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

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 BARTON HEALTHCARE SYSTEM, DBA BARTON MEMORIAL HOSPITAL PHARMACY ONLY**

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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BEFORE THE
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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 Barton Healthcare System, dba Barton Memorial Hospital Pharmacy 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 May 12, 1980, the Board issued Original Permit Number No. HSP 21312 to Respondent. The Original Permit Number was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 5541, and will expire on February 1, 2017, unless renewed.

4. On or about June 30, 2014, the Board issued Original Sterile Compounding Permit No. LSC 100403 to Respondent. The Original Sterile Compounding Permit will expire on February 1, 2017, unless renewed.

JURISDICTION

5. 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 its Notice of Defense contesting the First Amended Accusation.

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

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in 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.

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

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

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

CULPABILITY

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

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

CONTINGENCY

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

13. 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.

14. 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.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Permit Number No. HSP 21312 and Original Sterile Compounding Permit No. LSC 100403 issued to Respondent Barton Healthcare System, dba Barton Memorial Hospital Pharmacy, are revoked. However, the revocation is stayed and Respondent is placed on probation for three (3) years on the following terms and conditions.

1. **Obey All Laws**

Respondent owner shall obey all state and federal laws and regulations.

Respondent owner 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 Permit or Original Sterile Compounding Permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

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

2. **Report to the Board**

Respondent owner shall report to the board quarterly, on a schedule as directed by the board

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

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent owner 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 owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent owner shall pay to the board its costs of investigation and prosecution in the amount of $11,085.60. Respondent owner 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 owner shall not relieve respondent of their responsibility to reimburse the board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a

schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

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

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

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

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises 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.

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

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five

days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

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

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. **Notice to Employees**

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

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

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

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty

of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

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

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

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

12. **Violation of Probation**

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

If respondent owner violates probation in any respect, the board, after giving respondent owner 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.

13. **Completion of Probation**

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

14. **Independent Consultant**

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

15. **Staff Training**

Within thirty (30) days of the effective date of this decision, respondent owner shall submit to the board or its designee an appropriate program of staff training related to sterile compounding. The program of staff training shall consist of at least ten (10) CE hours in sterile compounding, which shall be completed by all of respondent's staff involved with compounding and at respondent's own expense. All staff training 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 staff training shall be considered a violation of probation. The period of probation will be automatically extended until such staff training 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's staff, at respondent's own expense, to take an approved examination to test the knowledge of the course. If the respondent's staff 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's staff to take another course approved by the board in the same subject area.

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 the Original Permit and Original Sterile Compounding Permit of Barton Healthcare System, dba Barton Memorial Hospital Pharmacy. 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: Jan 13, 2017

CLINT PURVANCE, PRESIDENT/CEO
BARTON HEALTHCARE SYSTEM, DBA BARTON MEMORIAL HOSPITAL PHARMACY
Respondent

DATED: 1/13/17

MEMBER, BOARD OF DIRECTORS
BARTON HEALTHCARE SYSTEM, DBA BARTON MEMORIAL HOSPITAL PHARMACY
Respondent

I have read and fully discussed with Respondent Barton Healthcare System, dba Barton Memorial Hospital Pharmacy 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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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:

...

(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

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

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