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

In the Matter of the Accusation Against:	Case No. 5541
BARTON HEALTHCARE SYSTEM, DBA BARTON MEMORIAL HOSPITAL PHARMACY **2170 South Avenue** **So. Lake Tahoe, CA 95731**	OAH No. 2016080425
Original Permit No. HSP 21312 **Original Sterile Compounding Permit No. LSC 100403,**	**STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**
and	**FOR RESPONDENT TERRIANN HUGHES CHERRY ONLY**
TERRIANN HUGHES CHERRY **PO Box 551425** **So. Lake Tahoe, CA 96155**	
Original Pharmacist License No. RPH 33004	
Respondents.	

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on March 20, 2017.

It is so ORDERED on February 17, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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In the Matter of the Accusation Against: **BARTON HEALTHCARE SYSTEM, DBA BARTON MEMORIAL HOSPITAL PHARMACY** **2170 South Avenue** **So. Lake Tahoe, CA 95731** **Original Permit No. HSP 21312** **Original Sterile Compounding Permit No. LSC 100403,** **and** **TERRIANN HUGHES CHERRY** **PO Box 551425** **So. Lake Tahoe, CA 96155** **Original Pharmacist License No. RPH 33004** Respondents.	Case No. 5541 OAH No. 2016080425 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** **FOR RESPONDENT TERRIANN HUGHES CHERRY 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

Kathleen A. Kenealy, Acting Attorney General of the State of California, by David E. Brice, Deputy Attorney General.

2. Respondent Terriann Hughes Cherry is represented in this proceeding by attorney Thomas O. Perry, whose address is: Kroloff, Belcher, Smart, Perry & Christopherson, 7540 Shoreline Drive, Stockton, CA 95219.

3. On or about August 14, 1979, the Board issued Original Pharmacist License No. RPH 33004 to Respondent. The Original Pharmacist License was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 5541, and will expire on October 31, 2018, unless renewed.

JURISDICTION

4. First Amended Accusation No. 5541 was filed before the Board, and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on June 13, 2016. Respondent timely filed her Notice of Defense contesting the First Amended Accusation.

5. A copy of First Amended Accusation No. 5541 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 5541. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on her 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.

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

CULPABILITY

9. Respondent admits the truth of each and every charge and allegation in First Amended Accusation No. 5541.

10. Respondent agrees that her Original Pharmacist License is subject to discipline and she agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or her counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw her 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.

12. 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.

13. 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.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Pharmacist License No. RPH 33004 issued to Respondent Terriann Hughes Cherry is 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 Original Pharmacist License or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report 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 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 her probation. Failure to cooperate shall be considered a violation of probation.

5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 5541 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5541, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

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If respondent works for or is employed by or through a pharmacy employment service, respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 5541 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that she has read the decision in case number 5541 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. **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 $2,771.40. Respondent shall make said payments according to a payment plan approved by the board.

There shall be no deviation from this schedule 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 shall not relieve respondent of her responsibility to reimburse the board its costs of investigation and prosecution.

9. **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.

10. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

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

11. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender her license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish her pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted.

Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. **Tolling of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of thirty (30) hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of thirty (30) hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least thirty (30) hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least thirty (30) hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

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, and probation shall automatically be 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. 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.

15. **Completion of Probation**

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

16. **Remedial Education**

Within sixty (60), days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to the grounds for discipline. The program of remedial education shall consist of thirty (30) hours, which shall be completed at not more than ten (10) hours per year over the term of probation at

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respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

17. **Supervised Practice**

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and her license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Within thirty (30) days of the effective date of this decision, respondent shall have her supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 5541 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have her new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 5541 and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

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18. **No Ownership of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

19. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Thomas O. Perry. I understand the stipulation and the effect it will have on my Original Pharmacist 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: 1/13/2017

TERRIANN HUGHES CHERRY
Respondent

I have read and fully discussed with Respondent Terriann Hughes Cherry the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 1/13/17

THOMAS O. PERRY
Attorney for Respondent

ENDORSEMENT

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

Dated: 1/13/2017

Respectfully submitted,

KATHLEEN A. KENEALY
Acting Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

DAVID E. BRICE
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 5541

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Attorneys for Complainant

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In the Matter of the Accusation Against: **BARTON HEALTHCARE SYSTEM, DBA BARTON MEMORIAL HOSPITAL PHARMACY** **2170 South Avenue** **So. Lake Tahoe, CA 95731** **Original Permit No. HSP 21312** **Original Sterile Compounding Permit No. LSC 100403,** **and** **TERRIANN HUGHES CHERRY** **PO Box 551425** **So. Lake Tahoe, CA 96155** **Original Pharmacist License No. RPH 33004** Respondent.	Case No. 5541 **FIRST AMENDED** **ACCUSATION**

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 May 12, 1980, the Board of Pharmacy issued Original Permit Number HSP 21312 to Barton Healthcare System, dba Barton Memorial Hospital Pharmacy (Respondent

BMHP). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2017, unless renewed.

3. On or about June 30, 2014, the Board of Pharmacy issued Original Sterile Compounding Permit Number LSC 100403 to Respondent BMHP. The Original Sterile Compounding Permit will expire on February 1, 2017, unless renewed.

4. On or about August 14, 1979, the Board of Pharmacy issued Original Pharmacist License Number RPH 33004 to Terriann Hughes Cherry (Respondent Cherry). The Original Pharmacist License will expire on October 31, 2016, 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 4300.1 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."

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

> "The board shall take action against any holder of a license who is guilty of unprofessional conduct ... Unprofessional conduct shall include, but is not limited to, any of the following:
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> ...
>
> (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.
>
> ..."

STATUTORY REFERENCES

8. Code section 4059 states, in pertinent part:

"(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied."

9. Code section 4059.5 states, in pertinent part:

"(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices."

10. Code section 4113 states, in pertinent part:

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

...

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

11. Code section 4169 states, in pertinent part:

"(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy."

FEDERAL REGULATION

12. Section 1305.03 of title 21 of the Code of Federal Regulations states, in pertinent part: "Either a DEA Form 222 or its electronic equivalent ... is required for each distribution of a Schedule I or II controlled substance..."

CALIFORNIA REGULATIONS

13. Section 1735.2 of title 16 of the California Code of Regulations (16 CCR 1735.2) states, in pertinent part:

"(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) Equipment to be used.
(3) Expiration dating requirements.
(4) Inactive ingredients to be used.
(5) Process and/or procedure used to prepare the drug.
(6) Quality reviews required at each step in preparation of the drug.
(7) Post-compounding process or procedures required, if any."

14. 16 CCR 1735.3 states, in pertinent part:

"(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, expiration date 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 seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
(7) A pharmacy assigned reference or lot number for the compounded drug product.
(8) The expiration date of the final compounded drug product.
(9) The quantity or amount of drug product compounded."

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15. 16 CCR 1735.8 states, in pertinent part:

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula."

16. 16 CCR 1751 states, in pertinent part:

"(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents."

17. 16 CCR 1751.3 states, in pertinent part:

"(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist."

18. 16 CCR 1751.4 states, in pertinent part:

"(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.

...

(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."

19. 16 CCR 1751.6 states, in pertinent part:

"(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents."

20. 16 CCR 1751.7 states, in pertinent part:

"(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.

...

(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."

21. 24 CCR 1250.4 (California Building Code) states, in pertinent part:

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

...

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

COST RECOVERY

22. 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.

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CAUSES FOR DISCIPLINE

Barton Memorial Hospital Pharmacy (BMHP)

FIRST CAUSE FOR DISCIPLINE

(Failure to follow proper garbing procedures)

23. Respondent BMHP is subject to disciplinary action under title 16 of the California Code of Regulations, section 1751.4, subdivision (b), (16 CCR 1751.4(b)), by and through Code section 4301(o), in that they failed to follow proper garbing procedures. The circumstances are as follows:

24. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP had staff don personal protective equipment in an unsafe manner and inconsistent with their stated standards, including donning booties and hair covers while standing on carpet outside of the ante room, donning sterile gowns prior to sanitizing hands, donning face masks after sanitizing hands, and using non-sterile gloves.

SECOND CAUSE FOR DISCIPLINE

(Failure to train staff who compound sterile products)

25. Respondent BMHP is subject to disciplinary action under 16 CCR 1751.6(b), by and through Code section 4301(o), in that they failed to train staff that compound sterile products. The circumstances are as follows:

26. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP did not administer didactic training and test staff who prepared compounded sterile products, in accordance with their policies and procedures. Additionally, there were no competency tests on file for Pharmacist-in-Charge Terriann Cherry. And there were no training records on file for environmental services staff who cleaned the clean room documenting their training to perform this service.

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THIRD CAUSE FOR DISCIPLINE

(Noncompliant Cleanable Surfaces)

27. Respondent BMHP is subject to disciplinary action under 16 CCR 1751(b) as it relates to 24 CCR 1250.4(2), by and through Code section 4301(o), in that they allowed porous and uncleanable surfaces in a clean room. The circumstances are as follows:

28. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP had exposed particle board on the underside of countertops in the buffer area, a wood entry door, voids in walls and a compact disc player with compact discs, which were either not cleanable or were porous surfaces. On re-inspection by a Board inspector on January 20, 2016, porous and uncleanable surfaces remained, including exposed particle board and unsealed ceiling tiles.

FOURTH CAUSE FOR DISCIPLINE

(Noncompliant Quality Assurance Plan for Qualitative and Quantitative Testing)

29. Respondent BMHP is subject to disciplinary action under 16 CCR 1735.8(c), by and through Code section 4301(o), in that they failed to conduct qualitative and quantitative testing of compounded sterile products. The circumstances are as follows:

30. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP did not have a quality assurance plan to test batch produced compounded sterile products for integrity, potency, quality, or labeled strength.

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FIFTH CAUSE FOR DISCIPLINE

(Failure to Conduct Quality Assurance Tests)

31. Respondent BMHP is subject to disciplinary action under 16 CCR 1751.7(a) and (d), by and through Code section 4301(o), in that they did not conduct quality assurance tests for end product testing and for sterility testing of batch produced compounded sterile products. The circumstances are as follows:

32. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP did not conduct any end product testing for labeled potency or for sterility of batch compounded sterile preparations. On re-inspection by a Board inspector on January 20, 2016, Respondent BMHP had not conducted the required testing as outlined in its correction plan, nor had it completed required end product testing from January 9, 2015, to the date of re-inspection.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Master Formulas)

33. Respondent BMHP is subject to disciplinary action under 16 CCR 1735.2(d), by and through Code section 4301(o), in that they did not create a master formula for every product compounded prior to making the compounded product. The circumstances are as follows:

34. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP had no master formulas for any of the compounded sterile products routinely prepared.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to have Pharmacists Review Preparations Prior to Compounding)

35. Respondent BMHP is subject to disciplinary action under 16 CCR 1751.3(b), by and through Code section 4301(o), in that they failed to have a pharmacist review preparations prior to compounding. The circumstances are as follows:

36. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP did not have a pharmacist review the ingredients and written compounding process for each preparation prior to compounding.

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EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounded Products)

37. Respondent BMHP is subject to disciplinary action under 16 CCR 1735.3(a), by and through Code section 4301(o), in that no record was made for compounded drug products. The circumstances are as follows:

38. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP made no record documenting:

a. the manufacturer and lot number of each component,

b. the date the drug product was compounded,

c. the identity of the pharmacy personnel who compounded the drug product,

d. the identity of the pharmacist reviewing the final drug product, and

e. the quantity of each component used in compounding the drug product.

NINTH CAUSE FOR DISCIPLINE

(Failure to follow standards for frequency of cleaning)

39. Respondent BMHP is subject to disciplinary action under 16 CCR 1751.4(d), by and through Code section 4301(o), in that they failed to follow proper frequency for cleaning. The circumstances are as follows:

40. On or about May 12, 2014, until on or about January 9, 2015, Respondent BMHP sanitized the walls, ceilings, shelves, tables, and stools monthly when it was required to be done weekly.

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TENTH CAUSE FOR DISCIPLINE

(Furnishing to an Unlicensed Facility)

41. Respondent BMHP is subject to disciplinary action under Code sections 4169(a)(1), 4059(b), and 4059.5(e), by and through Code section 4301(j), in that they furnished dangerous drugs and controlled substances to an unlicensed entity. The circumstances are as follows:

42. On or about October 1, 2014, until on or about January 10, 2015, Respondent BMHP furnished to Lake Tahoe Surgical Center (LTSC), in Zephyr Cove, Nevada, a surgical center without a California license:

a. 421 doses of 7 different schedule II controlled substances in various strengths and sizes,

b. 168 doses of 3 schedule III-IV controlled substances in various strengths and sizes, and

c. 1269 doses of 57 different dangerous drugs in various strengths and sizes.

ELEVENTH CAUSE FOR DISCIPLINE

(Furnishing Schedule II Controlled Substances Without Required Order Form)

43. Respondent BMHP is subject to disciplinary action under section 1305.03 of title 21 of the Code of Federal Regulations, by and through Code section 4301(o), in that they furnished to LTSC schedule II controlled substances without the required DEA 222 order forms. The circumstances are as follows:

44. On twelve separate dates, October 7, 24, 28, and 29, 2014, November 4, 11, and 18, 2014, December 8, 9, 10, and 22, 2014, and January 8, 2015, Respondent BMHP furnished to LTSC 27 line items of schedule II controlled substances in various strengths and sizes, totaling 421 doses of 7 controlled substances to LTSC without executing a DEA 222 order form for each transaction.

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Terriann Hughes Cherry

45. Respondent Terriann Hughes Cherry was the designated Pharmacist-In-Charge for Barton Memorial Hospital Pharmacy under Code section 4113(a) from March 1, 2013, to January 8, 2016. As pharmacist-in-charge for BMHP, Respondent Cherry was responsible for BMHP's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy under Code section 4113(c).

TWELFTH CAUSE FOR DISCIPLINE

(Failure to follow proper garbing procedures)

46. Respondent Cherry is subject to disciplinary action under title 16 of the California Code of Regulations, section 1751.4, subdivision (b), (16 CCR 1751.4(b)), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to follow proper garbing procedures. The circumstances are set forth in paragraph 24 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to train staff who compound sterile products)

47. Respondent Cherry is subject to disciplinary action under 16 CCR 1751.6(b), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to train staff that compound sterile products. The circumstances are set forth in paragraph 26 above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Cleanable Surfaces)

48. Respondent Cherry is subject to disciplinary action under 16 CCR 1751(b) as it relates to 24 CCR 1250.4(2), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, allowed porous and uncleanable surfaces in a clean room. The circumstances are set forth in paragraph 28 above.

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FIFTEENTH CAUSE FOR DISCIPLINE

(Noncompliant Quality Assurance Plan for Qualitative and Quantitative Testing)

49. Respondent Cherry is subject to disciplinary action under 16 CCR 1735.8(c), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to conduct qualitative and quantitative testing of compounded sterile products. The circumstances are set forth in paragraph 30 above.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Conduct Quality Assurance Tests)

50. Respondent Cherry is subject to disciplinary action under 16 CCR 1751.7(a) and (d), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, did not conduct quality assurance tests for end product testing and for sterility testing of batch produced compounded sterile products. The circumstances are set forth in paragraph 32 above.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Master Formulas)

51. Respondent Cherry is subject to disciplinary action under 16 CCR 1735.2(d), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, did not create a master formula for every product compounded prior to making the compounded product. The circumstances are set forth in paragraph 34 above.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to have Pharmacists Review Preparations Prior to Compounding)

52. Respondent Cherry is subject to disciplinary action under 16 CCR 1751.3(b), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to have a pharmacist review preparations prior to compounding. The circumstances are set forth in paragraph 36 above.

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NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Compounded Products)

53. Respondent Cherry is subject to disciplinary action under 16 CCR 1735.3(a), by and through Code section 4301(o), as pharmacist-in-charge for BMHP, in that no record was made for compounded drug products. The circumstances are set forth in paragraph 38 and its subparts above.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to follow standards for frequency of cleaning)

54. Respondent Cherry is subject to disciplinary action under 16 CCR 1751.4(d), by and through Code section 4301(o), in that she, as pharmacist-in-charge for BMHP, failed to follow proper frequency for cleaning. The circumstances are set forth in paragraph 40 above.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Furnishing to an Unlicensed Facility)

55. Respondent Cherry is subject to disciplinary action under Code sections 4169(a)(1), 4059(b), and 4059.5(e), by and through Code section 4301(j), in that she, as pharmacist-in-charge for BMHP, furnished dangerous drugs and controlled substances to an unlicensed entity. The circumstances are set forth in paragraph 42 and its subparts above.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Furnishing Schedule II Controlled Substances Without Required Order Form)

56. Respondent Cherry is subject to disciplinary action under section 1305.03 of title 21 of the Code of Federal Regulations, by and through Code section 4301(j), in that she, as pharmacist-in-charge for BMHP, furnished schedule II controlled substances to LTSC without the required DEA 222 order forms. The circumstances are set forth in paragraph 44 above.

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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 Number HSP 21312, issued to Barton Healthcare System, dba Barton Memorial Hospital Pharmacy

2. Revoking or suspending Original Sterile Compounding Permit Number LSC 100403, issued to Barton Healthcare System, dba Barton Memorial Hospital Pharmacy;

3. Revoking or suspending Original Pharmacist License Number RPH 33004, issued to Terriann Hughes Cherry

4. Ordering Barton Healthcare System, dba Barton Memorial Hospital Pharmacy, and Terriann Hughes Cherry 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: 6/2/16

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

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