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

In the Matter of the Accusation Against:

SUTTER COAST HOSPITAL, INC., DBA
SUTTER COAST HOSPITAL PHARMACY,
Original Pharmacy Permit No. HSP 37160
Sterile Compounding License No. LSC 100197; and

MEGAN ASHLEY KRAMER,
Pharmacist License No. RPH 70124,

Respondents.

Agency Case No. 7027

OAH No. 2022030908

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 July 26, 2023.

It is so ORDERED on June 26, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
CHRISTOPHER M. YOUNG
Deputy Attorney General
State Bar No. 238532
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 510-3554
Facsimile: (415) 703-5480
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **SUTTER COAST HOSPITAL, INC., DBA SUTTER COAST HOSPITAL PHARMACY** **800 E. Washington Blvd** **Crescent City, CA 95531** **Original Pharmacy Permit No. HSP 37160** **Sterile Compounding License No. LSC 100197** **MEGAN ASHLEY KRAMER** **26 Bilotto Dr.** **Cedar Crest, NM 87008** **Pharmacist License No. RPH 70124** Respondents.	Case No. 7027 OAH No. 2022030908 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** **(RESPONDENT SUTTER COAST HOSPITAL PHARMACY 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 Respondent Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy. It does not apply to Megan Ashley Kramer.

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 Christopher M. Young, Deputy Attorney General.

2. Respondent Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy (Respondent) is represented in this proceeding by attorney Stefan Chacon, whose address is: Hanson Bridgett, 425 Market Street, 26th Floor, San Francisco, CA 94105-2173.

3. On or about February 4, 1992, the Board of Pharmacy issued Original Pharmacy Permit Number HSP 37160 to Respondent Sutter. The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2024, unless renewed.

4. On or about May 29, 2014, the Board of Pharmacy issued Sterile Compounding License Number LSC 100197 to Respondent Pharmacy. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2024, unless renewed.

JURISDICTION

5. Accusation No. 7027 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 November 17, 2021. Respondent timely filed its Notice of Defense contesting the Accusation.

6. A copy of Accusation No. 7027 is attached as exhibit A and incorporated herein by reference.

/ / /

/ / /

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7027. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

10. Respondent admits the truth of each and every charge and allegation in Accusation No. 7027.

11. Respondent agrees that its Original Pharmacy Permit and Sterile Compounding License are subject to discipline and it 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 its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, 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 Pharmacy Permit No. HSP 37160 and Sterile Compounding License No. LSE 100197, issued to Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy, are revoked. However, the revocation is stayed and Respondent is placed on probation for three (3) years on the following terms and conditions:

1. Definition: Respondent

For the purposes of these terms and conditions, "respondent" shall refer to Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

/ / /

2. 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; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's original pharmacy permit or sterile compounding license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance.

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

3. 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.

4. 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.

5. 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 the 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.

6. 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 $18,000.00. 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.

7. 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.

8. Status of License

Respondent shall, at all times while on probation, maintain current Original Pharmacy Permit and Sterile Compounding License with the board. Failure to maintain current licensure shall be considered a violation of probation.

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

9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent wish to discontinue business, respondent may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new 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.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. Notice to Employees

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall submit

written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

12. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and all of its officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a hospital pharmacy in California for a minimum of 100 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a hospital pharmacy for a minimum of 100 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 minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a hospital pharmacy in

California for a minimum of 100 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. Posted Notice of Probation

Respondent shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

15. Violation of Probation

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

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

16. Completion of Probation

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

17. Remedial Education

Within thirty (30) 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

USP 797 compounding for all compounding staff. The program of remedial education shall consist of at least five (5) hours, having 50% in-person training or live webinar online classes, which shall be completed within one year 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 or other licensed pharmacy personnel. 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's compounding staff, at respondent's expense, to take an approved examination to test the compounding staff's knowledge of the course. If the compounding staff do 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.

18. Consultant Review of Pharmacy Operations (Compounding)

During the period of probation, Respondent Pharmacy shall retain an independent consultant, who specializes in compounding, at its own expense who shall be responsible for reviewing pharmacy operations on a quarterly basis for compliance by Respondent Pharmacy with state and federal laws and regulations governing the practice of a compounding pharmacy, and for compliance by respondent.

The consultant shall provide the board with an inspection agenda for approval prior to conducting the inspection. Any inspection conducted without prior approval of the inspection agenda shall not be accepted. The consultant shall also provide the board with reports documenting the inspection. The reports shall be provided directly to the board, and receive confirmation of receipt from the board, prior to providing to the respondent. Should the board determine that the consultant is not appropriately assessing the operations of respondent, or providing the appropriate written reports, the board shall require respondent to obtain a different consultant through the same process outlined above, by submitting a new name of an expert

within sixty (60) days of respondent being notified of the need for a new consultant. During the period of probation, the board shall retain discretion to modify the frequency of the consultant's review.

Respondent's proposed consultant, Sterile Compounding Coordinator Melanie Horn, is approved. If Respondent seeks to change its sterile compounding consultant, Respondent must seek approval from the board. Failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation. Any proposed replacement consultant shall be a pharmacist licensed by and not on probation with the board or other professional as appropriate and not on probation with the board, who has been approved by the board to serve in this position. The consultant shall have sufficient education, training, and professional experience to be able to provide guidance to respondent related to the causes for discipline in Case No. 7027. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Stefan Chacon. I understand the stipulation and the effect it will have on the Original Pharmacy Permit, and Sterile Compounding 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: _____

SUTTER COAST HOSPITAL, INC., DBA SUTTER COAST HOSPITAL PHARMACY
Respondent

within sixty (60) days of respondent being notified of the need for a new consultant. During the period of probation, the board shall retain discretion to modify the frequency of the consultant's review.

Respondent's proposed consultant, Sterile Compounding Coordinator Melanie Horn, is approved. If Respondent seeks to change its sterile compounding consultant, Respondent must seek approval from the board. Failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation. Any proposed replacement consultant shall be a pharmacist licensed by and not on probation with the board or other professional as appropriate and not on probation with the board, who has been approved by the board to serve in this position. The consultant shall have sufficient education, training, and professional experience to be able to provide guidance to respondent related to the causes for discipline in Case No. 7027. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Stefan Chacon. I understand the stipulation and the effect it will have on the Original Pharmacy Permit, and Sterile Compounding 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: 5/3/2023

SUTTER COAST HOSPITAL, INC., DBA SUTTER COAST HOSPITAL PHARMACY
Respondent

I have read and fully discussed with Respondent Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

STEFAN CHACON
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,

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

CHRISTOPHER M. YOUNG
Deputy Attorney General
Attorneys for Complainant

SF2020401197
43673687.docx

I have read and fully discussed with Respondent Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: May 3, 2023

STEFAN CHACON
Attorney for Respondent

ENDORSEMENT

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

DATED: May 24, 2023

Respectfully submitted,

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General

Christopher M. Young

CHRISTOPHER M. YOUNG
Deputy Attorney General
Attorneys for Complainant

SF2020401197
43673687.docx

Exhibit A

Accusation No. 7027

ROB BONTA
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
CHRISTOPHER M. YOUNG
Deputy Attorney General
State Bar No. 238532
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 510-3554
Facsimile: (415) 703-5480
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **SUTTER COAST HOSPITAL, INC., DBA SUTTER COAST HOSPITAL PHARMACY** **800 E. Washington Blvd** **Crescent City, CA 95531** **Original Pharmacy Permit No. HSP 37160** **Sterile Compounding License No. LSC 100197** **MEGAN ASHLEY KRAMER** **26 Bilotto Dr.** **Cedar Crest, NM 87008** **Pharmacist License No. RPH 70124** Respondents.	Case No. 7027 **ACCUSATION**

PARTIES

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

2. On or about February 4, 1992, the Board of Pharmacy issued Original Pharmacy Permit Number HSP 37160 to Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy

(Respondent Pharmacy). The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2022, unless renewed.

3. On or about May 29, 2014, the Board of Pharmacy issued Sterile Compounding License Number LSC 100197 to Respondent Pharmacy. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2022, unless renewed.

4. On or about October 24, 2013, the Board of Pharmacy issued Pharmacist License Number RPH 70124 to Megan Ashley Kramer (Respondent Kramer). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2023, unless renewed. From on or about July 27, 2017 through on or about July 12, 2019, Respondent Kramer served as the Pharmacist in Charge (PIC) of Respondent Pharmacy.

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.]. Further pursuant to Code section 4011, the Board also administers and enforces the Uniform Controlled Substances Act.

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. Business and Professions Code section 4113, subdivision (c), states that 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."

11. Business and Professions 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:
>
> . . .
>
> (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
>
> . . .
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> . . .
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the

applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

. . .

12. Business and Professions Code section 4306.5 states, in pertinent part:

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.

. . .

REGULATORY PROVISIONS

13. California Code of Regulations, title 16, section 1714, subdivision (c) states, in pertinent part:

. . .

(c) 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.

. . .

14. California Code of Regulations, title 16, section 1715, subdivisions (a) and (b) state, in pertinent part:

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

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

. . .

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

. . .

15. California Code of Regulations, title 16, section 1735.2, subdivision (k) states, in pertinent part:

. . .

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

. . .

16. California Code of Regulations, title 16, section 1735.3, subdivision (a) states, in pertinent part:

(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.

. . .

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

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

17. California Code of Regulations, title 16, section 1735.5, subdivisions (a), (b), and (c) state, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written policies and

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

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

(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.

. . .

(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.

. . .

18. California Code of Regulations, title 16, section 1751, subdivision (b) states, in pertinent part:

(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.7 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. The environments within the pharmacy shall meet the following standards:

. . .

(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

/ / /

19. California Code of Regulations, title 16, section 1751.1, subdivisions (a) and (c) state, in pertinent part:

> (a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:
>
> (1) Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.
>
> (2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
>
> (3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
>
> . . .
>
> (c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

20. California Code of Regulations, title 16, section 1751.3, subdivision (a) states, in pertinent part:

> (a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:
>
> (1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
>
> (2) Airflow considerations and pressure differential monitoring.
>
> (3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
>
> (4) Cleaning and maintenance of ISO environments and segregated compounding areas.
>
> (5) Compounded sterile drug preparation stability and beyond use dating.
>
> (6) Compounding, filling, and labeling of sterile drug preparations.
>
> (7) Daily and monthly cleaning and disinfection schedule for the controlled

areas and any equipment in the controlled area as specified in section 1751.4.

. . .

(9) Facility management including certification and maintenance of controlled environments and related equipment.

. . .

(11) Hand hygiene and garbing.

. . .

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

. . .

21. California Code of Regulations, title 16, section 1751.4, subdivision (d) states, in pertinent part:

. . .

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

. . .

22. California Code of Regulations, title 16, section 1751.5, subdivision (a) states, in pertinent part:

(a) When compounding sterile drug preparations the following standards must be met:

(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) Personal protective equipment must be donned and removed in an ante-area or immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

. . .

23. California Code of Regulations, title 16, section 1751.6, subdivisions (b), (c), and (e) state, in pertinent part:

. . .

(b) The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

. . .

(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area.

. . .

(2) Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

24. California Code of Regulations, title 16, section 1751.7, subdivisions (b), (c), and (d) state, in pertinent part:

. . .

(b)

(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

. . .

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.

. . .

25. California Code of Regulations, title 16, section 1751.8, subdivision (e) 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:
>
> . . .
>
> (e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled for "immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.
>
> . . .

26. California Code of Regulations, title 24, section 1250.4, subdivision (4) states, in pertinent part:

> The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:
>
> . . .
>
> (4) A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.

COST RECOVERY

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

FACTUAL ALLEGATIONS

January 3, 2019 Routine Inspection

28. A Board investigator conducted a routine inspection of Respondent Pharmacy, located in Crescent City, California, on January 3, 2019. Respondent Kramer, the Pharmacist in Charge, was present during the inspection. Prior to the inspection, the Board investigator requested copies of policies and procedures from Respondent Kramer. Following the inspection, the Board investigator followed up several times with Respondent Kramer and Respondent Pharmacy staff for clarification and to correct deficiencies identified by the Board investigator.

29. During the inspection at Respondent Pharmacy, the investigator found that the only sink available was in a restroom, when Pharmacy Law requires that a sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.

30. Respondent Pharmacy's records showed that two prior pharmacists, D. Nguyen and G. Orat, conducted compounding without training, and none of the pharmacy technicians employed at Respondent Pharmacy had conducted training. Records of training for the past three years, as required by Pharmacy Law, were not retained by Respondents or available to the investigator.

31. Respondents did not have a written program for training and performance evaluation for the PIC, the staff pharmacists, and the pharmacy technicians. Respondent Kramer and her staff had not conducted most of the training required prior to commencing compounding. The investigator asked Respondent Kramer, and Respondent Pharmacy staff, to demonstrate their knowledge of aseptic handwashing, garbing, cleaning of a controlled environment, and the ability to accurately document each compounded drug product. The investigator noted major deficiencies in knowledge of applicable regulations.

32. Respondents documented sterile compounding with a system called EPIC and did not ensure the records kept included all the required elements. Specifically, records for completed compounded drug products for vancomycin, ketamine, and Remicade did not contain all ingredients used to compound the products, did not contain the beyond use date of the final compounded products, and did not contain final volumes.

33. During the inspection, the Board investigator observed that compounding staff failed to wear appropriate clothing. Specifically, compounding staff: failed to wear non-shedding gowns, and wore isolation gowns instead; failed to don personal protective equipment immediately outside the segregated compounding area; did not dry hands with a low-lint towel prior to donning a non-shedding gown; and wore visible jewelry.

34. Respondents did not provide written policies and procedures which contained all required categories for a licensed sterile compounding pharmacy. The Board investigator requested the written policies and procedures several times, and Respondents failed to provide complete copies. Compounding staff at Respondent Pharmacy did not follow their own policies and procedures relating to handwashing, garbing, orientation, training, and competency evaluation. Moreover, Respondent Kramer did not ensure that the applicable annual review of policies occurred, and that Respondent Pharmacy's staff had reviewed the policies and procedures on an annual basis. Respondents did not maintain records of training and competency as required by Pharmacy Law for a period of three years.

35. During the inspection, the Board investigator observed unsanitary conditions, including that Respondent Pharmacy did not clean the hoods, all surfaces and floors with a germicidal detergent and sterile water. Respondent Pharmacy's policies and procedures stated that cleaning must be conducted with a detergent, but the pharmacy only used isopropyl alcohol and water for cleaning.

36. Respondents failed to ensure that process validation and quality assurance in relation to sterile compounding. Specifically, staff pharmacists had not completed three-fingertip tests or media fill prior to compounding. Records were not available to ensure that all of Respondent Pharmacy staff had completed these tests. Respondent Kramer failed to demonstrate competency

on aseptic technique and practices prior to compounding, or to show that Respondent Pharmacy's staff were adequately trained in process validation and quality assurance.

37. Respondent Kramer did not prepare accurate compounding self-assessments as required by Pharmacy Law. Respondent Kramer signed and dated a self-assessment, under penalty of perjury, stating that Respondent Pharmacy was in compliance with regulations when it was not. The Board investigator observed several areas that were not in compliance with Pharmacy Law at the inspection. Respondent Kramer wrongly stated that:

- Respondent Pharmacy had an adequate sink for a sterile compounding pharmacy, when it did not;
- Respondent Pharmacy had a "CAI hood," when it had a laminar flow hood;
- Respondent Pharmacy was in compliance with hand-washing and garbing regulations;
- Competency training and process validation was conducted prior to compounding;
- "Beyond Use Dates" were assigned to compounded drugs;
- That compounding records were adequately maintained, when in fact they were not kept for three years;
- That policies and procedures were followed, when in fact there was inadequate cleaning, record-keeping, and compounding practices.

January 7, 2020 Routine Inspection

38. A Board investigator conducted a routine inspection of Respondent Pharmacy on January 7, 2020. Respondent's Pharmacist in Charge at the time of the inspection, Ram Malhotra, was present for the inspection.

39. Prior to the January 7, 2020 inspection, Malhotra sent an e-mail to Board investigators, on October 10, 2019, stating that emergent compounding with immediate use Beyond Use Dates was taking place in Respondent Pharmacy only when necessary, and all other patient-specific compounding was being conducted in the infusion cleanroom located on the same campus. Respondent Pharmacy was undergoing a complete remodel at that time. Board investigators responded to Malhotra that some of the compounds being prepared at Respondent

Pharmacy were outside the allowance for immediate use, and that insufficient evidence of immediate need and/or emergency need was not provided. Board investigators provided the regulatory criteria for emergency need, and confirmed with Malhotra the allowable practices for compounding during the pharmacy remodel.

40. Between on or about October 10, 2019, and January 6, 2020, at least 340 sterile preparations were compounded in a manner that was not compliant with Pharmacy Law. The circumstance for immediate need was either not documented, or the general statement "patient care compromised when delayed or ED patient" was documented as the circumstance. Immediate-use compounding was not used in limited situations where failure to administer could result in loss of life or intense suffering, but was used for several first doses of non-emergent medications such as supplements and antibiotics.

41. During the January 7, 2020 inspection, Board investigators learned that Malhotra began as PIC at Respondent Pharmacy on or about July 29, 2019, but did not conduct the hospital and compounding self-assessments until on or about December 11, 2019.

FIRST CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Improper Sink in Pharmacy)

42. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1751, subdivision (b)(3), and/or California Code of Regulations, title 16, section 1714, subdivision (c), and/or California Code of Regulations, title 24, section 1250.4, subdivision (4). As described above in paragraph 29, the only sink in the sterile compounding pharmacy was in a restroom.

SECOND CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Failure to Train Sterile Compound Staff)

43. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1751.6, subdivisions (c), and/or (e). As described above in

paragraphs 30 and 31, Respondents failed to maintain adequate records of training, and failed to demonstrate knowledge of sterile compounding practical skills required by Pharmacy Law.

THIRD CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Failure to Maintain Compounding Records)

44. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1735.3, subdivision (a), in that Respondents failed to ensure that all required information for compounded drug products was kept in the required records for those compounded drugs, as described above in paragraph 32.

FOURTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Hand Washing and Garbing)

45. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1751.5, subdivision (a). Compounding staff at Respondent Pharmacy failed to wear adequate clothing and wash their hands according to regulation, as described above in paragraph 33.

FIFTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Failure to Maintain and Follow Written Procedures)

46. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1751.3, subdivision (a), in that inadequate written policies and procedures were provided to the Board investigator, and of those policies available, pharmacy staff did not follow all policies, as described above in paragraph 34.

SIXTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Failure to Complete Annual Review of Policies)

47. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), California Code of Regulations, title 16, section 1735.5, subdivisions (b), and/or (c), and/or California Code of

Regulations, title 16, section 1751.3, subdivision (e), in that an annual review of policies and procedures was not conducted, and pharmacy staff were not required to review on an annual basis, as described above in paragraph 34.

SEVENTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Failure to Keep Training Records for Three Years)

48. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1751.1, subdivisions (a), and/or (c), in that Respondents failed to maintain records of training and competency for three years, as described above in paragraph 34.

EIGHTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Inadequate Cleaning)

49. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1751.4, subdivision (d), in that Respondent Pharmacy was not cleaned with a germicidal detergent, and areas were not cleaned according to policy, as described above in paragraph 35.

NINTH CAUSE FOR DISCIPLINE

(Respondents Pharmacy and Kramer: Failure to Conduct Process Validation)

50. Respondents Pharmacy and Kramer are subject to disciplinary action under Code section 4301, subdivisions (j) and/or (o), Code section 4113, subdivision (c), and/or California Code of Regulations, title 16, section 1751.7, subdivisions (b), and/or (c), and/or (d), in that required tests to ensure process validation and quality assurance were not completed prior to compounding, as described above in paragraph 36.

TENTH CAUSE FOR DISCIPLINE

(Respondent Kramer: Dishonesty, Fraud, or Deceit)

51. Respondent Kramer is subject to disciplinary action under Code section 4301, subdivision (f), (j), and/or (o), Code section 4113, subdivision (c), Code section 4306.5, and/or

California Code of Regulations, title 16, section 1735.2, subdivision (k), in that Respondent Kramer completed a compounding pharmacy self-assessment attesting to facts that did not exist, as stated above in paragraph 37.

ELEVENTH CAUSE FOR DISCIPLINE

(Respondent Pharmacy: Incomplete Documentation of Immediate Use Compounding; Immediate Use Compounding Not Limited to Certain Situations)

52. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivisions (j), and/or (o), and/or California Code of Regulations, title 16, section 1751.8, subdivision (e), in that sterile compounded drug preparation was compounded under conditions that did not meet regulations, as described above in paragraphs 39 and 40.

TWELFTH CAUSE FOR DISCIPLINE

(Respondent Pharmacy: Late Self-Assessment of Pharmacy by PIC)

53. Respondent Pharmacy is subject to disciplinary action under Code section 4301, subdivisions (j), and/or (o), and/or California Code of Regulations, title 16, section 1715, subdivision (b)(2), in that Malhotra did not complete the hospital pharmacy self-assessment and compounding self-assessment within thirty days as required, as described above in paragraph 41.

DISCIPLINE CONSIDERATIONS

54. To determine the degree of discipline, if any, to be imposed on Respondent Kramer, Complainant alleges that on or about November 8, 2019, in a prior action, the Board of Pharmacy issued Citation and Fine Number CI-2019-85775 and ordered Respondent Kramer to pay a fine of $500, or proof of four (4) hours of remedial education in "hazardous compounding." During the time period of January 3, 2018 through August 22, 2018, employees under Respondent Kramer's supervision were compounding hazardous preparations in a positive pressure primary engineering control (PEC), when preparation of those agents required a negative pressure PEC (Cal. Code Regs., tit. 16, section 1751.4, subdivision (g)). That Citation was paid, and is now final.

55. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that the following citations have been issued to Respondent Pharmacy:

a. On or about November 8, 2019, in a prior action, the Board of Pharmacy issued Citation Numbers CI-2019-85774 and CI-2018-81806 to Respondent Pharmacy, and ordered Respondent Pharmacy to pay a $1,000 fine. During the time period of January 3, 2018 through August 22, 2018, employees under Respondent Kramer's supervision were compounding hazardous preparations in a positive pressure PEC, when preparation of those agents required a negative pressure PEC (Cal. Code Regs., tit. 16, section 1751.4, subdivision (g)). Those Citations were paid and are now final.

b. On or about July 10, 2017, in a prior action, the Board of Pharmacy issued Citation Numbers CI-2016-75817 and CI-2016-73021 to Respondent Pharmacy, and ordered Respondent Pharmacy to pay a fine of $2,000 for each Citation. During an inspection occurring on or about November 8, 2016, Respondent Pharmacy had unsanitary conditions including a filthy under-grate on the PEC in the designated compounding area, as well as open porous areas on the door and near the PEC in the compounding area (Cal. Code Regs., tit. 16, section 1751.4, subdivisions (c) and (d)). Those Citations were paid and are now final.

c. On or about October 12, 2016, in a prior action, the Board of Pharmacy issued Citation Numbers CI-2016-72387 and CI-2015-68643 to Respondent Pharmacy, and ordered Respondent Pharmacy to pay fines totaling $4,250. During an inspection occurring on or about January 5, 2016, Respondent had unsanitary conditions in that shelves and storage bins were not documented as being regularly cleaned (Cal. Code Regs., tit. 16, section 1751.4, subdivision (d)); there were inadequate master formulas for compounded drug products (Cal. Code Regs., tit. 16, section 1735.2, subdivision (d)); inadequate records of compounding were kept (Cal. Code Regs., tit. 16, section 1735.3, subdivision (a)); a biennial inventory was unavailable for review (Title 21, Code of Federal Regulations section 1304.11); the compounding clean room was not maintained properly (Cal. Code Regs., tit. 16, section 1751.4, subdivision (c)); end product testing for potency on compounded products had not been performed (Cal. Code Regs., tit. 16, section 1735.8, subdivisions (c) and (d)); there were inadequate records of training for compounding staff (Cal. Code Regs., tit. 16, section 1735.7, subdivision (a)); and compounding policies and procedures were inadequate (Cal. Code Regs., tit. 16, section 1735.5, subdivision (c)(1)).

OTHER MATTERS

56. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy License Number HSP 37160, 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 Number HSP 37160 is placed on probation, or until reinstatement if Respondent Pharmacy License Number HSP 37160 is revoked.

57. Pursuant to Code section 4307, if discipline is imposed on Respondent Pharmacy License Number HSP 37160 issued to Respondent Pharmacy while Respondent Kramer was the pharmacist-in-charge, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Respondent Kramer 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 Number HSP 37160 is placed on probation, or until reinstatement if Respondent Pharmacy License Number HSP 37160 is revoked.

PRAYER

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

1. Revoking or suspending Original Pharmacy Permit Number HSP 37160, issued to Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy;

2. Revoking or suspending Sterile Compounding License Number LSC 100197, issued to Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 70124, issued to Megan Ashley Kramer;

4. Prohibiting Sutter Coast Hospital, Inc., dba Sutter Coast Hospital Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy Permit Number HSP 37160 is placed on probation, or until reinstatement if Original Pharmacy Permit Number HSP 37160 is revoked;

5. Prohibiting Megan Ashley Kramer from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Pharmacy

Permit Number HSP 37160 is placed on probation, or until reinstatement if Original Pharmacy Permit Number HSP 37160 is revoked;

6. Ordering Respondent Pharmacy and Respondent Kramer, 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,

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

DATED: 11/6/2021

Signature on File

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

SF2020401197
42639094.docx