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

In the Matter of the First Amended Accusation Against:

PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL,

Pharmacy Permit No. HSP 55890,

Sterile Compounding License No. LSC 101129;

LEIGH ANN WITHERSPOON,

Registered Pharmacist License No. RPH 72914;

BLAINE SCOT GUINN,

Registered Pharmacist License No. RPH 42192; and

HENRY MAUHANG CHAN,

Registered Pharmacist License No. RPH 53602,

Respondents.

Agency Case No. 7137

OAH No. 2022100700

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 25, 2023.

It is so ORDERED on July 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
DIANN SOKOLOFF
Supervising Deputy Attorney General
SUSANA A. GONZALES
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Attorneys for Complainant

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

In the Matter of the First Amended Accusation Against: **PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL** **1165 Montgomery Drive** **Santa Rosa, CA 95405** **Pharmacy Permit No. HSP 55890** **Sterile Compounding License No. LSC 101129** **LEIGH ANN WITHERSPOON** **1367 Holly Park Way** **Santa Rosa, CA 95403** **Registered Pharmacist License No. RPH 72914** **BLAINE SCOT GUINN** **2235 Keever Court** **Reno, NV 89509** **Registered Pharmacist License No. RPH 42192**	Case No. 7137 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL AS TO RESPONDENT HENRY MAUHANG CHAN ONLY** **[Bus. & Prof. Code § 495]**

HENRY MAUHANG CHAN
19 Burlwood Dr.
San Francisco, CA 94127

Registered Pharmacist License No. RPH 53602

Respondents.

IT IS HEREBY STIPULATED AND AGREED by and between the parties identified below that the following matters are true:

PARTIES

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

2. Henry Mauhang Chan is represented in this proceeding by attorney Emily L. Brinkman whose address is: 44 Montgomery Street, Ste. 3500, San Francisco, CA 94104.

3. On or about August 23, 2002, the Board of Pharmacy issued Registered Pharmacist License Number RPH 53602 to Henry Mauhang Chan (Respondent Chan). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought in First Amended Accusation and 7137, and will expire on September 30, 2024, unless renewed.

JURISDICTION

4. First Amended Accusation No. 7137 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent Chan on June 23, 2022. Respondent Chan timely filed his Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 7137 is attached as exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

5. Respondent Chan has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7137. Respondent Chan has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

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

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

CULPABILITY

8. Respondent Chan understands and agrees that the charges and allegations in First Amended Accusation No. 7137, if proven at a hearing, constitute cause for imposing discipline upon his Registered Pharmacist License.

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

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

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent Chan 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 Chan or his counsel. By signing the stipulation, Respondent Chan understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Registered Pharmacist License Number RPH 53602, issued to Henry Mauhang Chan (Respondent Chan) shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 7137, attached as exhibit A.

ACCEPTANCE

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

DATED: 3/23/2023

HENRY MAUHANG CHAN
Respondent Chan

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

DATED: 3/23/2023

EMILY L. BRINKMAN
Attorney for Respondent Chan

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: 3/24/2023

Respectfully submitted,

ROB BONTA
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General

Susana A. Gonzales

SUSANA A. GONZALES
Deputy Attorney General
Attorneys for Complainant

Exhibit A

First Amended Accusation No. 7137

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Attorneys for Complainant

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

In the Matter of the First Amended Accusation Against: **PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL** **1165 Montgomery Drive** **Santa Rosa, CA 95405** **Pharmacy Permit No. HSP 55890** **Sterile Compounding License No. LSC 101129** **LEIGH ANN WITHERSPOON** **1367 Holly Park Way** **Santa Rosa, CA 95403** **Registered Pharmacist License No. RPH 72914** **BLAINE SCOT GUINN** **2235 Keever Court** **Reno, NV 89509** **Registered Pharmacist License No. RPH 42192**	Case No. 7137 **FIRST AMENDED ACCUSATION**

HENRY MAUHANG CHAN
19 Burlwood Dr.
San Francisco, CA 94127

Registered Pharmacist License No. RPH 53602

Respondents.

PARTIES

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

2. On or about April 4, 2018, the Board of Pharmacy issued Sterile Compounding License Number LSC 101129 to Providence Santa Rosa Memorial Hospital (Respondents). The Sterile Compounding License expired on October 1, 2020, and has not been renewed.

3. On or about April 1, 2018, the Board of Pharmacy issued Original Permit Number HSP 55890 to Providence Santa Rosa Memorial Hospital (Respondents). The Original Permit was in full force and effect at all times relevant to the charges brought in this First Amended Accusation and will expire on April 1, 2022, unless renewed.

4. On or about August 31, 1988, the Board of Pharmacy issued Original Pharmacist License Number RPH 42192 to Blaine Scot Guinn (Respondents). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought brought in this First Amended Accusation and will expire on May 31, 2022, unless renewed.

5. On or about August 14, 2015, the Board of Pharmacy issued Original Pharmacist License Number RPH 72914 to Leigh Ann Witherspoon (Respondents). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought brought in this First Amended Accusation and will expire on March 31, 2023, unless renewed.

6. On or about August 23, 2002, the Board of Pharmacy issued Registered Pharmacist License Number RPH 53602 to Henry Mauhang Chan (Respondents). The Registered Pharmacist

License was in full force and effect at all times relevant to the charges brought brought in this First Amended Accusation and will expire on September 30, 2022, unless renewed.

JURISDICTION

7. This First Amended 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.

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

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

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

11. Section 4342 of the Code states in relevant part:

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

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STATUTORY PROVISIONS

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

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

. . .

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs

. . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

13. Section 4113, subdivision (c) of the Code states:

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

14. 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.

REGULATORY PROVISIONS

15. California Code of Regulations, title 16, section 1714 states:

(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(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.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

(f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

(g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

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

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

(1) The master formula document.
(2) A compounding log consisting of a single document containing all of the following:
(A) Name and Strength of the compounded drug preparation.
(B) The date the drug preparation was compounded.
(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.
(D) The identity of the pharmacist reviewing the final drug preparation.
(E) The quantity of each ingredient used in compounding the drug preparation.
(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

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

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

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

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

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

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for

drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) 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 last in effect. 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).

17. 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:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

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

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

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

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

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and
(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(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

18. 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

December 2020 Inspection

19. On December 3, 2020, the Board received a complaint against Respondent Providence alleging that there were serious regulatory violations and unsafe practices occurring at Respondent Providence for the past several months. According to the complainant, staff at Respondent Providence voiced their concerns to Pharmacist-in-Charge (PIC) Respondent Witherspoon, but she dismissed the concerns. The complainant later submitted photographs of a staff break room refrigerator where vaccines and antibiotics were improperly stored.

20. On December 15, 2020, the Board received an email from DD, a pharmacist and pharmaceutical consultant for the California Department of Public Health (CDPH). DD reported that she was at Respondent Providence on December 14, 2020, and she found the IV room blocked off for construction. IV rooms, often used in hospital and pharmacy applications, are a place for the sterile preparation of medications. DD observed a pharmacy technician preparing immediate use compounded sterile products (CSP) for first doses and emergency doses on a countertop in a room within the pharmacy. A one-hour beyond-use date (BUD) was hand-written

on the prescription label, and a green auxiliary sticker was affixed to the medication indicating to hang the product within one hour. DD was told that this immediate use room was set-up on November 30, 2020, and that the Board had approved the set-up.

21. On December 15, 2020, Board inspector SH went to Respondent Providence to conduct a routine partial inspection. SH was assisted by PIC Respondent Witherspoon and Pharmacy Director, Respondent Guinn. The inspector observed and took pictures of various parts of the pharmacy, including the part of the pharmacy intended as the Segregated Compounding Area (SCA). The SCA was a carpeted office room adjacent to the pharmacy. A cork bulletin board was above the compounding tray, printers which generated labels were near the compounding tray, non-sterile gloves were available, CSP's were placed on a non-sterile pad, and the ceiling tiles were made of a porous material.

22. During the inspection, SH also reviewed CSP compounding records from November 30, 2020, to December 15, 2020. SH reminded Respondent Witherspoon of a conversation they had during an previous inspection on July 1, 2020, regarding the Board regulation concerning any sterile compounded drug preparation compounded either outside of an ISO class 5 Primary Engineering Control, or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d) of California Code of Regulations, title 16, section 1751.8. An ISO 5 is a cleanroom classification. Pursuant to California Code of Regulations, title 16, section 1735.1, subdivision (ab), "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. SH found that Respondent Providence's compounding records lacked detailed documentation to support immediate use compounding in at least 593 instances between November 30, 2020, and December 13, 2020.

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FIRST CAUSE FOR DISCIPLINE

(Immediate Use Compounding Not Used in Limited Situations)

23. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1751.8. "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. Specifically, between November 30, 2020, and December 13, 2020, Respondent Providence compounded at least 593 "immediate use" sterile preparations outside of an ISO Class 5 PEC without meeting the circumstances to justify an immediate need in these 593 instances. The circumstances are set forth in further detail in paragraphs 18 through 21, above.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Compounding Log Documentation)

24. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(H). Specifically, between November 30, 2020, and December 13, 2020, at least 593 of Respondent Providence's compounding logs lacked complete documentation of the beyond use date and time of the final compounded drug preparation. The circumstances are set forth in further detail in paragraphs 18 through 21, above.

THIRD CAUSE FOR DISCIPLINE

(Final Quantity of Drug Not Present)

25. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist

License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(I). Specifically, between at least November 30, 2020, and December 13, 2020, compounding logs for at least 593 drug preparations lacked documentation of the final quantity or amount of drug preparation compounded for dispensing. The circumstances are set forth in further detail in paragraphs 19 through 22, above.

FOURTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Log Documentation)

26. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(J). Specifically, between at least November 30, 2020, and December 13, 2020, compounding logs for at least 593 compounded drug preparations lacked documentation of quality reviews and post-compounding process and procedures. The circumstances are set forth in further detail in paragraphs 19 through 22, above.

FIFTH CAUSE FOR DISCIPLINE

(Operational Standards and Security)

27. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence failed to maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured, and distributed in accordance with California Code of Regulations, title 16, section 1714, subdivision (b). Specifically, between at least September 21, 2020, and November 1, 2020, Respondent Providence was not properly monitoring medication storage refrigerator temperatures appropriately. The refrigerator also contained improperly stored food items with medications

during this time period. The circumstances are set forth in further detail in paragraphs 19 through 22, above.

SIXTH CAUSE FOR DISCIPLINE

(Aiding and Abetting Violations of Pharmacy Law)

28. Respondent Witherspoon and Respondent Guinn have subjected their Original Pharmacist Licenses to discipline under Code section 4301, subdivision (o), in that they aided and abetted the violation of the Board's regulations governing pharmacy law. Specifically, between at least November 30, 2020, and December 13, 2020, Respondent Witherspoon, as Pharmacist-in-Charge, and Respondent Guinn, as pharmacy director of Respondent Providence, aided and abetted Respondent Providence and several of the pharmacists employed at Respondent Providence in violating California Code of Regulations, title 16, sections 1751.8, subdivision (e), 1714, subdivision (b), and 1735.3, subdivisions (a)(2)(H), (I), and (J), as more fully set forth in paragraphs 19 through 27, above.

FACTUAL ALLEGATIONS

November 2021 Inspection

29. On November 17, 2021, Board inspector SH conducted a partial inspection at Respondent Providence after the Board received an anonymous complaint that Respondent Providence was compounding batches of non-patient specific epidural syringes. Respondent Providence had a segregated compounding area/room where it was capable of compounding low risk compounded sterile products and a maximum 12 hour beyond use date. During this inspection, SH was assisted by Pharmacist-in-Charge Respondent Chan. Respondent Chan explained that the hospital could no longer buy fentanyl/bupivacaine from its former supplier, thus staff were instructed to compound three syringes of fentanyl/bupivacaine/sodium chloride syringes for epidural injection twice daily for the Labor and Delivery (L&D) department. The Board's inspection revealed that Respondent Providence was anticipatorily compounding and then storing the epidural syringes, which were non-patient specific, in the pharmacy refrigerator. The pharmacy would transport the syringes to the L&D floor within fifteen minutes of a request for one by the L&D department. Before a syringe was transported to L&D, the pharmacy staff

would create a patient-specific label and affix it to the syringe. The pharmacy wasted the syringes that were not used after 12 hours of being compounded.

SEVENTH CAUSE FOR DISCIPLINE

(Sterile Compounded Drug Preparations)

30. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Chan has subjected his Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1751.8, subdivision (d)(1)-(3). Specifically, on November 17, 2021, Respondent Providence compounded fentanyl/bupivacaine/sodium chloride syringes for epidural injection. This compounded sterile product required three entries to the administration syringe. Pharmacy law does not allow more than two entries into any one container or package of sterile infusion solution or administration container or device.

EIGHTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Log)

31. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Chan has subjected his Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(G). Specifically, on November 14, 2021, and November 15, 2021, Respondent Providence compounded non-patient specific fentanyl/bupivacaine/sodium chloride syringes for epidural injection and used the date as the reference number rather than a pharmacy-assigned unique reference or lot number.

OTHER MATTERS

32. Pursuant to section 4307 of the Code, if discipline is imposed on Original Permit Number HSP 55890 or on Sterile Compounding License Number LSC 101129, then any person who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or

association which received this discipline or denial, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control, had knowledge of or knowingly participated in any conduct leading to discipline or denial, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for: five years if Original Permit Number HSP 55890 or Sterile Compounding License Number LSC 101129 is placed on probation or until any license revoked or denied is issued or reinstated.

33. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacist License Number RPH 72914, issued to Leigh Ann Witherspoon, Original Pharmacist License Number RPH 42192, issued to Blaine Scot Guinn, or Original Pharmacist License Number RPH 53602, issued to Henry Mauhang Chan, then the licensee so disciplined shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for: five years if the license is placed on probation; or if the license is revoked, until it is reinstated or reissued.

DISCIPLINE CONSIDERATIONS

34. To determine the degree of discipline, if any, to be imposed on Respondent Guinn, Complainant alleges that on July 3, 2020, the Board issued Citation No. CI 2019 88576 to Respondent Guinn based upon his conviction of a crime substantially related to the practice of pharmacy (Bus. & Prof. Code, § 4301, subd. (l)), and his self-administration of a dangerous drug, controlled substance, or alcohol in a manner injurious to himself. (Bus. & Prof. Code, § 4301, subd. (h).) The citation assessed a civil penalty of $400.00. That Citation is incorporated by reference and is now final.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this First Amended Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Sterile Compounding License Number LSC 101129, issued to Providence Santa Rosa Memorial Hospital;

2. Revoking or suspending Original Permit Number HSP 55890, issued to Providence Santa Rosa Memorial Hospital;

3. Revoking or suspending Original Pharmacist License Number RPH 42192, issued to Blaine Scot Guinn;

4. Revoking or suspending Original Pharmacist License Number RPH 72914, issued to Leigh Ann Witherspoon;

5. Revoking or suspending Registered Pharmacist License Number RPH 53602, issued to Henry Mauhang Chan;

6. Ordering Respondent Providence, Respondent Witherspoon, Respondent Guinn, and Respondent Chan 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 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: 6/12/2022

Signature on File

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

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