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

In the Matter of the Accusation Against: **MIMI N. CLAYTON** **18300 Avenue 296** **Exeter, CA 93221** **Pharmacist License No. RPH 46784** Respondent.	Case No. 5810 OAH No. 2017010178

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on November 29, 2017.

It is so ORDERED on October 30, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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BEFORE THE
BOARD OF PHARMACY
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In the Matter of the Accusation Against: **MIMI N. CLAYTON** **18300 Avenue 296** **Exeter, CA 93221** **Pharmacist License No. RPH 46784** Respondent.	Case No. 5810 OAH No. 2017010178 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

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

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by David E. Brice, Deputy Attorney General.

2. Mimi N. Clayton (Respondent) is represented in this proceeding by attorney Rachele Berglund, whose address is: Herr Pedersen & Berglund, 100 Willow Plaza, Suite 300, Visalia, California, 93291.

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3. On or about October 15, 1993, the Board issued Pharmacist License No. RPH 46784 to Respondent. The Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 5810, and will expire on April 30, 2019, unless renewed.

JURISDICTION

4. Accusation No. 5810 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 27, 2016. Respondent timely filed her Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 5810 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 Accusation No. 5810. 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 Accusation; the right to confront and cross-examine the witnesses against her; 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 Accusation No. 5810.

10. Respondent agrees that her 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.

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 Pharmacist License No. RPH 46784 issued to Respondent Mimi N. Clayton is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

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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 contendere 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 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 5810 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 5810, 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.

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 5810 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 5810 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, Supervision of Compounding, 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, supervise any compounding practice, 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. After respondent completes two (2) years of probation, the board or its designee, in its discretion and without the need for respondent to petition the board, may lift the prohibition on supervision of compounding practice as deemed appropriate; this does not preclude respondent from exercising any right of petition that exists under California law.

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 $11,194.50. 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.

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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

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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 forty (40) 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 forty (40) 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 forty (40) 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 forty (40) 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. **Community Service Program**

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least 20 hours per year during each year of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service

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program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

17. **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 compounding, pharmacy law, and managing/supervising a pharmacy. The program of remedial education shall consist of at least ten (10) hours during each year of the period of probation, which shall be completed at respondent's own expense. At least five (5) of these ten (10) units shall be completed by attending "in person" C.E. 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.

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 in pharmacy law and compounding, 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.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Rachele Berglund. I understand the stipulation and the effect it will have on my 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: 9-25-17

MIMI N. CLAYTON
Respondent

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

DATED: 9-25-17

RACHELE BERGLUND
Attorney for Respondent

ENDORSEMENT

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

Dated: 9/25/2014

Respectfully submitted,

XAVIER BECERRA
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

Accusation No. 5810

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BEFORE THE
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In the Matter of the Accusation Against: **MIMI N. CLAYTON** **18300 Avenue 296** **Exeter, CA 93221** **Pharmacist License No. RPH 46784** Respondent.	Case No. 5810 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.

2. On or about October 15, 1993, the Board issued Pharmacist License Number RPH 46784 to Mimi N. Clayton ("Respondent"). On or about January 31, 2015, Respondent became the pharmacist-in-charge of Emanuel Medical Center ("EMC") located in Turlock, California. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2017, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code ("Code") unless otherwise indicated.

4. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

5. Code section 4300.1 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.

STATUTORY AND REGULATORY PROVISIONS

6. Code section 4301 states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . . .
>
> (c) Gross negligence.
>
> . . . .
>
> (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 . . . .

7. Code section 4113, subdivision (c), states that "[t]he 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."

8. Title 16, California Code of Regulations ("CCR"), section 1711 states, in pertinent part:

> (a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
>
> (b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
>
> (c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.
>
> (2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
>
> (A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
>
> (B) Communicate to the prescriber the fact that a medication error has occurred.
>
> . . . .
>
> (3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
>
> . . . .
>
> (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

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(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created . . .

9. Title 16, CCR, section 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 . . .

COST RECOVERY

10. Code section 125.3 provides, in pertinent part, that a Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of

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the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG CLASSIFICATIONS

11. "Vancocin" is the brand name for vancomycin, an antibiotic. Vancocin is a dangerous drug pursuant to Code section 4022.

STATEMENT OF FACTS

12. On or about March 9, 2015, Respondent contacted Board Inspector D. P. and informed her that L. L., a staff pharmacist at EMC, had made a medication error on March 8, 2015. Respondent reported that L. L. had prepared vancomycin IV bags with a medication dose less than the labeled dose. Respondent asked the inspector if the medication error needed to be reported to the Board. The inspector told Respondent that the Board's first concern was the determination of patient care issues related to the medication error; the Board's second concern was that the medication error was appropriately investigated per Title 16, CCR, section 1711.

13. On or about March 10, 2015, Respondent called the inspector and told her that the medication error had caused the death of a patient (Respondent informed the inspector later that the sub-therapeutic dose of vancomycin was not a factor in the patient's death). Respondent also stated that L. L. had been placed on administrative leave because she admitted she had not checked the strength of the vancomycin stock bottle, but had just verified it was the right drug.

14. That same day (March 10, 2015), the inspector received various emails from L. L., which she had sent to Respondent, including an email dated March 8, 2015. L. L. stated in the email that she had discovered her medication error that day. L. L. explained that she had used a stock vial containing 5 gm of vancomycin instead of 10 gm of vancomycin and that the compounded vancomycin IV bags had contained one-half of the labeled strength of the drug. L. L. found that 51 vancomycin IV bags had been prepared incorrectly on March 6 and 7, 2015, and that 29 doses had been administered to patients. Once L. L. discovered the error, she immediately pulled all of the incorrect doses from all areas of EMC. L. L. identified 14 patients, who might have received the reduced doses of vancomycin, and contacted almost all of the patients' physicians. On or about March 8, 2015, Respondent sent L. L. an email asking her to

see if patients needed to be notified of the medication error, and instructing her to review the current policy. Respondent also instructed L. L. to create a new storage bin for the vancomycin 5 gm dose and to contact "Thao" (pharmacist T. L., EMC's Clinical Pharmacy Coordinator) to create a new compound worksheet.

15. On or about March 9, 2015, L. L. sent Respondent an email, stating that she had contacted all of the physicians whose patients may have received a reduced dose of vancomycin and that the kinetic pharmacist was following all of the patients who were currently on vancomycin. Respondent sent L. L. an email stating that she ("Respondent") would speak to the patients. Respondent again instructed L. L. to find the policy on disclosing medication errors to patients. L. L. sent Respondent a reply, stating that since she was working as a staff pharmacist, T. L. would be doing the "Verge" reporting (Verge was the in-house name for the medication error/quality assurance reports).

16. On or about March 11, 2015, the inspector had several telephone discussions with L. L. L. L. told the inspector EMC had discovered that other pharmacists had also made the same medication error; i.e., they had used a 5 gm stock bottle rather than a 10 gm stock bottle of vancomycin. L. L. stated that pharmacy staff had not been informed EMC had received a vancomycin 5 gm stock bottle when a vancomycin 10 gm stock bottle had been used previously, which contributed to the medication error.

17. On or about March 12, 2015, the inspector called EMC and spoke with T. L. T. L. told the inspector she was responsible for investigating and documenting medication errors and that for some unknown reason, she was being excluded from the vancomycin investigation.

18. On or about March 13, 2015, the inspector went to EMC to conduct an inspection of the pharmacy. The inspector met with T. L. and obtained copies of T. L.'s email communications with Respondent and EMC's medication error policies and procedures. T. L. told the inspector that as Clinical Coordinator, she had always been in charge of investigations of medication errors and of entering the errors into EMC's "Verge" system. T. L. stated that she had come a long way in the investigation of the vancomycin error before Respondent told her to stop. The inspector reviewed the emails and found as follows:

a. T. L. told Respondent in an email dated March 9, 2015, that she was completing the Verge incident reports and investigation of patients affected by the vancomycin medication error. Respondent sent T. L. a reply, asking T. L. to keep her in the loop of any updates.

b. On March 11, 2015, T. L. sent Respondent an email containing a summary of her vancomycin medication error findings, including the following: 1) 25 vials of vancomycin 5 gm had been delivered to EMC on February 26, 2015, and 15 vials had been delivered on March 9, 2015; 2) T. L. identified the 2 lot numbers involved; 3) potentially 130 bags of IV vancomycin were compounded incorrectly, starting on February 26, 2015; 4) it was unknown how many bags had reached the patients because the pharmacy department did not track which lot was dispensed to which patients; and 5) T. L. ran a Meditech report, which showed that a total of approximately 87 patients received IV vancomycin between February 19, 2015 and March 8, 2015.

c. On March 12, 2015, Respondent sent T. L. an email, stating that she (T. L.) was "independently doing this (the investigation)" without any instructions from Respondent and that Respondent needed her to stop.

19. During the inspection, the inspector went to the pharmacy and observed Respondent and pharmacy technician A. W. digging through a pharmacy waste bin. About 15 empty glass vials were laid out on the floor. The inspector asked Respondent and A. W. what they were doing. A. W. told the inspector they were looking at empty vancomycin bottles to try and determine all of the vancomycin lot numbers that were involved in the medication error. The inspector asked Respondent why they were just now looking to identify the lot numbers of the vancomycin. Respondent stated that they just found out more patients received inaccurate doses of the drug. The inspector asked Respondent who was in charge of the investigation. Respondent stated L. L. The inspector asked Respondent how that would work since L. L. was on administrative leave. Respondent claimed that A. W. was actually in charge, then admitted that she, herself, was in charge of the investigation. The inspector asked A. W. if there was a master formula or compounding log worksheet for 5 gm vancomycin in the pharmacy prior to the time the vancomycin 5 gm was received. A. W. said no.

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20. The inspector asked Respondent if she had written quality assurance reports on all of the affected patients. Respondent stated that medication error information on 19 patients had been input into the Verge program, but admitted that quality assurance reports were not prepared for 68 patients. The inspector asked Respondent to show her the medication error forms. Respondent stated that she did not have access to the Verge program, but would have the forms printed. Respondent left to obtain copies of the forms. Later, A. W. provided the inspector with only one of the 19 medication error forms. The inspector asked Respondent for a copy of EMC's medication error policy. Respondent began checking her computer. About 15 minutes later, Respondent found the policy and provided a copy to the inspector.

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Quality Assurance Program)

21. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent failed to comply with Title 16, CCR, section 1711, as follows:

a. On or about March 13, 2015, Respondent failed to immediately retrieve or provide to Board Inspector D. P. EMC pharmacy's quality assurance policy and procedure.

b. Respondent provided Board Inspector D. P. with a copy of only one quality assurance report relating to the pharmacy's vancomycin medication error when, in fact, there were a total of approximately 87 patients who could have been affected by the medication error.

SECOND CAUSE FOR DISCIPLINE

(Gross Negligence)

22. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (b), in that Respondent committed acts or omissions constituting gross negligence, as follows:

a. Respondent failed to identify the patients who received the wrong dose of the vancomycin within 2 business days from the date the medication error was discovered.

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b. Respondent made an assessment that no patient had been harmed by the pharmacy's vancomycin medication error prior to identifying all of the patients who were possibly affected by the medication error.

c. Respondent failed to concentrate on patient care issues during the initial investigation of the vancomycin medication error and instead, focused the investigation on assigning blame to the person(s) involved in the error.

d. Respondent failed to follow EMC's Administrative Policy No. 07-09-01 to promote a non-punitive process in the investigation of the vancomycin medication error in that Respondent initiated punitive action against L. L., who discovered and reported the medication error.

e. Respondent failed to utilize all resources available to her to investigate and determine the cause of the vancomycin medication error, to identify the patients who could possibly have been affected by the medication error, and to provide an appropriate response to the medication error as part of a mission to improve the quality of EMC's pharmacy service and prevent errors.

f. Respondent failed to identify the lot numbers of the vancomycin 5 gm vials that were obtained and used in error in the preparation of the compounded vancomycin IV bags within 5 days from the discovery of the vancomycin medication error.

g. Respondent failed to review the pharmacy's compounding records to determine the actual number of vancomycin preparations that were compounded in error.

h. Respondent failed to immediately retrieve or provide to Board Inspector D. P. the pharmacy's quality assurance policy and procedure, as set forth in subparagraph 21 (a) above.

i. Respondent failed to immediately identify herself to Board Inspector D. P. as the person in charge of EMC's investigation of the vancomycin medication error.

j. Respondent failed to provide accurate medication error event data to Board Inspector D. P.

k. Respondent subverted, or attempted to subvert, a thorough investigation of the vancomycin medication error.

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THIRD CAUSE FOR DISCIPLINE

(Failure to Prepare Master Formulas Prior to Compounding)

23. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent violated Title 16, CCR, section 1735.2, subdivision (d), as follows: Respondent failed to prepare a written master formula for the use of the vancomycin 5 gm that was used in the compounding of the vancomycin IV bags, which contributed to the pharmacy's vancomycin medication error.

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 Pharmacist License Number RPH 46784, issued to Mimi N. Clayton;

2. Ordering Mimi N. Clayton to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 10/10/16

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

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