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

In the Matter of the Accusation Against: **WESTSIDE PHARMACY** **302 Fresno St.,** **Fresno, CA 93706** **WILLIE JAMES WHISENHUNT** **Pharmacist-in Charge** **Original Permit Number No. PHY 15178,** **and** **WILLIE JAMES WHISENHUNT** **5807 E. Park Circle** **Fresno, CA 93727** **Pharmacist license No. RPH 26308** Respondents.	Case No. 4385 **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.

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2. On or about August 5, 1969, the Board of Pharmacy issued Pharmacist license Number RPH 26308 to Willie James Whisenhunt (Respondent)[1]. Said license was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2013, unless renewed.

3. On or about October 22, 1969, the Board of Pharmacy issued Original Permit Number PHY 15178 to Westside Pharmacy (Respondent). The Original Permit Number was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2013, unless renewed.

JURISDICTION

4. 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.

5. 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.

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[1] Both Westside Pharmacy and Pharmacist-in-Charge Whisenhunt will be referred to collectively throughout this accusation as "Respondents". All charges and allegations are equally applicable to both respondents.

6. Section 4081 of the Code states in pertinent part:

"(a) All records of manufacture and of sale, acquisition, 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... pharmacy...holding a currently valid and unrevoked certificate, license, permit, registration... who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section."

...

7. 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).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321."

8. Title 16 CCR section 1707.2 states:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(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.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy;

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

9. Title 16 CCR section 1707.3 states:

"Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems."

10. Title 16 CCR section 1707.6 states:

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or

only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

11. Title 16 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.

...

(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..."

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12. Title 16 CCR section 1714 states in pertinent part:

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(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.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition..."

13. Title 16 CCR section 1715 states in pertinent part:

"(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..."

14. Title 16 CCR section 1718 states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory."

15. Title 21 CFR section 1304.4 states in pertinent part:

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

...

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy…"

16. Title 21 CFR section 1304.11 states in pertinent part:

…

"(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date…"

17. Title 21 CFR section 1305.13 states in pertinent part:

" (a) A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

…

(e) The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser…"

18. 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.

JANUARY 13, 2011 PHARMACY INSPECTION

19. On January 13, 2011, a California Board of Pharmacy Inspector conducted a pharmacy inspection of Respondent Westside Pharmacy, 320 Fresno Street, Fresno California. The inspection was prompted by a complaint of a medication error incident.

20. During the inspection, a notice of noncompliance was issued for a number of violations of pharmacy laws. The violations that were observed are as follows:

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FIRST CAUSE FOR DISCIPLINE

(Failure to maintain current self-assessment)

21. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR section 1715(a) for failure to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law, in that on January 13, 2011, respondents did not have in their possession a self-assessment from the 2009 period.

SECOND CAUSE FOR DISCIPLINE

(Operational standards)

22. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR section 1714 (b) and (c) for failure to keep the facilities so that drugs are safely and properly prepared, maintained, secured and distributed and that the pharmacy be kept in a clean and orderly condition, in that on January 13, 2011, during an inspection of the licensed premises, the pharmacy had prescription medications scattered on the filling counter in bottle lids, and in plastic containers throughout the rest of the pharmacy. The pharmacy was dirty. There were open food items in the refrigerator along with prescription medications.

THIRD CAUSE FOR DISCIPLINE

(Failure to maintain current inventory)

23. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR section 1718 for failure to keep complete accountability for all dangerous drugs, in that on January 13, 2011, during an inspection of the licensed premises, the pharmacy had prescription medications scattered on the filling counter in bottle lids, and in plastic containers throughout the rest of the pharmacy. The medications were not labeled or separated in any fashion.

FOURTH CAUSE FOR DISCIPLINE

(Failure to maintain records for inspection)

24. Respondents are subject to disciplinary action under Code section 4301(j) by and through their violation of Code section 4081(a) for failure to maintain all records of acquisition, or disposition of dangerous drugs open to inspection during business hours, in that on January 13,

2011, during an inspection of the licensed premises, the pharmacy did not have records of acquisition and disposition for the loose tablets and capsules scattered throughout the pharmacy.

FIFTH CAUSE FOR DISCIPLINE

(Failure to maintain DEA inventory)

25. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CFR section 1304.11(c) for failure to take a new inventory of all stocks of controlled substances at least every two years, in that on January 13, 2011, during an inspection of the licensed premises, the pharmacy did not have a new DEA inventory taken in the last two years.

SIXTH CAUSE FOR DISCIPLINE

(Failure to maintain separate records for schedule II drugs)

26. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CFR section 1304.04(h)(1) for failure to separately maintain records for schedule II drugs, in that on January 13, 2011, during an inspection of the licensed premises, the pharmacy did not have Schedule II invoices or DEA 222's filed separately as required.

SEVENTH CAUSE FOR DISCIPLINE

(DEA form 222 not properly endorsed)

27. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CFR section 1305.13(e) for failure to record on copy 3 of the DEA form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers were received by the purchaser, in that during the January 13, 2011 inspection, it was discovered that on April 15, 2010 respondents did not complete the DEA form 222 as required.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to complete quality assurance review of medication error incident)

28. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR 1711(d) and (e) for failure to complete a quality assurance review of a medication error, in that on or about October 20, 2010, Respondents filled a prescription for Benazepril for patient R.Y., who subsequently went to the emergency room for bruising. At that

time the Physician discovered that the bottle labeled as Benazepril actually contained Warfarin 5mg (an anti-coagulant). The physician immediately contacted respondents as well as R.Y. to inform them of the error. During the inspection of respondent pharmacy on January 13, 2011, a quality assurance review of the incident was not immediately retrievable.

APRIL 4, 2012 PHARMACY INSPECTION

29. On April 4, 2012, a California Board of Pharmacy Inspector conducted a call back pharmacy inspection of Respondent Westside Pharmacy, 320 Fresno Street, Fresno California. The inspection was conducted in order to judge the pharmacy's compliance with the January 13, 2011 notice of noncompliance.

30. During the inspection, Respondent Whisenhunt asserted that he did not remember the prior pharmacy inspection of January 13, 2011. A number of continuing violations of pharmacy laws were observed as follows:

NINTH CAUSE FOR DISCIPLINE

(Failure to maintain current self-assessment)

31. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR section 1715(a) for failure to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law, in that on April 4, 2012, respondents did not have in their possession a self-assessment from the 2009 or 2011 period.

TENTH CAUSE FOR DISCIPLINE

(Operational standards)

32. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR section 1714 (b) and (c) for failure to keep the facilities so that drugs are safely and properly prepared, maintained, secured and distributed and that the pharmacy be kept in a clean and orderly condition, in that on April 4, 2012, during a call back inspection of the licensed premises, the pharmacy had prescription medications scattered on the filling counter in unmarked bottles and plastic containers. The pharmacy was disorganized and dirty. There were open food items in the refrigerator along with prescription medications.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to maintain current inventory)

33. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR section 1718 for failure to take a new inventory of all stocks of controlled substances at least every two years, in that on April 4, 2012, during a call back inspection of the licensed premises, the pharmacy did not have the inventory for the current period.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to maintain records for inspection)

34. Respondents are subject to disciplinary action under Code section 4301(j) by and trough their violation of Code section 4081(a) for failure to maintain all records of acquisition, or disposition of dangerous drugs open to inspection during business hours, in that on April 4, 2012, during a call back inspection of the licensed premises, the pharmacy did not have records of acquisition and disposition for the loose tablets and capsules scattered throughout the pharmacy.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to maintain DEA inventory)

35. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CFR section 1304.11(c) for failure to take a new inventory of all stocks of controlled substances at least every two years, in that on April 4, 2012, during a call back inspection of the licensed premises, the pharmacy did not have a new DEA inventory taken in the last two years.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to maintain separate records for schedule II drugs)

36. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CFR section 1304.04(h)(1) for failure to separately maintain records for schedule II drugs, in that on April 4, 2013, during a call back inspection of the licensed premises, the pharmacy did not have Schedule II invoices or DEA 222's filed separately as required.

FIFTEENTH CAUSE FOR DISCIPLINE

(DEA form 222 not properly endorsed)

37. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CFR section 1305.13(e) for failure to record on copy 3 of the DEA form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers were received by the purchaser, in that during the April 4, 2012 call back inspection, there were no DEA form 222's on file at all. Therefore, respondents did not complete the DEA form 222's as required.

SIXTEENTH CAUSE FOR DISCIPLINE

(Notice to Consumers posters not posted)

38. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR 1707.6 for failure to post the required notices in the pharmacy, in that on or about January 13, 2011 and April 4, 2012, during inspections of the pharmacy, the respondents did not have the posters displayed as required.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to review drug therapy and patient medication profile prior to delivery)

39. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of CCR 1707.3 for failure to review patients drug therapy and medication record before each prescription drug is delivered, in that on or about April 4, 2012, during the call back inspection of the pharmacy, respondent Whisenhunt was observed, while working as pharmacist-in-charge and dispensing prescriptions, to not refer to the pharmacy computer at any time to review any consumers' drug profile. Respondent Whisenhunt further admitted to the inspector that he did not do so.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Drugs lacking in quality and strength)

40. Respondents are subject to disciplinary action under section 4301(o) by and through their violation of section 4342(a) for keeping outdated prescription medications in the active stock of the pharmacy available for dispensing, in that on or about April 4, 2012, during the call back

inspection of the pharmacy, outdated prescription medications were found in the active stock of the pharmacy available for dispensing.

DISCIPLINE CONSIDERATIONS

41. On July 19, 2006 an inspection was conducted of respondents' licensed premises by a pharmacy board inspector. The inspection resulted in the issuance of correction orders for many of the same violations alleged above, to wit: B&P section 4081, CCR sections 1711, 1715, and CFR sections 1304.04, 1304.11, and 1305.09.

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 Permit Number PHY 15178, issued to Westside Pharmacy ;

2. Revoking or suspending Pharmacist license Number RPH 26308, issued to Willie James Whisenhunt.;

3. Ordering Westside Pharmacy and Willie James Whisenhunt 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: 4/28/13

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

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