KAMALA D. HARRIS
Attorney General of California
JOSHUA A. ROOM
Supervising Deputy Attorney General
ROSAILDA PEREZ
Deputy Attorney General
State Bar No. 284646
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 703-1618
Facsimile: (415) 703-5480
*Attorneys for Complainant*

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

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| In the Matter of the Accusation Against:<br><br>**NORTH BAY CUSTOM CARE PHARMACY**<br>**NANCY KONG CHAO, PRES/PIC**<br>**ROBERT KONG, SEC/TRES/CFO**<br>**CAROLYN KONG, SHAREHOLDER**<br><br>**1460 N. Camino Alto, Ste. 101**<br>**Vallejo, CA 94589-2567**<br><br>**Pharmacy License No. PHY 49934**<br><br>**and**<br><br>**NANCY KONG CHAO**<br>**23 Railroad Avenue #366**<br>**Danville, CA 94526**<br><br>**Pharmacist License No. RPH 48087**<br><br>Respondents. | Case No. 5207<br><br>**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 June 5, 2009, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 49934 to North Bay Custom Care Pharmacy dba North Bay Custom Care

Pharmacy, Nancy Kong Chao, PRES/PIC, Robert Kong, SEC/TRES/CFO (Respondent Pharmacy). The Original Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein. It expired on June 1, 2014 and was cancelled on July 22, 2014.

3. On or about August 10, 1995, the Board of Pharmacy issued Pharmacist License No. RPH 48087 to Nancy Kong Chao (Respondent Pharmacist). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2016, unless renewed, and for all time periods relevant to the charges herein, Respondent Pharmacist served and/or was reflected in Board records as the Pharmacist in Charge (PIC) for Respondent North Bay.

## JURISDICTION

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

5. Code section 4300 provides that every license issued by the Board may be suspended or revoked.

6. 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 PROVISIONS

7. Code section 4081 states:

"(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and

unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"..."

8. Code section 4105 states:

"(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

"..."

9. Code section 4160 states:

"(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

"..."

10. Code section 4301 states:

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

"...

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

"(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

"...

"(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.

"...

"(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

"..."

11. Code section 4342 states:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

"..."

12. Health and Safety Code section 11165 provides, in pertinent part:

"...

"(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

"...

"(10) Date of dispensing of the prescription.

"..."

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13. California Code of Regulations, Title 16, section 1707.2, provides, in pertinent part:

"...

"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

"(A) whenever the prescription drug has not previously been dispensed to a patient; or

"(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

"(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

"(A) of his or her right to request consultation; and

"(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

"..."

14. California Code of Regulations, Title 16, section 1707.5, provides, in pertinent part:

"(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

"(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

"(A) Name of the patient

"(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

"(C) The directions for the use of the drug.

"(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

"..."

15. California Code of Regulations, Title 16, section 1711, provides, in pertinent part:

"...

"(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.

"(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.

"..."

16. California Code of Regulations, Title 16, section 1714, provides, in pertinent part:

"...

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

"..."

## COST RECOVERY

17. Code section 125.3 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.

## FACTS

18. On or about August 6, 2013 and August 29, 2013, two Board Inspectors inspected Respondent Pharmacy after receiving a complaint. They were met and assisted by Respondent Pharmacist. During the course of the inspections, the Inspectors discovered the following:

a. Respondents failed to reverse billing claims for prescriptions that were never dispensed to patients;

b. Respondents misrepresented the drug manufacturer used (to fill prescriptions) to insurance providers;

c. Respondents misrepresented prescription fill dates;

d. Respondents misrepresented dispensing dates of prescriptions to CURES;

e. Respondents accepted returned medications from patients for destruction;

f. Respondents did not refer patient L.W.[1] for a new medication consultation;

g. Respondents did not ensure patients received written notification of their right to request a consultation and a telephone number to obtain the consultation;

h. Respondents had expired medication in the pharmacy's drug inventory;

i. Respondents did not have patient-centered labeling on bubble packed medications;

j. Respondents did not have a written policy or procedure to assist patients with limited English proficiency;

k. Respondents failed to report and investigate medication errors related to short-counted prescriptions;

l. Respondent's pharmacy dispensing area was cluttered and disorganized.

[1] Patient name has been withheld to maintain confidentiality.

19. Between approximately December 2013 and July 2014, a Board Inspector investigated an additional complaint and discovered the following:

a. Respondents failed to maintain current drug inventory;

b. Respondents failed to maintain records of acquisition and disposition on a licensed premise;

c. Respondents knowingly signed and filed a Discontinuation of Business form that contained false statements; and

d. Respondents subverted the Board's investigation.

**FIRST CAUSE FOR DISCIPLINE**

(Act Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

20. Respondents are subject to discipline under Code section 4301, subdivisions (f) and (o), in that they were dishonest and committed fraud when they billed insurance providers for medication that was not dispensed, as described in paragraph 18, above.

**SECOND CAUSE FOR DISCIPLINE**

(Knowingly Make or Sign Certificate or Document Falsely Representing Existence or Nonexistence of a State of Facts)

21. Respondents are subject to disciplinary action under Code section 4301, subdivisions (g) and (o), in that they knowingly made misrepresentations when they billed insurance providers for the medications they did not dispense as described in paragraph 18, above.

**THIRD CAUSE FOR DISCIPLINE**

(Knowingly Make or Sign Certificate or Document Falsely Representing Existence or Nonexistence of a State of Facts)

22. Respondents are subject to disciplinary action under Code section 4301, subdivision (g) and (o), in that they knowingly falsified records indicating when a prescription was dispensed, as described in paragraph 18, above.

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**FOURTH CAUSE FOR DISCIPLINE**

(Failure to Comply with CURES Reporting)

23. Respondents are subject to disciplinary action under Code section 4301, subdivisions (g) and (o), and/or Health and Safety Code section 11165, subdivision (d)(10), in that they misrepresented the dispensing dates of prescriptions, as described in paragraph 18, above.

**FIFTH CAUSE FOR DISCIPLINE**

(Acting Like Wholesaler Without License)

24. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and 4160, subdivision (a), in that Respondents accepted returned medication from patients for destruction without having the required license to do so, as described in paragraph 18, above.

**SIXTH CAUSE FOR DISCIPLINE**

(Failed to Refer Patient for New Medication Consultation)

25. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1707.2, subdivision (b)(1)(A), in that Respondents failed to refer patient L.W. for a new medication consultation, as described in paragraph 18, above.

**SEVENTH CAUSE FOR DISCIPLINE**

(Failed to Notify Patients of Right to Consultation)

26. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1707.2, subdivision (b)(2), in that they failed to ensure patients received written notification of their right to a consultation and a telephone number to obtain the consultation, as described in paragraph 18, above.

**EIGHTH CAUSE FOR DISCIPLINE**

(Drugs Lacking Quality of Strength)

27. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and 4342, subdivision (a), because they had expired medications in their drug inventory, as described in paragraph 18, above.

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**NINTH CAUSE FOR DISCIPLINE**

(Failed to Have Patient-Centered Labels)

28. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and California Code of Regulations, title 16, section 1707.5, subdivision (a), because the pharmacy did not meet the patient-centered labeling requirements for bubble-packed medication orders, as described in paragraph 18, above.

**TENTH CAUSE FOR DISCIPLINE**

(Failed to Have Translation Services)

29. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and California Code of Regulations, title 16, section 1707.5, subdivision (d), in that they did not have written policies and procedures in place to assist patients with limited English proficiency, as described in paragraph 18, above.

**ELEVENTH CAUSE FOR DISCIPLINE**

(Failed to Investigate Medication Errors)

30. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and California Code of Regulations, title 16, section 1711 subdivision (d)(e), in that Respondents did not investigate medication errors through pharmacy's quality assurance program, as described in paragraph 18, above.

**TWELFTH CAUSE FOR DISCIPLINE**

(Failed to Keep Record Quality Assurance Review)

31. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and California Code of Regulations, title 16, section 1711 subdivision (e), in that Respondents did not keep a record of the quality assurance review related to the medication errors, as described in paragraph 18, above.

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**THIRTEENTH CAUSE FOR DISCIPLINE**

(Disorganized Dispensing Area)

32. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), and California Code of Regulations, title 16, section 1714 subdivision (b), in that the pharmacy's dispensing area was cluttered and disorganized, as described in paragraph 18, above.

**FOURTEENTH CAUSE FOR DISCIPLINE**

(Failure to Maintain Current Inventory)

33. Respondents are subject to disciplinary action under Code section 4081, subdivision (a), because they failed to maintain a current inventory of drugs in the pharmacy, as described in paragraph 19, above.

**FIFTEENTH CAUSE FOR DISCIPLINE**

(Failure to Maintain Records of Acquisition and Disposition on Licensed Premises)

34. Respondents are subject to disciplinary action under Code section 4105, subdivision (a), in that they did not keep the records of acquisition and disposition on a licensed premise between approximately January 18, 2014 and January 29, 2014, as described in paragraph 19, above.

**SIXTEENTH CAUSE FOR DISCIPLINE**

(Knowingly Sign Document with False Statements)

35. Respondents are subject to disciplinary action under Code section 4301, subdivision (g), in that they knowingly misrepresented where the records of acquisition and disposition were maintained in the Discontinuation of Business form, as described in paragraph 19, above.

**SEVENTEENTH CAUSE FOR DISCIPLINE**

(Subverting an Investigation)

36. Respondents are subject to disciplinary action under Code section 4301, subdivision (q), in that they were untruthful about the location of the records of acquisition and disposition, as described in paragraph 19, 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 Pharmacy Permit Number PHY 49934, issued to North Bay Custom Care Pharmacy dba North Bay Custom Care Pharmacy, Nancy Kong Chao, PRES/PIC, Robert Kong, SEC/TRES/CFO (Respondent Pharmacy);

2. Revoking or suspending Pharmacist License No. RPH 48087, issued to Nancy Kong Chao (Respondent Pharmacist);

3. Ordering Respondents 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;

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

DATED: 1/7/16

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

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