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

In the Matter of the Accusation Against:

UNIVERSITY OF CALIFORNIA SAN FRANCISCO – MISSION BAY, Original Hospital Pharmacy Permit No. HPE 50355; and

UNIVERSITY OF CALIFORNIA SAN FRANCISCO – MISSION BAY, Sterile Compounding Permit No. LSE 100209; and

RITA K. JEW – Original Pharmacist License No. RPH 43648

Respondents

Agency Case No. 6526

OAH No. 2020050049

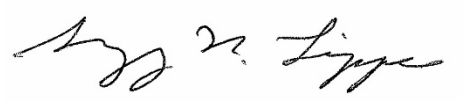
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary 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 December 23, 2020.

It is so ORDERED on November 23, 2020.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Greg Lippe
Board President

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

In the Matter of the Accusation Against: **UNIVERSITY OF CALIFORNIA SAN FRANCISCO – MISSION BAY** **1500 Owens Street # 460** **San Francisco, CA 94158-2322** **Original Hospital Pharmacy Permit No. HPE 50355** **Sterile Compounding Permit No. LSE 100209,** **and** **RITA K. JEW, RPH, PHARMACIST IN CHARGE** **1500 Owens Street # 460** **San Francisco, CA 94158-2322** **Original Pharmacist License No. RPH 43648** Respondents.	Case No. 6526 OAH No. 2020050049 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT RITA JEW ONLY**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will

be submitted to the Board for approval and adoption as the final disposition of the Accusation solely with respect to Rita K. Jew, RPh. It does not apply to the University of California, San Francisco--Mission Bay.

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 Xavier Becerra, Attorney General of the State of California, by Christopher M. Young, Deputy Attorney General.

2. Respondent Rita K. Jew, RPh (Respondent) is represented in this proceeding by attorney Edward Idell, whose address is: 355 South Grand Ave., Ste. 1750, Los Angeles, CA 90071-1562.

3. On or about August 1, 1990, the Board issued Original Pharmacist License Number RPH 43648 to Rita K. Jew. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2022, unless renewed.

JURISDICTION

4. Accusation No. 6526 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on February 15, 2019. Respondent timely filed her Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 6526 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6526. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of her 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 her; the right to present evidence and to testify on her 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.

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

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 6526, if proven at a hearing, constitute cause for imposing discipline upon her Pharmacist License.

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

11. Respondent agrees that her Original Pharmacist License is subject to discipline and she agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent 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 or her counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw her 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 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.

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

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

15. 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 Original Pharmacist License No. RPH 43648 issued to Respondent Rita K. Jew is revoked. However, the revocation is stayed and Respondent is placed on probation for two (2) years on the following terms and conditions:

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws

a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment

a conviction of any crime

the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves

respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

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

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of Entity probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. **Continuing Education**

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

6. **Reporting of Employment and Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 6526 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of each of Entity employer(s), and the name(s) and telephone number(s) of all of Entity direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) Entity direct supervisor, (b) Entity pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of Entity employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6526, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c)

during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 6526, and the terms and conditions imposed thereby.

If respondent works for or is employed by or through an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 6526, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

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

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

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

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

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8. **Restrictions on Supervision and Oversight of Licensed Facilities**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $10,000. Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

10. **Probation Monitoring Costs**

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

11. **Status of License**

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

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

/ / /

12. **License Surrender While on Probation/Suspension**

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

Upon acceptance of the surrender, respondent shall relinquish her pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a Pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the board or its designee.

If respondent does not practice as a Pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the

interruption or reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a Pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in Accusation No. 6526 shall be deemed true and correct.

15. **Completion of Probation**

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

16. **Remedial Education**

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding (USP 797). The program of remedial education shall consist of at least 10 hours each year of probation, having 50% in-person training or live webinar online classes, at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at Entity own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

ACCEPTANCE

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

DATED: _____

_____
RITA K. JEW, RPH
Respondent

16. **Remedial Education**

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding (USP 797). The program of remedial education shall consist of at least 10 hours each year of probation, having 50% in-person training or live webinar online classes, at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at Entity own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

ACCEPTANCE

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

DATED: 10/8/20

RITA K. JEW, RPH
Respondent

I have read and fully discussed with Respondent Rita K. Jew the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

EDWARD IDELL
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

CHRISTOPHER M. YOUNG
Deputy Attorney General
Attorneys for Complainant

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I have read and fully discussed with Respondent Rita K. Jew the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 10-9-20

EDWARD IDELL
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: October 15, 2020

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

Christopher M. Young

CHRISTOPHER M. YOUNG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 6526

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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
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In the Matter of the Accusation Against**:** **UNIVERSITY OF CALIFORNIA SAN FRANCISCO – MISSION BAY** **1500 Owens Street # 460** **San Francisco, CA 94158-2322** **Original Hospital Pharmacy Permit No. HPE 50355** **Sterile Compounding Permit No. LSE 100209,** **and** **RITA K. JEW, RPH, PHARMACIST IN CHARGE** **1500 Owens Street # 460** **San Francisco, CA 94158-2322** **Original Pharmacist License No. RPH 43648** Respondents.	Case No. 6526 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about July 22, 2010, the Board issued Original Hospital Pharmacy Permit Number HPE 50355 to The Regents of the University of California (Respondent Pharmacy). The Original Hospital Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2019, unless renewed.

3. On or about May 29, 2014, the Board issued Sterile Compounding Permit Number LSE 100209 to Respondent Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2019, unless renewed.

4. On or about August 1, 1990, the Board issued Original Pharmacist License Number RPH 43648 to Rita K. Jew, Pharmacist-in-Charge (Respondent Jew). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2020, unless renewed.

JURISDICTION

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

6. Code section 4011 provides that the Board shall administer and enforce the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.].

7. Code section 4300, subdivision (a), provides that every license issued by the Board may be suspended or revoked.

8. Code section 4300.1 provides that the expiration, cancellation, forfeiture, suspension, or voluntary surrender of a license "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."

9. Code section 4307, subdivision (a), 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.

STATUTORY PROVISIONS

10. Code section 4059 states in pertinent part:

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

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that

correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

11. Code section 4081, subdivision (a), states in pertinent part:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, 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.

12. Code section 4105, subdivision (a), states in pertinent part:

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

13. Code section 4128 states in pertinent part:

(a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.

(2) Preparing sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

14. Code section 4128.2, subdivision (a), states in pertinent part:

(a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

15. Code section 4301 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 includes, but is not limited to, any of the following:

. . .

(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.

16. Code section 4333, subdivision (a), states in pertinent part:

(a) All prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

REGULATORY PROVISIONS

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

(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

. . .

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(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.

. . .

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

. . .

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

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

18. 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:

. . .

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

. . .

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

19. California Code of Regulations, title 16, section 1735.4, states in pertinent part:

(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.

. . .

20. California Code of Regulations, title 16, section 1751.8, states in pertinent part:

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the

absence of passing a sterility test in accordance with standards for sterility testing 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, that would justify an extended beyond use date, conforms to the following limitations:

. . .

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

. . .

COST RECOVERY

21. Code section 125.3 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.

FACTUAL BACKGROUND

22. Respondent Pharmacy, located in San Francisco, California, and Respondent Jew engaged in unlicensed activity by compounding and distributing medications without the appropriate specialized license to engage in such activities. Moreover, Respondent Pharmacy and

Respondent Jew improperly and knowingly assigned extended Beyond Use Dates to medications where it was improper to do so.

23. From on or about October 6, 2015, through on or about May 7, 2018, inspections conducted at Respondent Pharmacy revealed noncompliance with the Pharmacy Law. Respondent Jew was the pharmacist-in-charge (PIC) at all times during this period.

Unlicensed Practice

24. On January 1, 2013, Code section 4128.2(a) was added requiring a specialty license for all locations acting as a Centralized Hospital Packaging (CHP) Pharmacy under Code section 4128.

25. On or about October 6, 2015, Board inspectors issued a report finding that Respondent Pharmacy was acting as a CHP by distributing sterile compounded products to several locations, including UCSF Mission Bay Hospital, USCS Parnassus, UCSF Mt Zion Hospital, Spinal Tap Clinic Parnasus, and CRHPROC. Acting as a CHP would require a specialized license. On or about October 13, 2016, a subsequent inspection report found that Respondent Pharmacy continued to act as a CHP. A third inspection report, dated on or about September 5, 2017, found that Respondent Pharmacy continued to act as a CHP.

26. Board staff received an application for a CHP license from Respondent Pharmacy on or about October 2, 2017. On or about May 7, 2018, Respondent Pharmacy's application for a CHP license was withdrawn by the Executive Officer because Respondent Pharmacy did not meet licensure requirements. A subsequent Board investigation, on or about June 5, 2018, determined that Respondent Pharmacy continued to act as a CHP despite not qualifying for licensure as a CHP. Respondent Pharmacy knowingly continues to operate as a CHP without a license.

Improper Assignment of Beyond Use Dates (BUDs)

27. On or about October 13, 2016, inspectors requested that Respondents Pharmacy and Jew ensure that extension of all BUDs was supported by the appropriate testing as outlined in CCR 1735.2(i). On or about September 5, 2017, a subsequent inspection determined that extended BUDs were not being used by Respondent Pharmacy as required by regulation. Board staff requested that Respondent Pharmacy send a corrective action plan to its inspector.

Respondents were required to comply with the Order of Correction in a memo dated December 20, 2017. Respondents were afforded 30 days to comply.

28. On or about January 19, 2018, Respondent Jew supplied a compliance plan to Board staff. In the compliance plan, Respondent Jew affirmed that as of February 1, 2018, sterile to sterile compounded products with previously assigned BUDs of 180 days would be reduced to 90 days for all products compounded, commencing on February 1, 2018.

29. On or about May 8, 2018, Respondent Jew indicated via email to Board inspectors that certain required testing had been delayed, including method suitability tests, stability studies, and container closure integrity tests. Board inspectors requested that Respondent Jew provide the Method Suitability Test, Container Closure Integrity Test, and Suitability Studies used to support the assigned BUDs.

30. On or about May 9, 2018, Respondent Jew wrote and delivered a statement to the Board inspector explaining that Respondents failed to comply with the January 19, 2018, compliance plan. Numerous products prepared after February 1, 2018, still had BUDs longer than 90-days.

31. On or about June 5, 2018, Board staff issued a violation to Respondent Jew for non-compliance with California Code of Regulations, title 16, sections 1735.2(i)(3), 1735.5(a), and 1751.8(a), by assigning BUDs in excess of allowable dating without having evidence of performing the appropriate tests and studies, failing to follow Respondent Pharmacy's policies regarding assigning BUDs to midazolam, and assigning BUDs longer than 14 days at controlled refrigerated temperature for sterile compounded products without the appropriate extension testing as required by California Code of Regulations, title 16, section 1735.2(i)(3).

32. On or about June 5, 2018, Board staff received a document titled "Management of Compounded Products" from Respondent Pharmacy stating that Respondent Pharmacy was to assign BUDs in compliance with the United States Pharmacopeia (USP) 797 standards. Board staff also received Respondent Pharmacy's Extended BUD testing plan, showing that as of June 5, 2018, none of the products made by Respondent Pharmacy had completed method suitability test, container closure integrity test, and stability studies, but all of them were assigned BUDs of

90 days. Later, on or about July 5, 2018, Board staff received an updated document titled "Management of Compounded Products" from Respondent Pharmacy stating that "extended BUD beyond USP <797> standard is allowable if method suitability, container closure integrity, and stability studies are conducted and study results kept on file."

33. Respondent Pharmacy, from at least on or about February 11, 2018, to June 3, 2018, assigned BUDs greater than 30 hours at room temperature without documentation of passing a sterility test[1].

Non-Compliance with Pharmacy Law

34. The Board investigation revealed that Respondents failed to correctly label drug preparations. Multiple lots of preparations had labels without listing the required rate of infusion. Other lots of preparations had two BUDs, stating "180 day or 48 hours," or "90 day or 48 hours."

35. The Board investigation revealed that Respondents were not compliant with Pharmacy law from at least on or about February 1, 2018, to May 7, 2018, when it compounded and sold over 1,000 bags of Heparin, 480 syringes of Milrinone, 8,416 syringes of phenylephrine, 144 bags of ropivacaine, and 4,658 syringes of sodium citrate. Moreover, Respondents did not retain sales records for these dangerous drugs, nor did Respondents retain valid disposition records for these dangerous drugs, in violation of Pharmacy Law.

36. From at least February 1, 2018, through June 3, 2018, Respondents failed to document the quality reviews and required post-compounding process and procedures.

37. From at least April 25, 2018, to June 3, 2018, Respondents failed to document the identity of the pharmacist reviewing the final drug preparation on multiple drug compounds.

FIRST CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Incorrect Compound Labeling)

38. Respondents Pharmacy and Jew are subject to disciplinary action under Code section 4301 (j) and/or (o), and California Code of Regulations, section 1735.4, which requires that each compounded drug preparation of admixed IV solutions be affixed with a container label prior to

[1] In the absence of a passing sterility test that would justify an extended BUD, the BUD shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state.

dispensing that contains the rate of infusion. As described above in paragraphs 22-23 and 34, Respondents failed to label their drug preparations with the required rate of infusion.

SECOND CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Multiple Beyond Use Dates)

39. Respondents Pharmacy and Jew are subject to disciplinary action under Code section 4301 (j) and/or (o), and California Code of Regulations, section 1735.4, which requires that each compounded IV drug preparation be labeled with a BUD. As described above in paragraphs 22-23 and 34, Respondents labeled certain IV drugs with multiple BUDs.

THIRD CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Inappropriate Beyond Use Dates)

40. Respondents Pharmacy and Jew are subject to disciplinary action under Code section 4301 (j) and/or (o), and California Code of Regulations, section 1735.2, which requires that the BUD Date for sterile compounded drug preparations must be supported by data supporting the chemical stability of the combination of all compounded ingredients in the sterile compounded drug preparation. As described above in paragraphs 22-23 and 27-33, Respondents compounded and sold drug preparations without having data to support the chemical stability of the combination of all ingredients in the sterile compounded drug preparations.

FOURTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Failure to Support Beyond Use Dates)

41. Respondents Pharmacy and Jew are subject to disciplinary action under Code section 4301 (j) and/or (o), and California Code of Regulations, section 1735.2, which requires that every compounded drug preparation shall be given a BUD representing the date or date and time beyond which the compounded drug preparation should not be used. For sterile compounded drug preparations, extended BUDs are only allowable when supported by a Method Suitability Test, a Container Closure Integrity Test, and Stability Studies. As described above in paragraphs 22-23 and 27-33, Respondents assigned extended BUDs to sterile compounded drug preparations without the support of a method suitability test, container closure integrity test, or stability studies.

FIFTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Unlawful Compounding)

42. Respondents Pharmacy and Jew are subject to disciplinary action under Code section 4301 (j) and/or (o), and California Code of Regulations, section 1735.2, which requires that a pharmacy may only prepare and store a limited quantity of compounded drug preparations in advance of receipt of a patient-specific prescription. As described above in paragraphs 22-23 and 35, Respondents compounded and sold drug preparations without advanced receipt of patient-specific prescriptions or a documented history of prescriptions for the patient population at UCSF.

SIXTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Failure to Retain Sales Records)

43. Respondents Pharmacy and Jew are subject to disciplinary action under Code sections 4301 (j) and/or (o), and 4059, for failing to retain sales records of dangerous drugs, as described above in paragraphs 22-23 and 35.

SEVENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Failure to Maintain Proper Disposition Records)

44. Respondents Pharmacy and Jew are subject to disciplinary action under Code sections 4301 (j) and/or (o), and 4081, 4105, and/or 4333, for failing to maintain proper disposition records, as described above in paragraphs 22-23 and 35.

EIGHTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Incomplete Compounding Records)

45. Respondents Pharmacy and Jew are subject to disciplinary action under Code section 4301 (j) and/or (o), and California Code of Regulations, section 1735.3, for failing to document the quality reviews and required post-compounding process and procedures in a compounding log, as described above in paragraphs 22-23 and 36.

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NINTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Incomplete Compounding Records)

46. Respondents Pharmacy and Jew are subject to disciplinary action under Code section 4301 (j) and/or (o), and California Code of Regulations, section 1735.3, for failing to document the identity of the pharmacist reviewing the final drug preparation, as described above in paragraphs 22-23 and 37.

TENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Inappropriate Beyond Use Dates)

47. Respondents Pharmacy and Jew are subject to disciplinary action under Code section 4301 (j) and/or (o), and California Code of Regulations, section 1751.8, which requires that the BUD Date for sterile compounded drug preparations, in the absence of passing a sterility test, must be assigned specific BUDs, as described above in paragraphs 22-23 and 27-33. Respondents assigned BUDs greater than 30 hours at room temperature for multiple compounded drug preparations without evidence of passing a sterility test.

ELEVENTH CAUSE FOR DISCIPLINE

(Respondent Jew: Unprofessional Conduct—False Documentation)

48. Respondent Jew is subject to disciplinary action under Code section 4301 (j) and/or (o), and subdivision (g), for unprofessional conduct, for knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts. As described above in paragraphs 22-23 and 27-31, Respondent Jew made unsupported statements to the Board and failed to correct those statements in a timely manner.

TWELFTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Jew: Unlicensed Activity)

49. Respondents Pharmacy and Jew are subject to disciplinary action under Code sections 4301 (j) and/or (o), and 4128.2, for operating a compounding pharmacy without the proper license, as described above in paragraphs 22-26.

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/ / /

OTHER MATTERS

50. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy License Numbers LSE100209 and HPE50355, Respondent Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Respondent Pharmacy License Numbers LSE100209 and HPE50355 are placed on probation, or until reinstatement if Respondent Pharmacy License Numbers LSE100209 and HPE50355 are revoked.

51. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy License Numbers LSE100209 and HPE50355 issued to Respondent Pharmacy while Respondent Jew was the pharmacist-in-charge, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Respondent Jew shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Respondent Pharmacy License Numbers LSE100209 and HPE50355 are placed on probation, or until reinstatement if Respondent Pharmacy License Numbers LSE100209 and HPE50355 are 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 Licensed Sterile Compounding License No. LSE 100209 issued to UCSF Mission Bay (Respondent Pharmacy);

2. Revoking or suspending Hospital Pharmacy License No. HPE 50355 issued to UCSF Mission Bay (Respondent Pharmacy);

3. Revoking or suspending Pharmacist License No. RPH 43648 issued to Rita Jew (Respondent Jew);

4. Prohibiting Rita Jew from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Licensed Sterile Compounding License No. LSE 100209 or Hospital Pharmacy License No. HPE 50355 are placed on probation,

or until reinstatement if Licensed Sterile Compounding License No. LSE 100209 or Hospital Pharmacy License No. HPE 50355 are revoked.

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

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

DATED: February 11, 2019

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

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