 75062 is reinstated if it is revoked.

67. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 76346 issued to Respondent Acharya, Respondent Acharya 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 76346 is placed on probation or until Pharmacist License Number RPH 76346 is reinstated if it is revoked.

68. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 24981 issued to Respondent Martin, Respondent Martin 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 24981 is placed on probation or until Pharmacist License Number RPH 24981 is reinstated if it is revoked.

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DISCIPLINE CONSIDERATIONS

69. To determine the degree of discipline, if any, to be imposed on Respondent San Jose Compounding Pharmacy, Complainant alleges that on or about July 18, 2018, in a prior action, the Board of Pharmacy issued Citation Number CI 2016 74000 and ordered Respondent San Jose Compounding Pharmacy to pay a fine of $5,000.00 for unprofessional conduct in violation of Business and Professions Code sections 4301, subdivision (f) and 651, subdivision (a). That citation is now final.

70. To determine the degree of discipline, if any, to be imposed on Respondent Sorci, Complainant alleges that on or about February 15, 2017, in a prior action, the Board of Pharmacy issued Citation Number CI 2016 74022 and ordered Respondent Sorci to pay a fine of $2,750.00 for violations of Health and Safety Code section 11164, subdivision (a), and California Code of Regulations, title 16, section 1761. That Citation is now final.

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 54957, issued to Respondent White House Pharmacy Inc., dba San Jose Compounding Pharmacy; Patrick Joseph D'Angelo Chief Financial Officer, President, Secretary, Treasurer and sole shareholder;

2. Revoking or suspending Pharmacist License Number RPH 45060, issued to Respondent John T. Sorci;

3. Revoking or suspending Pharmacist License Number RPH 75062, issued to Respondent Mara Tibayan Rase;

4. Revoking or suspending Pharmacist License Number RPH 76346, issued to Respondent Shivan Acharya;

5. Revoking or suspending Pharmacist License No. RPH 24981, issued to Respondent Gary Edward Martin;

6. Prohibiting Respondents from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if an applicable license is placed

on probation or until any license revoked or denied is issued or reinstated;

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

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

DATED: 4/12/2022

Signature on File

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

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