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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 **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.
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> (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:
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> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
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> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
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> (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:
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> . . . .
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> (c) Gross negligence.
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> . . . .
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> (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.
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> (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.
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> (2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
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> (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.
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> . . . .
>
> (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.
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> . . . .
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> (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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