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

In the Matter of the Accusation Against: **RX3 PHARMACY** **7855 Redpine Road** **Richmond, VA 23237** **Non Resident Pharmacy Permit No. NRP 925** Respondent.	Case No. 4773 **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 July 15, 2009, the Board issued Non Resident Pharmacy Permit Number NRP 925 to RX3 Pharmacy (Respondent). The Non Resident Pharmacy Permit expired on July 1, 2013, and has not been renewed.

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. 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."

STATUTORY AND REGULATORY PROVISIONS

5. Section 4300 of the Code 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.

. . .

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

6. 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 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:

. . .

"(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. Section 4303 of the Code states in pertinent part:

"(b) The board may deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located."

8. California Code of Regulations, title 16, section 1735.3 provides in relevant 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.

"(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

. . .

"(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created."

9. California Code of Regulations, title 16, section 1751.7 provides in relevant part:

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

"(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."

COSTS

10. 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.

FACTUAL BACKGROUND

11. Respondent holds a permit to conduct a pharmacy in the Commonwealth of Virginia (permit no. 0201-003685). Respondent's pharmacist-in-charge, Christopher K. Currin (Currin), is licensed as a pharmacist by the Virginia Board of Pharmacy (license no. 0202-011727).

12. In or around November 2012, an inspector with the Virginia Board of Pharmacy performed an inspection of Respondent's facility located in Chester, Virginia. Upon inspection, the inspector discovered that in January, February, April, June, August, and October 2012, a total

of 114 high-risk compounded sterile products (CSPs) were compounded at Respondent's facility. Of these 114 CSPs, Respondent did not have any records for 110 of the CSPs indicating whether sterility testing had been performed on them or whether the CSPs were batch compounded or compounded for a specific patient. The inspector also determined that the CSPs were labeled with beyond use dates (BUDs) longer than allowed by the United States Pharmacopeia (USP) 797.

13. The Virginia Board of Pharmacy inspector further discovered that between January 1 and October 31, 2012, Respondent compounded and dispensed 9,889 30ml vials of Medi-Bolic Booster and 14,386 30ml vials of pyridoxine/thiamine. When asked to produce compounding records for these products, Currin was only able to produce two records for the Medi-Bolic Booster and three compounding records for the pyridoxine/thiamine, which accounted for only 400 total doses. Furthermore, Respondent only had documentation for eight in-house sterility tests. Finally, all of the compounded materials were labeled with BUDs longer than allowed by USP 797.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Maintain Pharmacy Records)

14. Respondent is subject to disciplinary action under sections 4300, 4301, subdivision (o), and 4303, subdivision (b) of the Code and California Code of Regulations, title 16, section 1735.3, subdivisions (a)(1)-(9), (b), and/or (d), in that Respondent failed to maintain certain pharmacy records for CSPs and other drug products. The circumstances of Respondent's conduct are set forth above in paragraphs 12 and 13.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Perform Sterility Testing)

15. Respondent is subject to disciplinary action under sections 4300, 4301, subdivision (o), and 4303, subdivision (b) of the Code and California Code of Regulations, title 16, section 1751.7, subdivisions (c) and/or (d) in that in 2012, Respondent failed to perform sterility testing on various CSPs and other drug products. The circumstances of Respondent's conduct are set forth above in paragraphs 12 and 13.

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 Non Resident Pharmacy Permit Number NRP 925 issued to RX3 Pharmacy;

2. Ordering RX3 Pharmacy 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;

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

DATED: 5/8/14

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

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