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

In the Matter of the Accusation Against: **RITE AID CORP., dba RITE AID 5996** **1050 North Wilson Way** **Stockton, CA 95205** **Pharmacy Permit No. PHY 42812** Respondent.	Case No. 5853 **ACCUSATION**

Virginia Herold ("Complainant") alleges:

PARTIES

1. 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 February 21, 1997, the Board issued Pharmacy Permit Number PHY 42812 to Rite Aid Corp. dba Rite Aid 5996 ("Respondent"). The Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2017, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws:

BUSINESS AND PROFESSIONS CODE

4. Section 4006 of the Code states in pertinent part:

> The board may adopt regulations . . . limiting or restricting the furnishing of a particular drug upon a finding that the otherwise unrestricted retail sale of the drug . . . is dangerous to the public health or safety.

5. Section 4300 of the Code states:

> (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 . . .
>
> . . . .

6. Section 4300.1 of the Code states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

7. Section 4301 of the Code states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct 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:
>
> . . . .

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

. . . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

. . . .

CALIFORNIA CODE OF REGULATIONS

8. Regulation section 1707 states, in pertinent part:

. . . .

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

. . . .

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

9. Regulation section 1711 states, 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.

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10. Regulation section 1735 states, in pertinent part:

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances.

. . . .

11. Regulation 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.

. . . .

12. Regulation section 1735.3 states, in pertinent part:

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

. . . .

13. Regulation section 1735.5 states, in pertinent part:

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

. . . .

14. Regulation section 1735.7 states, in pertinent part:

. . . .

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

. . . .

15. Regulation section 1764 states:

No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist

serving the patient, or a person duly authorized by law to receive such information.

COST RECOVERY

16. Code section 125.3 provides, 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.

BACKGROUND

17. On or about July 8, 2015, the Board received a complaint from patient B.L. stating that she went to Respondent pharmacy on June 25, 2015 and picked up medication for herself. When she got home, she went through the bag of prescriptions and she noticed a bottle of pills in the bag with someone else's name and doctor. B.L. called Respondent pharmacy and informed them that she had received someone else's prescription. Respondent asked that B.L. return the medication.

18. On or about November 3, 2015, an inspector with the Board met with B.L. The inspector received the prescription bottle of medication that did not belong B.L.

19. On or about November 3, 2015, an inspector with the Board inspected Respondent pharmacy. The inspector found violations of Pharmacy Law, as follows: Respondent did not create a quality assurance report within 2 business days of receiving B.L.'s complaint, stacks of patient information was left unsecured in a storage warehouse, there was no annual review of Respondent's compounding policies and procedures, there was no training documentation or on-going competencies of compounding staff, there was no master formula for compounded medications, and there were no lot number or expiration dates of the ingredients used to compound medication or identification of who compounded the prescriptions.

FIRST CAUSE FOR DISCIPLINE

(Failure to Ensure Quality Assurance Programs)

20. Respondent's license is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1711, subdivision (d), in that Respondent failed to investigate a medication error within

two business days from the date the medication error was discovered, and/or failed to document the error. The circumstances are that on or about June 25, 2015, patient B.L. reported to Respondent pharmacy that she had received another patient's medication. Respondent pharmacy failed to investigate and/or document the error.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Storage Area for Pharmacy Records)

21. Respondent's license is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1707, subdivision (g)(2), in that Respondent failed to store pharmacy records in a secured area so that the confidentiality of any patient-related information was maintained. The circumstances are that Respondent stored pharmacy records in a warehouse where any store employee or other person could access them at any time.

THIRD CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Limitations and Requirements)

22. Respondent's license is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.2, subdivision (d), in that on or about October 21, 2015, Respondent compounded "magic mouthwash" without first having prepared a written master formula record that includes at least the active ingredients to be used, equipment to be used, expiration dating requirements, inactive ingredients to be used, process and/or procedure used to prepare the drug, quality reviews required at each step in preparation of the drug, and post-compounding process or procedures required, if any. Magic mouthwash is solution of medication used to treat mouth sores (oral mucositis).

FOURTH CAUSE FOR DISCIPLINE

(Failure to Comply with Records of Compounded Drug Products)

23. Respondent's license is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.3, subdivision (a), in that pharmacy compounded "magic mouthwash" for

prescription #2384749 and did not include the manufacturer, the expiration date, the lot number of individual ingredients, or the identity of the pharmacy personnel who compounded the drug product listed on the compounding record.

FIFTH CAUSE FOR DISCIPLINE

(Failed to Comply with Compounding Policies and Procedures)

24. Respondent's license is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.5, subdivision (b), in that at the time of the November 3, 2015, inspection, Respondent's Pharmacist-in-Charge ("PIC") had not reviewed the Respondent's compounding policies and procedures manual.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Document Training of Compounding Staff)

25. Respondent's license is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.7, subdivision (b), in that Respondent failed to document or retain documentation that all pharmacy personnel engaged in compounding drug products had training and demonstrated on-going competency.

SEVENTH CAUSE FOR DISCIPLINE

(Unauthorized Disclosure of Prescription/Medical Information)

26. Respondent's license is subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1764, in that the PIC allowed unauthorized revelation of the contents a prescription and medication information to a person other than the patient when on June 25, 2015, the PIC allowed medication that was intended for patient V.C. to be given to patient B.L. B.L. thereafter had unauthorized disclosure of prescription/medical information for V.C.

DISCIPLINE CONSIDERATIONS

27. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about June 29, 2011, the Board of Pharmacy issued Citation

Number CI 2010 45739, to Respondent. The Citation ordered Respondent to pay a $4,000 fine for violation of California Code of Regulations, title 16, section 1714, subdivision (b), for the loss of controlled substances relating to the failure to maintain adequate pharmacy security. That Citation is final and is incorporated by reference as if fully set forth.

28. As an additional disciplinary consideration, Complainant alleges that on or about April 2, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2011 51890. The Citation ordered Respondent to pay a $1,000 fine for violation of California Code of Regulations, title 16, section 4076, subdivision (a)(11)(A), for failing to comply with prescription container labeling requirements. That Citation is final and is incorporated by reference as if fully set forth.

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 Pharmacy License Number PHY 42812 issued to Rite Aid Corp., dba Rite Aid 5996 ;

2. Ordering Rite Aid Corp., dba Rite Aid 5996 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: 10/21/16

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

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