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

In the Matter of the Accusation Against: **ST. HELENA HOSPITAL CLEARLAKE** **15630 18th Avenue & Hwy 53** **Clearlake, CA 95422** **Original Permit No. HSP 43172** **Sterile Compounding License No. LSC 100039** **And** **JACARRE LYNN SHELTON** **591 62nd Street** **Oakland, CA 94609** **Pharmacist License No. RPH 66989** Respondents	Case No. 5753 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO Original Permit No HSP 43172 and Sterile Compounding License No. LSC 100039 Only**

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on August 2, 2017.

It is so ORDERED on July 3, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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BEFORE THE
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In the Matter of the Accusation Against: **ST. HELENA HOSPITAL CLEARLAKE** **15630 18th Avenue & HWY 53** **Clearlake, CA 95422** **Original Permit No. HSP 43172** **Sterile Compounding License No. LSC 100039** **and** **JACARRE LYNN SHELTON** **591 62nd Street** **Oakland, CA 94609** **Pharmacist License No. RPH 66989** Respondents.	Case No. 5753 OAH No. 2017010128 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** **As to Original Permit No. HSP 43172 and Sterile Compounding License No. LSC 100039 Only**

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

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by

Xavier Becerra, Attorney General of the State of California, by Geoffrey S. Allen, Deputy Attorney General.

2. Respondent St. Helena Hospital Clearlake (Respondent) is represented in this proceeding by attorney Norm Prior, whose address is: Porter Scott Attorneys, 350 University Ave., Ste. 200, Sacramento, CA 95825.

3. On or about August 6, 1998, the Board issued Original Permit Number HSP 43172 (Permit) to Respondent). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed.

4. On or about May 12, 2014, the Board of Pharmacy issued Sterile Compounding License Number LSC 100039 (License) to Respondent. The License was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed.

JURISDICTION

5. Accusation No. 5753 (Accusation) was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 10, 2016. Respondent timely filed its Notice of Defense contesting the Accusation.

6. A copy of the Accusation is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in the Accusation. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of

documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

10. Respondent understands and agrees that the charges and allegations in the Accusation, if proven at a hearing, constitute cause for imposing discipline upon its Permit and License.

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

12. Respondent agrees that its Permit and License are subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

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

16. 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 Permit No. HSP 43172 and Sterile Compounding License Number LSC 100039 issued to Respondent St. Helena Hospital Clearlake are revoked. However, the revocation is stayed and Respondent is placed on probation for three (3) years on the following terms and conditions.

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

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

- ☐ an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and Federal food and drug laws, or state and federal controlled substances laws
- ☐ a plea of guilty or nolo contendre in any state or Federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's Permit or License or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

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

2. **Report to the Board**

Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

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

4. **Cooperate with Board Staff**

Respondent shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of $13,554.00. Respondent shall be permitted to pay these costs in a payment plan approved by the Board or its designee. There shall be no deviation from and payment plan absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent owner shall not relieve Respondent of their

responsibility to reimburse the Board its costs of investigation and prosecution. .

6. **Probation Monitoring Costs**

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

7. **Consultant**

During the period of probation, Respondent shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent with state and Federal laws and regulations governing the practice of pharmacy. The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. During the period of probation, the Board or its designee retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent Pharmacy's operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation

8. **Status of License**

Respondent shall, at all times while on probation, maintain a current Permit with the Board. If Respondent owner submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the Permit, and the Respondent shall remain on probation as determined by the Board. Failure to maintain a current Permit shall be considered a violation of probation.

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

9. **Permit Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent owner discontinue

business, Respondent owner may tender the Permit to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the Permit, Respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent shall relinquish the wall and renewal Permit to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.

Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent may not apply for any new licensure from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

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

10. **Notice to Employees**

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

hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

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

11. **Owners and Officers: Knowledge of the Law**

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

12. **Posted Notice of Probation**

Respondent shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

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

Failure to post such notice shall be considered a violation of probation.

13. **Submission of Plans**

Respondent shall submit plans for its new compounding pharmacy to OSHPD within 45 days of the effective date of this decision.

Failure to submit such plans shall be considered a violation of probation.

14. **Violation of Probation**

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

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the License or Permit. If a petition to revoke probation or an accusation is filed against Respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in the Accusation shall be deemed true and correct.

15. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's Permit and License will be fully restored.

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ACCEPTANCE

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

DATED: 3-16-17

ST. HELENA HOSPITAL CLEARLAKE

By: David Santos, President + CEO
(Print Name and Title)
Respondent

I have read and fully discussed with Respondent St. Helena Hospital Clearlake the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 3/16/17

NORM PRIOR
Attorney for Respondent

ENDORSEMENT

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

Dated: 3/16/17

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General

GEOFFREY S. ALLEN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5753

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Complainant alleges:

PARTIES

1. Virginia Herold (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 August 6, 1998, the Board of Pharmacy issued Original Permit Number HSP 43172 (Permit) to St. Helena Hospital Clearlake (Respondent Hospital). The Permit was in

full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed.

3. On or about May 12, 2014, the Board of Pharmacy issued Sterile Compounding License Number LSC 100039 (Compounding License) to Respondent Hospital. The Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2017, unless renewed.

4. On or about August 31, 2012, the Board of Pharmacy issued Pharmacist License Number RPH 66989 (Pharmacist License) to Jacarre Lynn Shelton (Respondent Shelton). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2017, unless renewed.

JURISDICTION

5. 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 unless otherwise indicated.

6. Section 4300 of the Code states:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

"(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board

may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

"(1) Medical or psychiatric evaluation.

"(2) Continuing medical or psychiatric treatment.

"(3) Restriction of type or circumstances of practice.

"(4) Continuing participation in a board-approved rehabilitation program.

"(5) Abstention from the use of alcohol or drugs.

"(6) Random fluid testing for alcohol or drugs.

"(7) Compliance with laws and regulations governing the practice of pharmacy.

"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

7. Section 4300.1 of the Code states:

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

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STATUTORY AND REGULATORY PROVISIONS

8. Section 4301 of the Code states:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, 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.

. . ..

9. Section 4029 of the Code states:

"(a) 'Hospital pharmacy' means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

"(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan

administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide."

10. Section 4037 of the Code states:

"(a) 'Pharmacy' means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

"(b) 'Pharmacy' shall not include any area in a facility licensed by the State Department of Public Health where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility."

11. Section 4330 of the Code states:

"(a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

"(b) Any nonpharmacist owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor."

12. California Code of Regulations (CCR), 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."

13. CCR, Title 16, Section 1715 states:

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

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

"(1) A new pharmacy permit has been issued, or

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

"(3) There is a change in the licensed location of a pharmacy to a new address.

"(c) The components of this assessment shall be on Form 17M-13 (Rev. 01/11) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment and on Form 17M-14 (Rev. 01/11) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

"(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed."

14. CCR, Title 16, Section 1735.2 states:

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

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

"(c) Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:

"(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

"(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

"(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

"(1) Active ingredients to be used.

"(2) Inactive ingredients to be used.

"(3) Process and/or procedure used to prepare the drug.

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

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

"(6) Expiration dating requirements.

"(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

"(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

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

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

"(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

"(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board Form 17M-39 (Rev.01/11). That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of odd-numbered each year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

15. CCR, Title 16, Section 1735.3:

"(a) For each compounded drug product, the pharmacy records shall include:

"(1) The master formula record.

"(2) The date the drug product was compounded.

"(3) The identity of the pharmacy personnel who compounded the drug product.

"(4) The identity of the pharmacist reviewing the final drug product.

"(5) The quantity of each component used in compounding the drug product.

"(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

"(7) The equipment used in compounding the drug product.

"(8) A pharmacy assigned reference or lot number for the compounded drug product.

"(9) The expiration date of the final compounded drug product.

"(10) The quantity or amount of drug product compounded.

"(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) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration.

"(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 created."

16. CCR, Title 16, Section 1751.4:

"(a) No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

"(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.

"(c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.

"(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

"(e) Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation,

3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications, Certification records must be retained for at least three years."

17. CCR, Title 16, Section 1751.7:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

"(1) Cleaning and sanitization of the parenteral medication preparation area.

"(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.

"(3) Actions to be taken in the event of a drug recall.

"(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

"(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the

compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

"(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures."

18. CCR, Title 24, Section 1250.4:

"Compounding area for parenteral solutions. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

"1. In accordance with Federal Standard 209 (b), Clean Room and Work Station Requirements, Controlled Environment as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100 HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.

"2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.

"3. The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions. There shall be sufficient space, well separated from the laminar-flow hood area for the storage of bulk materials, equipment and waste materials.

"4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.

"5. Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:

"5.1 An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The clean room must have a positive air pressure differential relative adjacent areas.

"5.2 An ISO class 5 clean room.

"5.3 A barrier isolator that provides an ISO class 5 environment for compounding."

COST RECOVERY

19. 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.

FIRST CAUSE FOR DISCIPLINE

(Compounding Limitations: Beyond Use Dates)

20. Respondent Hospital has subjected its Permit to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to properly label compounded drugs with the correct expiration / beyond use dates. (Cal. Code Reg., tit. 16, §§ 1735.2, subd. (h), 1751.4, subd. (a); Cal. Code Reg., tit. 24, § 1250.4.)

SECOND CAUSE FOR DISCIPLINE

(Compounding Area for Parenteral Solutions)

21. Respondent Hospital has subjected its Permit to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to have a proper area for compounding drugs. Specifically, the area had bulk items around and beneath the hood, the ceilings were not sealed, the wall paint was peeling, the sink was not adjacent or near the compounding area, the area was not minimal to traffic flow, and the hood was rusted in several places. (Cal. Code Reg., tit. 24, § 1250.4.)

THIRD CAUSE FOR DISCIPLINE

(Operational Standards/ Pharmacy Sink)

22. Respondent Hospital has subjected its Permit to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to have the parenteral solution compounding area equipped with a sink dedicated for

pharmaceutical purposes or a sink within the parenteral solution compounding area or adjacent to it. (Cal. Code Reg., tit. 16, § 1714, subd. (c); Cal. Code Reg., tit. 24, § 1250.4.)

FOURTH CAUSE FOR DISCIPLINE

(Cleaning)

23. Respondent Hospital has subjected its Permit to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to clean the compounding area or maintain the cleaning logs. (Cal. Code Reg., tit. 16, §§ 1751.4, subd. (d), 1751.7, subd. (a)(1).)

FIFTH CAUSE FOR DISCIPLINE

(Master Formulas)

24. Respondent Hospital has subjected its Permit to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to maintain a written master formula including specific elements for all compounded drug products compounded at the pharmacy. Specifically, 80 drugs were identified as commonly compounded but only 22 drugs had master formulas prior to compounding. (Cal. Code Reg., tit. 16, § 1735.2, subd. (d).)

SIXTH CAUSE FOR DISCIPLINE

(Records of Compounded Products)

25. Respondent Hospital has subjected its Permit to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to maintain proper records for compounded drug products. Respondent Hospital failed to keep compounding records which included the quantity of each component used in compounding the drug product. (Cal. Code Reg., tit. 16, § 1735.3, subd. (a).)

SEVENTH CAUSE FOR DISCIPLINE

(Hospital Self-Assessment)

26. Respondent Hospital has subjected its Permit to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed

to complete the biennial self-assessment of the pharmacy's compliance with federal and state pharmacy law. (Bus. & Prof. Code, §§ 4029, 4037; Cal. Code Reg., tit. 16, § 1715.)

EIGHTH CAUSE FOR DISCIPLINE

(Interference with Pharmacist-In-Charge)

27. Respondent Hospital has subjected its Permit to discipline under Code section 4301, subdivisions (j) and (o) in that an inspection on July 2, 2015, revealed that the owners of Respondent Hospital interfered with the efforts of Pharmacist-In-Charge Jacarre Shelton in his efforts to bring the compounding area into compliance with the regulations of the State of California. (Bus. & Prof. Code, § 4330, subd. (b).)

NINTH CAUSE FOR DISCIPLINE

(Compounding Limitations: Beyond Use Dates)

28. Respondent Hospital has subjected its Compounding License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to properly label compounded drugs with the correct expiration / beyond use dates. (Cal. Code Reg., tit. 16, §§ 1735.2, subd. (h), 1751.4, subd. (a); Cal. Code Reg., tit. 24, § 1250.4.)

TENTH CAUSE FOR DISCIPLINE

(Compounding Area for Parenteral Solutions)

29. Respondent Hospital has subjected its Compounding License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to have a proper area for compounding drugs. Specifically, the area had bulk items around and beneath the hood, the ceilings were not sealed, the wall paint was peeling, the sink was not adjacent or near the compounding area, the area was not minimal to traffic flow, and the hood was rusted in several places. (Cal. Code Reg., tit. 24, § 1250.4.)

ELEVENTH CAUSE FOR DISCIPLINE

(Operational Standards/ Pharmacy Sink)

30. Respondent Hospital has subjected its Compounding License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015,

Respondent Hospital failed to have the parenteral solution compounding area equipped with a sink dedicated for pharmaceutical purposes or a sink within the parenteral solution compounding area or adjacent to it. (Cal. Code Reg., tit. 16, § 1714, subd. (c); Cal. Code Reg., tit. 24, § 1250.4.)

TWELFTH CAUSE FOR DISCIPLINE

(Cleaning)

31. Respondent Hospital has subjected its Compounding License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to clean the compounding area or maintain the cleaning logs. (Cal. Code Reg., tit. 16, §§ 1751.4, subd. (d), 1751.7, subd. (a)(1).)

THIRTEENTH CAUSE FOR DISCIPLINE

(Master Formulas)

32. Respondent Hospital has subjected its Compounding License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to maintain a written master formula including specific elements for all compounded drug products compounded at the pharmacy. Specifically, 80 drugs were identified as commonly compounded but only 22 drugs had master formulas prior to compounding. (Cal. Code Reg., tit. 16, § 1735.2, subd. (d).)

FOURTEENTH CAUSE FOR DISCIPLINE

(Records of Compounded Products)

33. Respondent Hospital has subjected its Compounding License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed to maintain proper records for compounded drug products. Respondent Hospital failed to keep compounding records which included the quantity of each component used in compounding the drug product. (Cal. Code Reg., tit. 16, § 1735.3, subd. (a).)

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FIFTEENTH CAUSE FOR DISCIPLINE

(Interference with Pharmacist-In-Charge)

34. Respondent Hospital has subjected its Compounding License to discipline under Code section 4301, subdivisions (j) and (o) in that an inspection on July 2, 2015, revealed that the owners of Respondent Hospital interfered with the efforts of Pharmacist-In-Charge Jacarre Shelton in his efforts to bring the compounding area into compliance with the regulations of the State of California. (Bus. & Prof. Code, § 4330, subd. (b).)

SIXTEENTH CAUSE FOR DISCIPLINE

(Compounding limitations: Beyond Use Dates)

35. Respondent Shelton has subjected his Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Shelton failed to properly label compounded drugs with the correct expiration / beyond use dates. (Cal. Code Reg., tit. 16, §§ 1735.2, subd. (h), 1751.4, subd. (a); Cal. Code Reg., tit. 24, § 1250.4.)

SEVENTEENTH CAUSE FOR DISCIPLINE

(Compounding Area for Parenteral Solutions)

36. Respondent Shelton has subjected his Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Shelton failed to have a proper area for compounding drugs. Specifically, the area had bulk items around and beneath the hood, the ceilings were not sealed, the wall paint was peeling, the sink was not adjacent or near the compounding area, the area was not minimal to traffic flow, and the hood was rusted in several places. (Cal. Code Reg., tit. 24, § 1250.4.)

EIGHTEENTH CAUSE FOR DISCIPLINE

(Operational Standards/ Pharmacy Sink)

37. Respondent Shelton has subjected his Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Shelton failed to have the parenteral solution compounding area equipped with a sink dedicated

for pharmaceutical purposes or a sink within the parenteral solution compounding area or adjacent to it. (Cal. Code Reg., tit. 16, § 1714, subd. (c); Cal. Code Reg., tit. 24, § 1250.4.)

NINETEENTH CAUSE FOR DISCIPLINE

(Cleaning)

38. Respondent Shelton has subjected his Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Shelton failed to clean the compounding area or maintain the cleaning logs. (Cal. Code Reg., tit. 16, §§ 1751.4, subd. (d), 1751.7, subd. (a)(1).)

TWENTIETH CAUSE FOR DISCIPLINE

(Master Formulas)

39. Respondent Shelton has subjected his Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Shelton failed to maintain a written master formula including specific elements for all compounded drug products compounded at the pharmacy. Specifically, 80 drugs were identified as commonly compounded but only 22 drugs had master formulas prior to compounding. (Cal. Code Reg., tit. 16, § 1735.2, subd. (d).)

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Records of Compounded Products)

40. Respondent Shelton has subjected his Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Shelton failed to maintain proper records for compounded drug products. Respondent Shelton failed to keep compounding records which included the quantity of each component used in compounding the drug product. (Cal. Code Reg., tit. 16, § 1735.3, subd. (a).)

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Hospital Self-Assessment)

41. Respondent Shelton has subjected his Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Shelton failed to complete the biennial self-assessment of the pharmacy's compliance with

federal and state pharmacy law. (Bus. & Prof. Code, §§ 4029, 4037; Cal. Code Reg., tit. 16, § 1715.)

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 Permit Number HSP 43172, issued to St. Helena Hospital Clearlake

2. Revoking or suspending Sterile Compounding License Number LSC 100039, issued to St. Helena Hospital Clearlake;

3. Revoking or suspending Pharmacist License Number RPH 66989, issued to Jacarre Lynn Shelton;

4. Ordering St. Helena Hospital Clearlake and Jacarre Lynn Shelton 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;

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

DATED: 9/23/16

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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