

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

In the Matter of the Accusation Against:

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 FOR PUBLIC
REPROVAL**

**As to Pharmacist License No. RPH 66989
Only**

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 September 6, 2017.

It is so ORDERED on August 7, 2017, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Victor Law, R.Ph.
Board Vice President

1 XAVIER BECERRA
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 GEOFFREY S. ALLEN
Deputy Attorney General
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9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:
12 **ST. HELENA HOSPITAL CLEARLAKE**
13 **15630 18th Avenue & HWY 53**
14 **Clearlake, CA 95422**
15 **Original Permit No. HSP 43172**
Sterile Compounding License No. LSC
16 **100039**
17 **and**
18 **JACARRE LYNN SHELTON**
591 62nd Street
19 **Oakland, CA 94609**
20 **Pharmacist License No. RPH 66989**
21 Respondents.

Case No. 5753
OAH No. 2017010128
STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL
As to Pharmacist License No. RPH 66989
Only
[Bus. & Prof. Code § 495]

22
23 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
24 entitled proceedings that the following matters are true:

25 PARTIES

26 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
27 (Board). She brought this action solely in her official capacity and is represented in this matter by
28

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

3 2. Respondent Jacarre Lynn Shelton (Respondent) is represented in this proceeding by
4 attorney Norm Prior, whose address is: Porter Scott Attorneys, 350 University Ave., Ste. 200,
5 Sacramento, CA 95825.

6 JURISDICTION

7 3. On or about August 31, 2012, the Board issued Pharmacist License No. RPH 66989
8 (License) to Respondent. The License was in full force and effect at all times relevant to the
9 charges brought in Accusation No. 5753 and will expire on August 31, 2017, unless renewed.

10 4. Accusation No. 5753 (Accusation) was filed before the Board, Department of
11 Consumer Affairs and is currently pending against Respondent. The Accusation and all other
12 statutorily required documents were properly served on Respondent on October 10, 2016.
13 Respondent timely filed his Notice of Defense contesting the Accusation. A copy of the
14 Accusation is attached as exhibit A and incorporated herein by reference.

15 ADVISEMENT AND WAIVERS

16 5. Respondent has carefully read, fully discussed with counsel, and understands the
17 charges and allegations in the Accusation. Respondent has also carefully read, fully discussed
18 with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for
19 Public Repeval.

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

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

1 CULPABILITY

2 8. Respondent understands and agrees that the charges and allegations in the
3 Accusation, if proven at a hearing, constitute cause for imposing discipline upon his License.

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

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

10 CONTINGENCY

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

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

24 13. This Stipulated Settlement and Disciplinary Order for Public Repeval is intended by
25 the parties to be an integrated writing representing the complete, final, and exclusive embodiment
26 of their agreement. It supersedes any and all prior or contemporaneous agreements,
27 understandings, discussions, negotiations, and commitments (written or oral). This Stipulated
28 Settlement and Disciplinary Order for Public Repeval may not be altered, amended, modified,

1 supplemented, or otherwise changed except by a writing executed by an authorized representative
2 of each of the parties.

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

6 **DISCIPLINARY ORDER**

7 IT IS HEREBY ORDERED that Pharmacist License No. RPH 66989 issued to Respondent
8 Jacarre Lynn Shelton shall be publicly reprovved by the Board of Pharmacy under Business and
9 Professions Code section 495 in resolution of Accusation No. 5753, attached as exhibit A.

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ACCEPTANCE

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

DATED: 3-16-17 
JACARRE LYNN SHELTON
Respondent


I have read and fully discussed with Respondent St. Helena Hospital Clearlake; Shelton, Jacarre Lynn the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Repeval. I approve its form and content.

DATED: 3/16/17 
NORM PRIOR
Attorney for Respondent

ENDORSEMENT

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

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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Attorneys for Complainant

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9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:
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13 **ST. HELENA HOSPITAL CLEARLAKE**
15630 18th Avenue & HWY 53
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15 Original Permit No. HSP 43172
Sterile Compounding License No. LSC
100039
16
17 and
18 **JACARRE LYNN SHELTON**
591 62nd Street
Oakland, CA 94609
19
20 Pharmacist License No. RPH 66989
21 Respondents.

Case No. 5753

A C C U S A T I O N

22 Complainant alleges:

23
24 **PARTIES**

- 25 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
26 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
27 2. On or about August 6, 1998, the Board of Pharmacy issued Original Permit Number
28 HSP 43172 (Permit) to St. Helena Hospital Clearlake (Respondent Hospital). The Permit was in

1 full force and effect at all times relevant to the charges brought herein and will expire on August
2 1, 2017, unless renewed.

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

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

11 JURISDICTION

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

15 6. Section 4300 of the Code states:

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

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

20 "(1) Suspending judgment.

21 "(2) Placing him or her upon probation.

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

23 "(4) Revoking his or her license.

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

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

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

3 "(1) Medical or psychiatric evaluation.

4 "(2) Continuing medical or psychiatric treatment.

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

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

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

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

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

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

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

19 7. Section 4300.1 of the Code states:

20 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by
21 operation of law or by order or decision of the board or a court of law, the placement of a license
22 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
23 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
24 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

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

3 10. Section 4037 of the Code states:

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

11 “(b) ‘Pharmacy’ shall not include any area in a facility licensed by the State Department of
12 Public Health where floor supplies, ward supplies, operating room supplies, or emergency room
13 supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of
14 patients registered for treatment in the facility or for treatment of patients receiving emergency
15 care in the facility.”

16 11. Section 4330 of the Code states:

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

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

25 12. California Code of Regulations (CCR), Title 16, Section 1714 states:

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

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

5 “(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly
6 condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly
7 lighted. The pharmacy shall be equipped with a sink with hot and cold running water for
8 pharmaceutical purposes.

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

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

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

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

23 13. CCR, Title 16, Section 1715 states:

24 “(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section
25 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's
26 compliance with federal and state pharmacy law. The assessment shall be performed before July
27 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote
28 compliance through self-examination and education.

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

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

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

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

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

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

13 14. CCR, Title 16, Section 1735.2 states:

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

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

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

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

1 “(2) is reasonable considering the intended use of the compounded medication and the
2 nature of the prescriber’s practice; and

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

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

8 “(1) Active ingredients to be used.

9 “(2) Inactive ingredients to be used.

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

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

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

13 “(6) Expiration dating requirements.

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

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

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

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

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

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

14 15. CCR, Title 16, Section 1735.3:

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

16 “(1) The master formula record.

17 “(2) The date the drug product was compounded.

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

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

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

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

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

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

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

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

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

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

9 “(d) Pharmacies shall maintain and retain all records required by this article in the
10 pharmacy in a readily retrievable form for at least three years from the date the record was
11 created.”

12 16. CCR, Title 16, Section 1751.4:

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

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

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

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

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

1 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-
2 8010) or manufacturer's specifications, Certification records must be retained for at least three
3 years."

4 17. CCR, Title 16, Section 1751.7:

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

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

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

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

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

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

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

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

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

11 18. CCR, Title 24, Section 1250.4:

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

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

18 “2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor
19 coverings.

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

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

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

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

3 FOURTH CAUSE FOR DISCIPLINE

4 (Cleaning)

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

9 FIFTH CAUSE FOR DISCIPLINE

10 (Master Formulas)

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

17 SIXTH CAUSE FOR DISCIPLINE

18 (Records of Compounded Products)

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

24 SEVENTH CAUSE FOR DISCIPLINE

25 (Hospital Self-Assessment)

26 26. Respondent Hospital has subjected its Permit to discipline under Code section 4301,
27 subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent Hospital failed
28

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

3 EIGHTH CAUSE FOR DISCIPLINE

4 (Interference with Pharmacist-In-Charge)

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

10 NINTH CAUSE FOR DISCIPLINE

11 (Compounding Limitations: Beyond Use Dates)

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

17 TENTH CAUSE FOR DISCIPLINE

18 (Compounding Area for Parenteral Solutions)

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

25 ELEVENTH CAUSE FOR DISCIPLINE

26 (Operational Standards/ Pharmacy Sink)

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

1 Respondent Hospital failed to have the parenteral solution compounding area equipped with a
2 sink dedicated for pharmaceutical purposes or a sink within the parenteral solution compounding
3 area or adjacent to it. (Cal. Code Reg., tit. 16, § 1714, subd. (c); Cal. Code Reg., tit. 24, §
4 1250.4.)

5 TWELFTH CAUSE FOR DISCIPLINE

6 (Cleaning)

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

11 THIRTEENTH CAUSE FOR DISCIPLINE

12 (Master Formulas)

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

19 FOURTEENTH CAUSE FOR DISCIPLINE

20 (Records of Compounded Products)

21 33. Respondent Hospital has subjected its Compounding License to discipline under
22 Code section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015,
23 Respondent Hospital failed to maintain proper records for compounded drug products.
24 Respondent Hospital failed to keep compounding records which included the quantity of each
25 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

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

3 NINETEENTH CAUSE FOR DISCIPLINE

4 (Cleaning)

5 38. Respondent Shelton has subjected his Pharmacist License to discipline under Code
6 section 4301, subdivisions (j) and (o) in that during an inspection on July 2, 2015, Respondent
7 Shelton failed to clean the compounding area or maintain the cleaning logs. (Cal. Code Reg., tit.
8 16, §§ 1751.4, subd. (d), 1751.7, subd. (a)(1).)

9 TWENTIETH CAUSE FOR DISCIPLINE

10 (Master Formulas)

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

17 TWENTY-FIRST CAUSE FOR DISCIPLINE

18 (Records of Compounded Products)

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

24 TWENTY-SECOND CAUSE FOR DISCIPLINE

25 (Hospital Self-Assessment)

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

1 federal and state pharmacy law. (Bus. & Prof. Code, §§ 4029, 4037; Cal. Code Reg., tit. 16, §
2 1715.)

3 PRAYER

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

6 1. Revoking or suspending Original Permit Number HSP 43172, issued to St. Helena
7 Hospital Clearlake

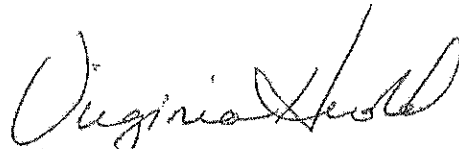
8 2. Revoking or suspending Sterile Compounding License Number LSC 100039, issued
9 to St. Helena Hospital Clearlake;

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

12 4. Ordering St. Helena Hospital Clearlake and Jacarre Lynn Shelton to pay the Board of
13 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
14 Business and Professions Code section 125.3;

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

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18 DATED: 9/23/16



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

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