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

In the Matter of the Accusation Against: **WALGREENS #04170** **4200 Arden Way** **Sacramento, CA 95864** **Pharmacy Permit No. PHY 53089** Respondent.	Case No. 5981 **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, Department of Consumer Affairs.

2. On or about December 31, 2014, the Board of Pharmacy issued Permit Number PHY 53089 to Walgreens #04170 (Respondent). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2017, unless renewed.

JURISDICTION

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

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4. Section 4300 of the Code states:

"(a) Every license issued may be suspended or revoked.

5. 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."

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 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."

7. Section 4076 of the Code states in pertinent part:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

"(7) The strength of the drug or drugs dispensed."

8. Section 4342 of the Code states in pertinent part:

"(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

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Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

HEALTH AND SAFETY CODE

9. Health and Safety Code section 11164 states in pertinent part:

"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

"(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

"(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed."

10. Health and Safety Code section 11200 states in pertinent part:

"(b) No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply."

11. Health and Safety Code section 111255 states:

"Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

12. Health and Safety Code section 111295 states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

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CALIFORNIA CODE OF REGULATIONS

13. California Code of Regulations, title 16, (Regulation) section 1714 states in pertinent part:

"(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes."

14. Regulation section 1715 states:

"(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

"(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

"(1) A new pharmacy permit has been issued, or

"(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

"(3) There is a change in the licensed location of a pharmacy to a new address.

"(c) The components of this assessment shall be on Form 17M-13 (Rev. 10/14) entitled "Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment" and on Form 17M-14 (Rev. 10/14) entitled "Hospital Pharmacy Self-Assessment" which are hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

"(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is performed."

15. Regulation section 1718.1 states:

"All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be

manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy or other persons authorized to dispense such drugs in California."

16. Regulation section 1735.2 states in pertinent part:

"(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

17. Regulation section 1735.3 states in pertinent part:

"(a) For each compounded drug preparation, pharmacy records shall include:

"(1) The master formula document.

"(2) A compounding log consisting of a single document containing all of the following:

"(A) Name and Strength of the compounded drug preparation.

"(B) The date the drug preparation was compounded.

"(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

"(D) The identity of the pharmacist reviewing the final drug preparation.

"(E) The quantity of each ingredient used in compounding the drug preparation.

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"(F) 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. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (*l*) shall apply.

"(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

"(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

"(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

"(I) The final quantity or amount of drug preparation compounded for dispensing.

"(J) Documentation of quality reviews and required post-compounding process and procedures.

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"(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 last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c)."

18. Regulation section 1735.4 states in pertinent part:

"(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

"(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

"(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

"(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

"(4) The beyond use date for the drug preparation;

"(5) The date compounded; and

"(6) The lot number or pharmacy reference number..."

COST RECOVERY

19. 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.

INSPECTION INFORMATION

20. From approximately March 6, 1997, through December 31, 2014, Respondent pharmacy operated under a previous license. On or about December 31, 2014, when the current license number 53089, was issued the previous license was cancelled.

21. On or about June 17, 2014, Respondent associated a new pharmacist in charge (PIC).

22. On or about March 1, 2016, Board of Pharmacy Inspector S.K. went to Respondent's facility to conduct an inspection. At this inspection, S.K. notified Respondent of several items that needed repair or replacement, one of which was a refrigerator containing vaccines where the door handle that was originally white in color was encrusted and black with dirt.

23. On or about March 30, 2016, S.K. returned to the pharmacy facility to follow up on the previous inspection. On this date, S.K. noted that the refrigerator handle was still extremely dirty and did not appear to have been cleaned since the previous visit.

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FIRST CAUSE FOR DISCIPLINE

(Expired Drugs Held For Sale)

24. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), for violating Code section 4342, subdivision (a), and Regulation section 1718.1, in that Respondent held for sale twenty-four (24) drugs intermingled in its inventory of active drug stock that were expired beyond the manufacturers' or pharmacy-assigned expiration dates, or had no labeled expiration date.

SECOND CAUSE FOR DISCIPLINE

(Adulterated Drugs Held For Sale)

25. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (j), for violating Health and Safety Code sections 111255 and 111295, in that Respondent held for sale twenty-four (24) drugs intermingled in its inventory of active drug stock that were adulterated in that they were expired beyond the manufacturers' or pharmacy-assigned expiration dates, or had no labeled expiration date.

THIRD CAUSE FOR DISCIPLINE

(Pharmacy and Fixtures Not Maintained)

26. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), for violating Regulation section 1714, subdivision (c) in that the pharmacy and fixtures were not maintained in a clean and orderly condition. Further, the sink did not have sufficient hot and cold running water for pharmaceutical purposes. The circumstances are that on or about March 1, 2016, at the first pharmacy inspection, S.K. made the following observations:

a. The sink had a fork and a straw in it as though being used for cleaning employee's dirty dishes.

b. The sink was stained brown and had two areas where unknown material or dirt had concentrated.

c. The sink's faucet aerator had a black growth, commonly referred to as mold or mildew, through which the water flowed.

d. The sink could not generate the water flow or pressure necessary for pharmaceutical purposes.

e. Next to the sink was a refrigerator used for storing vaccines, which are injected through a patient's skin and into a tissue layer or muscle below the skin. The refrigerator's handle was originally white, but was coated in dirt causing it to appear black in color.

FOURTH CAUSE FOR DISCIPLINE

(Failed to Complete Pharmacy Self-Assessment)

27. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), for violating Regulation section 1715, in that Respondent failed to complete mandatory pharmacy self-assessments. The circumstances are as follows:

a. Regulation section 1715, subdivision (a), requires a pharmacy self-assessment to be completed before July 1 of every odd numbered year. At the inspection on March 1, 2016, S.K. requested the self-assessment that should have been completed by July 1, 2015. Respondent was unable to produce a self-assessment for that date.

b. Regulation section 1715, subdivision (b)(1), requires a pharmacy self-assessment be completed within 30 days of the issuance of a new pharmacy permit. Respondent was issued a new pharmacy permit on or about December 31, 2014, so a self-assessment should have been completed no later than January 30, 2015. Respondent was unable to produce a self-assessment for that date.

FIFTH CAUSE FOR DISCIPLINE

(Failed to Complete Compounding Self-Assessment)

28. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), for violating Regulation section 1735.2, subdivision (k), in that Respondent failed to complete mandatory pharmacy compounding self-assessments. The circumstances are that Respondent was required to complete a compounding self-assessment no later than 30 days after the pharmacy permit was issued on or about December 31, 2014, and another compounding self-assessment no later than July 1, 2015. Respondent was unable to

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produce compounding self-assessments for either date. Respondent compounded approximately twenty-nine (29) prescriptions without a compounding self-assessment having been done.

SIXTH CAUSE FOR DISCIPLINE

(Failed to Maintain Compounding Records)

29. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), for violating Regulation section 1735.3, subdivisions (a) and (d), in that in and between December 31, 2014, and March 1, 2016, Respondent dispensed twenty (20) compounded prescriptions without maintaining records that included the master formula, the quantity of each component used in compounding the drug product, the manufacturer, expiration date, and lot number of each component used, the equipment used, and the expiration date of the final compounded product.

SEVENTH CAUSE FOR DISCIPLINE

(Failed to Comply with Compounding Label Requirements)

30. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), for violating Code section 4076, subdivision (a)(7), and Regulation section 1735.4, subdivision (a), in that in and between December 31, 2014, and March 1, 2016, Respondent dispensed twenty-nine (29) prescriptions that were not labeled with the generic name of the principal active ingredient and the strength of drugs dispensed.

EIGHTH CAUSE FOR DISCIPLINE

(Failed to Comply with Prescription Requirements for Controlled Substances)

31. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (j), for violating Health and Safety Code section 11164, subdivision (a)(1), in that between approximately December 31, 2014, through March 1, 2016, Respondent filled and dispensed nine (9) prescriptions for controlled substances based on facsimile prescriptions that were not signed and dated by the prescriber in ink.

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NINTH CAUSE FOR DISCIPLINE

(Excessive Refills of Controlled Substances)

32. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (j), for violating Health and Safety Code section 11200, subdivision (b), in that between approximately December 31, 2014, through March 1, 2016, Respondent filled and dispensed fourteen (14) prescriptions and refills that either exceeded five (5) refills or exceeded a 120-day supply of the controlled substance.

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 Permit Number PHY 53089, issued to Walgreens #04170;

2. Ordering Walgreens #04170 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: 2/22/17

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

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