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

In the Matter of the Accusation Against:

U.C. DAVIS MEDICAL CENTER,
Original Hospital Pharmacy Permit No. HPE 37803;

and

JULIANNA LANDON BURTON,
Original Pharmacist License No. RPH 51340,

Respondents

Agency Case No. 6881

OAH No. 2020050319

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on August 18, 2021.

It is so ORDERED on July 19, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General
PHILLIP L. ARTHUR
Deputy Attorney General
State Bar No. 238339
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7866
Facsimile: (916) 327-8643
E-mail: Phillip.Arthur@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **U.C. DAVIS MEDICAL CENTER** **UC Davis Medical Center** **2315 Stockton Boulevard** **Sacramento, CA 95817** **Original Hospital Pharmacy Permit No. HPE 37803,** **and** **JULIANNA LANDON BURTON** **400 Capitol Mall, Suite 1850** **Sacramento, CA 95814** **Original Pharmacist License No. RPH 51340** Respondents.	Case No. 6881 OAH No. 2020050319 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL [U.C. DAVIS MEDICAL CENTER ONLY]** **[Bus. & Prof. Code § 495]**

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

/ / /

/ / /

/ / /

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Matthew Rodriquez, Acting Attorney General of the State of California, by Phillip L. Arthur, Deputy Attorney General.

2. Respondent U.C. Davis Medical Center (Respondent U.C. Davis) is represented in this proceeding by attorney Derek S. Davis, whose address is: Cooper & Scully, P.C., 900 Jackson St. #100, Dallas, TX 75202.

JURISDICTION

3. On or about May 4, 1992, the Board issued Original Hospital Pharmacy Permit No. HPE 37803 to Respondent U.C. Davis. The Original Hospital Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 6881 and will expire on July 1, 2021, unless renewed.

4. Accusation No. 6881 was filed before the Board and is currently pending against Respondent U.C. Davis. The Accusation and all other statutorily required documents were properly served on Respondent U.C. Davis on April 20, 2020. Respondent U.C. Davis timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 6881 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent U.C. Davis has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6881. Respondent U.C. Davis has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent U.C. Davis 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 be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and 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.

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

CULPABILITY

8. Respondent U.C. Davis understands that the charges and allegations in Accusation No. 6881, if proven at a hearing, constitute cause for imposing discipline upon its Original Hospital Pharmacy Permit.

9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest that cause for discipline exists based on the charges in Accusation No. 6881. Respondent further agrees that in any future proceedings before the Board all of the allegations set forth in Accusation No. 6881, shall be deemed admitted.

10. Respondent U.C. Davis agrees that its Original Hospital Pharmacy Permit is subject to discipline and they agree to be bound by the Disciplinary Order below.

RESERVATION

11. The admissions made by Respondent U.C Davis herein are only for the purposes of this proceeding, or any other proceedings in which the Board or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent U.C. Davis 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 U.C. Davis or its counsel. By signing the stipulation, Respondent U.C. Davis 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 for Public Reproval shall be of no force or effect, except for this paragraph, it

shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

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 Hospital Pharmacy Permit No. HPE 37803 issued to Respondent U.C. Davis Medical Center (Respondent U.C. Davis) shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6881, attached as Exhibit A.

Cost Recovery. No later than 30 days from the effective date of the Decision, Respondent U.C. Davis shall pay $8,500.00 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code section 125.3. If Respondent U.C. Davis fails to pay the Board costs as ordered, Respondent U.C. Davis shall not be allowed to renew their Original Hospital Pharmacy Permit until Respondent U.C. Davis pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

/ / /

Full Compliance. As a resolution of the charges in Accusation No. 6881, this stipulated settlement is contingent upon Respondent U.C. Davis's full compliance with all conditions of this Order. If Respondent U.C. Davis fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent U.C Davis's Original Hospital Pharmacy Permit No. HPE 37803.

ACCEPTANCE

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

DATED: _____

BRADLEY SIMMONS
CHIEF ADMINISTRATOR U.C. DAVIS MEDICAL CENTER, FOR
U.C. DAVIS MEDICAL CENTER
Respondent

I have read and fully discussed with Respondent U.C. Davis Medical Center the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form.

DATED: _____

DEREK S. DAVIS
Attorney for Respondent U.C. Davis Medical Center

/ / /

/ / /

/ / /

Full Compliance. As a resolution of the charges in Accusation No. 6881, this stipulated settlement is contingent upon Respondent U.C. Davis's full compliance with all conditions of this Order. If Respondent U.C. Davis fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent U.C Davis's Original Hospital Pharmacy Permit No. HPE 37803.

ACCEPTANCE

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

DATED: May 27, 2021

BRADLEY SIMMONS
CHIEF ADMINISTRATOR U.C. DAVIS MEDICAL CENTER, FOR
U.C. DAVIS MEDICAL CENTER
Respondent

I have read and fully discussed with Respondent U.C. Davis Medical Center the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form.

DATED: May 27, 2021

DEREK S. DAVIS
Attorney for Respondent U.C. Davis Medical Center

///

///

///

ENDORSEMENT

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

DATED: May 27, 2021

Respectfully submitted,

ROB BONTA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General

Phillip Arthur

PHILLIP L. ARTHUR
Deputy Attorney General
Attorneys for Complainant

SA2020100088

ENDORSEMENT

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

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General

PHILLIP L. ARTHUR
Deputy Attorney General
Attorneys for Complainant

SA2020100088

Exhibit A

Accusation No. 6881

XAVIER BECERRA
Attorney General of California
DAVID E. BRICE
Supervising Deputy Attorney General
PHILLIP L. ARTHUR
Deputy Attorney General
State Bar No. 238339
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7866
Facsimile: (916) 327-8643
E-mail: Phillip.Arthur@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **U.C. DAVIS MEDICAL CENTER** **UC Davis Medical Center** **2315 Stockton Boulevard** **Sacramento, CA 95817** **Original Hospital Pharmacy Permit No. HPE 37803,** **and** **JULIANNA LANDON BURTON** **400 Capitol Mall, Suite 1850** **Sacramento, CA 95814** **Original Pharmacist License No. RPH 51340** Respondents.	Case No. 6881 **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 May 4, 1992, the Board of Pharmacy issued Original Hospital Pharmacy Permit Number HPE 37803 to The Regents of The University of California to do business as U.C. Davis Medical Center (Respondent U.C. Davis). 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, 2020, unless renewed.

3. On or about September 28, 1999, the Board of Pharmacy issued Original Pharmacist License Number RPH 51340 to Julianna Landon Burton (Respondent Burton). Respondent has been the Pharmacist-in-Charge of Respondent U.C. Davis from February 4, 2019 to the present. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2021, unless renewed.

JURISDICTION

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

5. Code section 4300.1 states:

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

6. Code section 4307 states:

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

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

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

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

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

7. Code section 4113 states:

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(d) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(e) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the

daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

BUSINESS AND PROFESSIONS CODE

8. Code section 4127.1(a) states, "A pharmacy that compounds sterile drug products shall possess a sterile compounding pharmacy license as provided in this article."

9. 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 procured by mistake. Unprofessional conduct includes, but is not limited to, any of the following:
>
> . . .
>
> (b) Incompetence.
>
> . . .
>
> (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.
>
> . . . .

10. Code section 4306.5(a) 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.

/ / /

/ / /

/ / /

REGULATIONS

11. California Code of Regulations, title 16, section 1735.3(a) states:

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

(1) The master formula document.

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

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

(B) The date the drug preparation was compounded.

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

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

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

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

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

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

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

/ / /

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

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

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

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

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

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

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

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

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

13. California Code of Regulations, title 16, section 1751.3(a)(1) states:

(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.

14. 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:

> . . .
>
> (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.
>
> . . . .

COST RECOVERY

15. Code section 125.3 provides, in pertinent part, that a 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.

BACKGROUND

16. On or about August 19, 2019, Respondent Burton informed the Board that the main pharmacy compounding area located in the basement of Respondent U.C. Davis in Sacramento had flooded. There was no other licensed compounding area within the hospital or at the U.C.

Davis Oncology Center located on the campus, so they were preparing compounded sterile preparations (CSPs)[1] as immediate use and assigning a four-hour beyond use date (BUD)[2].

17. In response to this notification, the Board provided Respondent Burton with California Code of Regulations, title 16, section 1751.8, subdivision (e), which describes the circumstances in which immediate use compounding is allowed and the parameters which must be met to comply with the regulation.

18. Later in the day on August 19, 2019, Respondent Burton sent the Board an e-mail stating they were moving two Primary Engineering Controls (PEC)[3] from the main pharmacy, which were not affected by the flood, to the sixth floor satellite pharmacy of Respondent U.C. Davis, so that it could serve as a segregated compounding area (SCA). The Board informed Respondent Burton that the PECs and room would need to be certified and viable testing results available before the permit could be issued for the space. The Board reminded Respondent Burton of the allowance of immediate use under California Code of Regulations, title 16, section 1751.8, subdivision (e).

19. On or about August 26, 2019, a Board Inspector went to Respondent U.C. Davis to perform an inspection.

20. During the August 26, 2019, inspection, Respondent U.C. Davis's pharmacy staff, including Respondent Burton, informed the inspector that since the flood, compounding activities had been relocated to the sixth floor satellite pharmacy which did not have a sterile compounding license. CSPs were being prepared as immediate use on the countertop and in PECs that were

[1] "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

[2] "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

[3] Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

moved into the space after the flood (at the time of the inspection, one PEC was certified and the other was not). On August 19, 2019, immediately following the flood, the CSPs prepared as immediate use were being assigned a four to six-hour BUD.

21. Following the August 26, 2019, inspection, the Board Inspector completed an inspection report which identified, among other deficiencies, that the compounding records which were on the computer were automatically populated with the BUD reference from the master formula. CSPs prepared as immediate use had an incorrect BUD on the record as they were not assigned as one-hour but rather with the automatic populated BUD. It was also noted that complete compounding logs could not be produced from the computer records, so a compounded products report was generated instead which did not contain all the required elements of a compounding log. The inspection report also noted that the labels for immediate use CSPs had two stickers on them: a "discard" date and time, which was six hours, and a "hang by" date and time, which was one hour. The Board Inspector discussed with Respondent Burton how this could be confusing to the nursing staff and would make it hard to determine the BUD. Following issuance of the inspection report, the Board Inspector educated Respondent Burton on the required elements of a compounding log per California Code of Regulations, title 16, section 1735.3, subdivisions (a)(2) (A-J), as well as the requirements for immediate use under California Code of Regulations, title 16, section 1751.8, subdivision (e).

22. From August 23 through September 23, 2019, Respondent U.C. Davis's leadership, mainly Respondent Burton, sent the Board daily e-mail updates which included: (1) the status of the PEC certifications and viable sampling results; (2) outsourcing updates; (3) staff training updates; (4) follow up to requested items; and (5) updates to their compounding status and processes.

23. On or about August 27, 2019, Respondent Burton sent the Board an e-mail which included a copy of the compounding logs for immediate use CSPs. In addition, Respondent Burton sent a copy of all emergent CSPs prepared from 1807 hours on August 26, 2019 to 1207 hours on August 27, 2019.

/ / /

24. A review of the report of CSPs prepared between August 19 and 25, 2019 (seven days) as immediate use revealed the following. Approximately 3,100 CSPs were prepared. At least 13 medium risk CSPs were prepared, which included epidurals and banana bags. There was no documentation present of the emergent need for any of the CSPs prepared. Respondent Burton was unable to retrieve complete compounding logs from the computer. The following elements were missing from the report she could retrieve:

a. The identity of any pharmacy personnel engaged in compounding the drug preparation;

b. The identity of the pharmacist reviewing the final drug preparation;

c. The manufacturer, expiration date, and lot number of each component;

d. The "beyond use date" or "beyond use date and time" of the final compounded drug preparation;

e. The final quantity or amount of drug preparation compounded for dispensing; and

f. Documentation of quality reviews and required post-compounding process and procedures.

25. A review of the compounding logs for CSPs prepared between 1807 hours on August 26, 2019, to 1207 hours on August 27, 2019, revealed the following. Approximately 200 CSPs were prepared. No documentation was present of the emergent need for any of the CSPs prepared. The space for the reason was left blank. The following elements of a compounding log were missing:

a. The identity of any pharmacy personnel engaged in compounding the drug preparation;

b. The identity of the pharmacist reviewing the final drug preparation;

c. The manufacturer, expiration date, and lot number of each component;

d. The "beyond use date" or "beyond use date and time" of the final compounded drug preparation (log states hang by time and expiration time);

e. The final quantity or amount of drug preparation compounded for dispensing; and

f. Documentation of quality reviews and required post-compounding process and procedures.

/ / /

26. A review of compounding logs for CSPs for August 27 through August 29, 2019, revealed the following. Approximately 175 compounded sterile products were prepared. Documentation of the emergent need started at 1247 hours on August 27, 2019. Before that, approximately 165 CSPs were prepared without documentation of the emergent need. The following elements of a compounding log were missing:

a. The identity of any pharmacy personnel engaged in compounding the drug preparation;

b. The identity of the pharmacist reviewing the final drug preparation;

c. The manufacturer, expiration date, and lot number of each component;

d. The "beyond use date" or "beyond use date and time" of the final compounded drug preparation (have hang by time and expiration time);

e. The final quantity or amount of drug preparation compounded for dispensing; and

f. Documentation of quality reviews and required post-compounding process and procedures.

27. An analysis of the CSPs compounding logs for August 19 through 29, 2019, revealed that approximately 3,400 compounded sterile preparations were prepared as immediate use. The emergent need for the immediate use was documented for only nine of those preparations. At least 13 of the CSPs prepared as immediate use were medium risk.

28. A review of the CSPs compounding logs for September 3 through September 5, 2019, revealed the following. Approximately 120 compounded sterile preparations were prepared. The following elements of a compounding log were missing:

a. The identity of any pharmacy personnel engaged in compounding the drug preparation;

b. The identity of the pharmacist reviewing the final drug preparation;

c. The manufacturer, expiration date, and lot number of each component;

d. The "beyond use date" or "beyond use date and time" of the final compounded drug preparation;

e. The final quantity or amount of drug preparation compounded for dispensing; and

f. Documentation of quality reviews and required post-compounding process and procedures.

29. On or about August 30, 2019, the Board issued a temporary sterile compounding permit to Respondent U.C. Davis's sixth floor satellite pharmacy.

30. On or about September 5, 2019, Respondent Burton called the Board Inspector to get clarification if BUD meant the time in which the infusion must be completed or the time in which the infusion must be started.

31. On or about September 6, 2019, Respondent Burton e-mailed the Board Inspector asking if medium-risk products could be compounded in Respondent U.C. Davis's licensed SCA.

32. On or about September 10, 2019, Respondent Burton finally provided the Board Inspector with an updated compounding log which included all of the required elements of a compounding log per California Code of Regulations, title 16, section 1735.3(a)(2)(A-J).

33. Respondent U.C. Davis provided the Board with certification reports of PECs and room sampling reports, dated August 23 and September 4, 5, 10, 11, 16, and 18, 2019. One of these reports revealed that viable air sampling performed on August 29, 2019 detected *Aspergillus Niger* (a mold), which is categorized as a highly pathogenic microorganism by United States Pharmacopeia (USP) chapter 797 and must be remedied immediately, regardless of colony-forming units (CFU) count, with the assistance of a competent microbiologist, infection control, or industrial hygienist. The policy and procedure did not include an action plan for how to respond to highly pathogenic microorganisms. On September 10, 2019, during a call between Respondent U.C. Davis's leadership and the Board, the requirements of USP chapter 797 was discussed regarding highly pathogenic microorganisms. This was because *Aspergillus Niger* was detected in an air sample from August 29, 2019, with results back on or about September 6, 2019. No remediation had been taken or at least not documented. During this conversation, no one from Respondent U.C. Davis's leadership was able to identify that there was a requirement for "immediate remedied regardless of CFU count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist."

/ / /

/ / /

/ / /

RESPONDENT U.C. DAVIS

FIRST CAUSE FOR DISCIPLINE

(Immediate Use Compounding Documentation Missing, Medium Risk CSPs Prepared as Immediate Use)

34. Respondent U.C Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1751.8(e), in that between at least August 19 and 29, 2019, approximately 3,400 compounded sterile preparations were prepared as immediate use. The emergent need for the immediate need was documented for only nine of those preparations. At least 13 of the CSPs prepared as immediate use were medium risk. On August 19, 2019, immediate use compounds were given a BUD of four to six hours. Between August 19 and 26, 2019, BUD assignment of one hour could not be verified as the BUD was automatically populated in the computer from the BUD stated in the master formula. The facts and circumstances are described with more particularity in paragraphs 16, 20-21, and 24-27, above.

SECOND CAUSE FOR DISCIPLINE

(Unlicensed Activity)

35. Respondent U.C. Davis is subject to disciplinary action under Code section 4127.1(a), by and through Code section 4301(o), in that between at least August 19 and 29, 2019, CSPs were being prepared in Respondent U.C. Davis's sixth floor satellite pharmacy which did not have a sterile compounding license. The facts and circumstances are described with more particularity in paragraphs 16, 20, 24-26, and 29, above.

THIRD CAUSE FOR DISCIPLINE

(Compounding Logs Not Present)

36. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2), in that compounding logs could not be produced or retrieved from the computer for compounded sterile preparations prepared between August 19 and 25, 2019. The facts and circumstances are described with more particularity in paragraph 21, above.

FOURTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Identity of Pharmacy Personnel Not Present)

37. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(C), in that between August 19 and September 10, 2019, compounding logs for 495 compounded drug preparations lacked documentation of the identity of the pharmacy personnel engaged in compounding the drug preparation. The facts and circumstances are described with more particularity in paragraphs 24-26, above.

FIFTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Identity of Pharmacist Reviewing the Final Preparation Not Present)

38. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(D), in that between August 19 and September 10, 2019, compounding logs for 495 compounded drug preparations lacked documentation of the identity of the pharmacist who reviewed the final drug preparation. The facts and circumstances are described with more particularity in paragraphs 24-26, above.

SIXTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Manufacturer, Expiration Date, Lots Not Present)

39. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(F), in that between August 26 and September 10, 2019, compounding logs for 495 compounded drug preparations lacked documentation of the manufacturer, expiration date, and lot number of each component. The facts and circumstances are described with more particularity in paragraphs 25-26, above.

SEVENTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Beyond Use Date Not Present)

40. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.2(a)(2)(H), in that between August 19 and September 10, 2019, compounding logs for 495 compounded drug preparations

lacked documentation of the BUD. The facts and circumstances are described with more particularity in paragraphs 24-26, above.

EIGHTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Final Quantity of Drug Preparation Not Present)

41. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(I), in that between August 26 and September 10, 2019, compounding logs for 495 compounded drug preparations lacked documentation of the final quantity or amount of drug preparation compounded for dispensing. The facts and circumstances are described with more particularity in paragraphs 25-26, above.

NINTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Compounding Log Documentation of Quality Reviews and Required Post-Compounding Processes)

42. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(J), in that between August 26 and September 10, 2019, compounding logs for 495 compounded drug preparations lacked documentation of quality reviews and post-compounding process and procedures. The facts and circumstances are described with more particularity in paragraphs 25-26, above.

TENTH CAUSE FOR DISCIPLINE

(Policy and Procedures - Viable Air and Surface Sampling)

43. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1751.3(a)(1), in that viable air sampling performed on August 29, 2019 detected *Aspergillus Niger* which is categorized as a highly pathogenic microorganism by USP chapter 797, and must be remedied immediately regardless of CFU count with the assistance of a competent microbiologist, infection control, or industrial hygienist. Respondent U.C. Davis's policy and procedure did not include an action plan for how to respond to highly pathogenic microorganisms. The facts and circumstances are described with more particularity in paragraph 33, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Label Packing Beyond Use Date)

44. Respondent U.C. Davis is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.4(a)(4), in that on August 26, 2019, during an inspection, it was discovered that the compounded sterile preparations were labeled with a "hang by" date and time and a "discard by" date and time, which were different. In addition, there was no BUD on the label. The facts and circumstances are described with more particularity in paragraphs 20-21, above.

RESPONDENT BURTON

45. Respondent Burton has been the designated Pharmacist-In-Charge for Respondent U.C. Davis under Business and Profession Code (Code) section 4113(a) since February 4, 2019. As Pharmacist-in-Charge for Respondent U.C. Davis, Respondent Burton was responsible for Respondent U.C. Davis's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy under Code section 4113(c).

TWELFTH CAUSE FOR DISCIPLINE

(Immediate Use Compounding Documentation Missing, Medium Risk CSPs Prepared as Immediate Use and Incorrect BUD Assignment)

46. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1751.8(e), as set forth in paragraph 34, above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Unlicensed Activity)

47. Respondent Burton is subject to disciplinary action under Code section 4127.1(a), as set forth in paragraph 35, above.

/ / /

/ / /

/ / /

FOURTEENTH CAUSE FOR DISCIPLINE

(Compounding Logs Not Present)

48. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2), as set forth in paragraph 36, above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Identity of Pharmacy Personnel Not Present)

49. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(C), as set forth in paragraph 37, above.

SIXTEENTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Identity of Pharmacist Reviewing the Final Preparation Not Present)

50. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(D), as set forth in paragraph 38, above.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Manufacturer, Expiration Date, Lots Not Present)

51. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(F), as set forth in paragraph 39, above.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Beyond Use Date Not Present)

52. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(H), as set forth in paragraph 40, above.

/ / /

/ / /

NINETEENTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Final Quantity of Drug Preparation Not Present)

53. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(I), as set forth in paragraph 41, above.

TWENTIETH CAUSE FOR DISCIPLINE

(Incomplete Compounding Records: Compounding Log Documentation of Quality Reviews and Required Post-Compounding Processes)

54. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.3(a)(2)(J), as set forth in paragraph 42, above.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Policy and Procedures - Viable Air and Surface Sampling)

55. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1751.3(a)(1), as set forth in paragraph 43, above.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Label Lacking Beyond Use Date)

56. Respondent Burton is subject to disciplinary action under Code section 4301(o), by and through California Code of Regulations, title 16, section 1735.4(a)(4), as set forth in paragraph 44, above.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

57. Respondent Burton is subject to disciplinary action under Code section 4301(b) in that while acting as the Pharmacist-in-Charge for Respondent U.C. Davis, Respondent Burton did not have knowledge of sterile compounding practice. The facts and circumstances are described with more particularity in paragraphs 16-18, 21, and 30-31, above.

/ / /

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

58. Respondent Burton is subject to disciplinary action under Code sections 4301 and 4306.5 in that while acting as the Pharmacist-in-Charge for Respondent U.C. Davis, on or about August 26, 2019, Respondent Burton was educated by a Board Inspector on the requirements for documenting emergent need for immediate use compounding and the required elements of a compounding log. Nonetheless, immediate use compounding continued without documentation of the emergent need until at least August 27, 2019, and Respondent Burton did not update the compounding logs to be in compliance until September 10, 2019. Respondent Burton thus failed to use her education, training, or experience as a pharmacist. The facts and circumstances are described with more particularity in paragraphs 16-17, 19-21, 23-28, and 32, above.

OTHER MATTERS

59. Pursuant to Code section 4307, if discipline is imposed on Original Hospital Pharmacy Permit Number HPE 37803 issued to The Regents of The University of California to do business as U.C. Davis Medical Center, The Regents of The University of California to do business as U.C. Davis Medical Center shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Hospital Pharmacy Permit Number HPE 37803 is placed on probation or until Original Hospital Pharmacy Permit Number HPE 37803 is reinstated if it is revoked.

60. Pursuant to Code section 4307, if discipline is imposed on Original Hospital Pharmacy Permit Number HPE 37803 issued to The Regents of The University of California to do business as U.C. Davis Medical Center while Julianna Landon Burton has been Pharmacist-in-Charge and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Julianna Landon Burton shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Hospital Pharmacy Permit Number HPE 37803 is placed on probation or until Original Hospital Pharmacy Permit Number HPE 37803 is reinstated if it is revoked.

/ / /

DISCIPLINE CONSIDERATIONS

61. To determine the degree of discipline, if any, to be imposed on Respondent U.C. Davis, Complainant alleges that on or about September 26, 2016, in a prior action, the Board of Pharmacy issued Citation Number CI 2014 65325 and ordered Respondent to pay a fine of $2,000.00. That Citation is now final.

PRAYER

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

1. Revoking or suspending Original Hospital Pharmacy Permit Number HPE 37803, issued to The Regents of The University of California to do business as U.C. Davis Medical Center;

2. Revoking or suspending Original Pharmacist License Number RPH 51340, issued to Julianna Landon Burton;

3. Prohibiting The Regents of The University of California to do business as U.C. Davis Medical Center from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Hospital Pharmacy Permit Number HPE 37803 is placed on probation or until Original Hospital Pharmacy Permit Number HPE 37803 is reinstated if Original Hospital Pharmacy Permit Number HPE 37803 issued to The Regents of The University of California to do business as U.C. Davis Medical Center is revoked;

4. Prohibiting Julianna Landon Burton from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Hospital Pharmacy Permit Number 37803 is placed on probation or until Original Hospital Pharmacy Permit Number HPE 37803 is reinstated if Original Hospital Pharmacy Permit Number HPE 37803 issued to The Regents of The University of California to do business as U.C. Davis Medical Center is revoked;

5. Ordering The Regents of The University of California dba U.C. Davis Medical Center and Julianna Landon Burton 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: April 14, 2020

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

SA2020100088
14489346.docx