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

In the Matter of the Accusation Against: **ST. JOSEPH'S MEDICAL CENTER; CATHOLIC HEALTHCARE WEST; DIGNITY HEALTH** **1800 North California Street** **Stockton, California 95204** **Original Permit No. HSP 45514** **and** **HARRIET FRANCES CATANIA** **3949 Glen Abby Circle** **Stockton, California 95219** **Original Pharmacist License No. RPH 26621** Respondents.	Case No. 5042 **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 July 16, 1970, the Board of Pharmacy issued Original Pharmacist License Number RPH 26621 to Harriet F. Catania (Respondent Catania). The Original Pharmacist

License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2016, unless renewed.

3. On or about March 15, 2002, the Board of Pharmacy issued Original Permit Number HSP 45514 to Catholic Healthcare West, dba St. Joseph's Medical Center (Respondent St. Joseph's). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2015, unless renewed.

4. On or about February 13, 2012, the Board of Pharmacy issued Original Permit Number HSP 45514 to Dignity Health, dba St. Joseph's Medical Center (Respondent St. Joseph's). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2015, unless renewed.

5. Respondent Harriet F. Catania served as the Pharmacist-in-Charge at Respondent St. Joseph's from March 15, 2002, through November 1, 2010.

JURISDICTION

6. 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.

7. Section 4300 of the Code states, in pertinent part:

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

STATUTORY PROVISIONS

8. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self use in humans or animals, and includes the following:

"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

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(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

9. 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 manufacturer, wholesaler, 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.

(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. . . ."

10. Section 4105 of the Code states, in pertinent part:

"(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.

"(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

"(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist in charge, the pharmacist on duty if the pharmacist in charge is not on duty, or, in the case of a veterinary food animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a

hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing related records maintained electronically. . . ."

11. 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."

12. 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. . . ."

13. Section 4333 of the Code states, in pertinent part, that all prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board licensed facility for at least three years.

REGULATIONS

14. California Code of Regulations, title 16, section 1714, states, 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.

". . .

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist. . . ."

15. California Code of Regulations, title 16, 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."

16. Code of Federal Regulations, title 21, section 1304.21, states:

"(a) Every registrant required to keep records pursuant to § 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

"(b) Separate records shall be maintained by a registrant for each registered location except as provided in § 1304.04 (a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

"(c) Separate records shall be maintained by a registrant for each independent activity for which he/she is registered, except as provided in § 1304.22(d).

(d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported,

or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips)."

COST RECOVERY

17. 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.

DANGEROUS DRUGS/CONTROLLED SUBSTANCES

18. ***Hydrocodone/acetaminophen (hc/apap)*** is a Schedule III controlled substance as designated by Health and Safety Code section 11056, subdivision (e)(4).

19. ***Ambien/zolpidem*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(32).

20. ***Lunesta***, which contains ***Eszopiclone***, is a Schedule IV controlled substance as designated by Code of Federal Regulations, title 21, section 1308.14, subdivision (c)(53).

21. ***Alprazolam*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(1).

22. ***Diazepam*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(9).

23. ***Lorazepam*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(16).

FACTUAL BACKGROUND

24. Respondent St. Joseph's was a 300-bed acute care hospital. It had a traditional "inpatient" pharmacy (IPRX) to care for hospitalized patients, and an outpatient pharmacy (OPRX), a traditional walk-up type pharmacy, located in another wing of the hospital than the IPRX, which dispensed medication solely to St. Joseph's employees and an occasional homeless or indigent patient being discharged from acute care. The OPRX was staffed by one pharmacist and one pharmacy technician. The OPRX opened on May 2, 2005, and closed on September 23, 2011, consolidating its records and drugs with the IPRX.

25. On or about December 20, 2010, the Board received a "Report of Theft or Loss of Controlled Substances" from Respondent St. Joseph's. According to the report, an internal audit revealed the loss of 24,311 tablets of hydrocodone with acetaminophen in seven strengths, as well as 92 alprazolam 1 mg tablets, from the OPRX. According to the report, the cause of the loss was employee pilferage.

26. Upon receipt of the report, the Board conducted an investigation. As part of the investigation, a Board inspector visited Respondent St. Joseph's on or about August 25, 2011. During this visit, the Board inspector noted that: (1) the loss of controlled substances appeared to be only at the OPRX; and (2) Respondent St. Joseph's OPRX and IPRX did not have invoices or records of acquisition on hand for the last three years—the oldest invoices in the IPRX were from August 30, 2010, and the oldest packing slips were from February 1, 2010.

27. On or about September 8, 2011, a Board inspector and two investigators from the Drug Enforcement Administration Diversion (DEA) interviewed several staff members of Respondent St. Joseph's. And, on or about November 15, 2011, a Board investigator and DEA investigator interviewed Respondent Catania. These interviews revealed that: (1) a pharmacy technician was regularly allowed to enter the OPRX pharmacy alone, by using an unsecured key, thirty minutes before a pharmacist arrived; (2) the after-hours security alarm at the OPRX pharmacy frequently was not activated; (3) a pharmacy technician regularly entered orders for medications at the OPRX, and these orders were never reviewed by a pharmacist; (4) hydrocodone products were stored in a "fast-mover" section at the OPRX, rather than the narcotic storage cabinet, and when the hydrocodone products were later moved to the narcotic storage cabinet, the cabinet was never locked; (5) housekeeping staff were allowed to clean, unsupervised by any pharmacy staff, in the "fast mover" area of the OPRX pharmacy; (6) OPRX pharmacy staff never checked to make sure there were no drug shortages, and there was no process in place to check for drug shortages; (7) there was no policy or procedure detailing access to the OPRX and IPRX; (8) the IPRX was missing 642 controlled substance invoices; (9) the OPRX was missing 194 controlled substance prescriptions; and (10) Catania was responsible for the OPRX and IPRX.

28. Three audits were subsequently conducted regarding the controlled substance loss at Respondent St. Joseph's OPRX and IPRX—St. Joseph's internal audit, a verification audit by Chan Healthcare Auditors (Chan), and a DEA audit. The results of these audits are as follows:

a. Respondent St. Joseph's audit, for variances[1] in controlled substances from July 1, 2008, through December 2, 2010, revealed the following:

i. -1,814 variance for hc/apap 5 mg/325 mg

ii. +714 variance for hc/apap 5 mg/500 mg

iii. -106 variance for hc/apap 7.5 mg/325 mg

iv. -2,983 variance for hc/apap 7.5 mg/500 mg

v. -5,361 variance for hc/apap 7.5 mg/ 750 mg

vi. -13,507 variance for hc/apap 10 mg/325 mg

vii. -6,363 variance for hc/apap 10 mg/500 mg

b. The Chan audit, for variances in controlled substances from July 1, 2008, through December 2, 2010, revealed the following:

i. -214 variance for hc/apap 5 mg/325 mg

ii. -1,786 variance for hc/apap 5 mg/500 mg

iii. -206 variance for hc/apap 7.5 mg/325 mg

iv. -2,983 variance for hc/apap 7.5 mg/500 mg

v. -1,861 variance for hc/apap 7.5 mg/ 750 mg

vi. -13,507 variance for hc/apap 10 mg/325 mg

vii. -6,363 variance for hc/apap 10 mg/500 mg

c. The DEA audit, for variances from June 30, 2008, through September 8, 2011, revealed the following:

i. -6,660 variance for hc/apap 5 mg/325 mg

[1] The variances were calculated by comparing the total amount of each controlled substance that Respondent St. Joseph's acquired from Cardinal Health (the sole vendor that St. Joseph's purchased controlled substances from) with the total amount of each controlled substance that St. Joseph's dispensed during the audit period. A negative variance indicates missing and unaccounted for dosage units. A positive variance indicates that St. Joseph's acquired more dosage units than St. Joseph's possesses records for.

ii. +839 variance for hc/apap 5 mg/500 mg

iii. -106 variance for hc/apap 7.5 mg/325 mg

iv. -3,403 variance for hc/apap 7.5 mg/500 mg

v. -1,840 variance for hc/apap 7.5 mg/ 750 mg

vi. -13,051 variance for hc/apap 10 mg/325 mg

vii. -4,590 variance for hc/apap 10 mg/500 mg

viii. +23 variance for Ambien CR 12.5 mg

iv. +128 variance for Lunesta 2 mg

v. -363 variance for alprazolam 1 mg

vi. +63 variance for alprazolam 0.5 mg

vii. +78 variance for alprazolam 0.25 mg

viii. -181 variance for diazepam 10 mg

ix. -48 variance for diazepam 5 mg

x. -141 variance for diazepam 2 mg

xi. -252 variance for lorazepam 2 mg

xii. -8 variance for lorazepam 0.5 mg

xiii. +32 variance for lorazepam 1 mg

29. On or about October 2012, the DEA audit disclosed that a Respondent St. Joseph's had a total of 836 missing invoices for controlled substances, and 570 invoices without the date received.

RESPONDENT ST. JOSEPH'S

FIRST CAUSE FOR DISCIPLINE

(Unsecured Pharmacy)

30. Respondent St. Joseph's is subject to disciplinary action under California Code of Regulations, title 16, section 1714, subsection (b), in that Respondent failed to maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed, as alleged above in paragraphs 26-29, and all of their subparts.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Current Inventory)

31. Respondent St. Joseph's is subject to disciplinary action under section 4081, subsection (a), of the Code, and California Code of Regulations, title 16, section 1718, in that Respondent failed to keep a controlled substance current inventory for at least three years after the date of the inventory, as alleged above in paragraphs 26-27, and 29.

THIRD CAUSE FOR DISCIPLINE

(Incomplete Records)

32. Respondent St. Joseph's is subject to disciplinary action under sections 4081, subsection (a), 4105, and 4133 of the Code in that Respondent failed to maintain all records of manufacture, sale, acquisition, or disposition of controlled substances open to inspection by authorized officers of the law, and failed to preserve these records for at least three years from the date of making, as alleged above in paragraphs 26-29 and all of their subparts.

FOURTH CAUSE FOR DISCIPLINE

(Incomplete Records)

33. Respondent St. Joseph's is subject to disciplinary action under Code of Federal Regulations, title 21, section 1304.21, subdivision (a), by and through Business and Professions Code sections 4081, 4105, and 4333, in that Respondent failed to maintain an accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of, as alleged above in paragraphs 26-29 and all of their subparts.

FIFTH CAUSE FOR DISCIPLINE

(Incomplete Records)

34. Respondent St. Joseph's is subject to disciplinary action under Code of Federal Regulations, title 21, section 1304.21, subdivision (d), by and through Business and Professions Code sections 4081, 4105, and 4333, in that Respondent failed to record dates of receipt, importation, distribution, exportation, or other transfers of controlled substances, as alleged above in paragraphs 26-29 and all of their subparts.

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RESPONDENT CATANIA

SIXTH CAUSE FOR DISCIPLINE

(Unsecured Pharmacy)

35. Respondent Catania is subject to disciplinary action under California Code of Regulations, title 16, section 1714, subdivision (d), in that as the Pharmacist-in-Charge for Respondent St. Joseph's, Catania failed to ensure that each pharmacist while on duty was responsible for the security of the prescription department, including provisions for effective control against theft or diversion of controlled substances, and records for such controlled substances, and that possession of a key to the pharmacy where dangerous drugs and controlled substances were stored was restricted to a pharmacist, as alleged above in paragraphs 25-28 and all of their subparts.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Current Inventory)

36. Respondent Catania is subject to disciplinary action under section 4081, subsection (a), of the Code, and California Code of Regulations, title 16, section 1718, in that as the Pharmacist-in-Charge for Respondent St. Joseph's, Catania failed to keep a controlled substance current inventory for at least three years after the date of the inventory, as alleged above in paragraphs 26-27, and 29.

EIGHTH CAUSE FOR DISCIPLINE

(Incomplete Records)

37. Respondent Catania is subject to disciplinary action under sections 4081, subsection (a), 4105, and 4133 of the Code in that as the Pharmacist-in-Charge for Respondent St. Joseph's, Catania failed to maintain all records of manufacture, sale, acquisition, or disposition of controlled substances open to inspection by authorized officers of the law, and failed to preserve these records for at least three years from the date of making, as alleged above in paragraphs 26-29 and all of their subparts.

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NINTH CAUSE FOR DISCIPLINE

(Incomplete Records)

38. Respondent Catania is subject to disciplinary action under Code of Federal Regulations, title 21, section 1304.21, subdivision (a), by and through Business and Professions Code sections 4081, 4105, and 4333, in that as the Pharmacist-in-Charge for Respondent St. Joseph's, Catania failed to maintain an accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of, as alleged above in paragraphs 26-29 and all of their subparts.

TENTH CAUSE FOR DISCIPLINE

(Incomplete Records)

39. Respondent Catania is subject to disciplinary action under Code of Federal Regulations, title 21, section 1304.21, subdivision (d), by and through Business and Professions Code sections 4081, 4105, and 4333, in that as the Pharmacist-in-Charge for Respondent St. Joseph's, Catania failed to record dates of receipt, importation, distribution, exportation, or other transfers of controlled substances, as alleged above in paragraphs 26-29 and all of their subparts.

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 HSP 45514, issued to St. Joseph's Medical Center; Catholic Healthcare West; Dignity Health;

2. Revoking or suspending Original Pharmacist License Number RPH 26621, issued to Harriet Frances Catania, Pharmacist-in-Charge at St. Joseph's Medical Center;

3. Ordering St. Joseph's Medical Center and Harriet F. Catania 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

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

DATED: 5/10/14

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

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