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

In the Matter of the Accusation Against: **DIGNITY HEALTH dba WOODLAND HEALTHCARE PHARMACY** **632 West Gibson** **Woodland, CA 95695** **Pharmacy Permit No. PHY 45513** **and** **WAYNE DALLAS** **826 Lakeside Drive** **Anderson, SC 29621** **Pharmacist License No. RPH 30680** Respondents.	Case No. 5512 **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 March 15, 2002, the Board of Pharmacy issued Pharmacy Permit Number PHY 45513 to Catholic Healthcare West to do business as Woodland Healthcare Pharmacy (Respondent Woodland). On or about February 13, 2012, Catholic Healthcare West

changed its name to Dignity Health. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2016, unless renewed.

3. On or about November 23, 1976, the Board of Pharmacy issued Pharmacist License Number RPH 30680 to Wayne Dallas (Respondent Dallas). Respondent Dallas was pharmacist-in-charge of Woodland from on or about August 16, 2004 to March 25, 2014. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and expired on March 31, 2015.

JURISDICTION

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

CALIFORNIA BUSINESS AND PROFESSIONS CODE

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

> (a) All records of manufacture and of sale, acquisition, receipt, shipment, 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 . . . permit . . . who maintains a stock of dangerous drugs or dangerous devices.
>
> (b) The owner, officer, and partner of a pharmacy . . . shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

6. 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.

7. 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.

8. 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. . . Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

. . .

(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.

. . .

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

9. Section 4113 of the Code states in pertinent part:

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

10. Section 4332 of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

HEALTH AND SAFETY CODE

11. Section 11007 of the Code states:

'Controlled substance,' unless otherwise specified, means a drug, substance, or immediate precursor which is listed in any schedule in Section 11054, 11055, 11056, 11057, or 11058.

12. The following drugs, audited during the inspection subject of this accusation, are Scheduled II controlled substances under section 11055 of the Code:

(a) hydrocodone/acetaminophen[1] (an opioid based narcotic);

(b) "Opana," a brand of oxymorphone (an opioid based narcotic);

(c) hydromorphone (an opioid based narcotic);

(d) fentanyl (an opioid based narcotic);

(e) methylphenidate (a stimulant);

(f) methadone (an opioid based narcotic).

CALIFORNIA CODE OF REGULATIONS

13. Title 16, section 1707.2 states in pertinent part:

(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.

14. 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.

[1] At the time of the audit, hydrocodone/acetaminophen was a Schedule III Controlled Substance under Health and Safety Code section 11056(e)(4).

Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

15. Title 16, section 1718 states in pertinent part:

'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.

CODE OF FEDERAL REGULATIONS

16. Title 21, Code of Federal Regulations, section 1304.03, subdivision (a), states:

Every registrant, including collectors, shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant that is authorized to conduct other activities without being registered to conduct those activities, pursuant to §§ 1301.22(b), 1307.11, 1307.13, or part 1317 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered or authorized to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately, nor that separate records are required for each activity. The intent of the Administration is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity. Also, the Administration does not wish to require separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled item, he must keep a record of the quantity manufactured; when he distributes a quantity of the item, he must use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place, and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.

17. Title 21, Code of Federal Regulations, section 1304.11 states, in pertinent part:

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which

he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

. . . .

(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 . . .

18. Title 21, Code of Federal Regulations, section 1304.21 states, in pertinent part:

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

. . . .

(d) In recording dates of receipt, importation, distribution, exportation, other transfers, or destruction, the date on which the controlled substances are actually received, imported, distributed, exported, otherwise transferred, or destroyed shall be used as the date of receipt, importation, distribution, exportation, transfer, or destruction (e.g., invoices, packing slips, or DEA Form 41) . . .

19. Title 21, Code of Federal Regulations, section 1305.13, subdivision (e), states that "[t]he 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."

COST RECOVERY

20. Code section 125.3 provides, in pertinent part, that a 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

21. On or about April 4, 2014, the board received a letter from the Pharmacy Director of Respondent Woodland indicating that during routine audits it was discovered the pharmacy was missing 21,839 tablets of hydrocodone/acetaminophen 10mg tablets.

22. On or about April 7, 2014, L.M., Enforcement Analyst with the Board requested additional documentation of the loss from Respondent Woodland. On or about May 5, 2014, the Board received audit documentation, statements, and interview summaries from an attorney representing Woodland.

23. On or about December 10, 2014, Board Inspectors J.H. and P.P.S. conducted an inspection at Respondent Woodland. During the inspection, the Board Inspectors observed Technician G.S. helping at least three patients with new prescriptions and technician G.S. did not inform a pharmacist of the need for new prescription consultations.

24. Inspector J.H. spoke extensively with D.F., Pharmacy Director of Respondent Woodland. D.F. advised that Respondent Woodland had terminated the previous Pharmacist in Charge (PIC), Respondent Wayne Dallas. The new PIC at the time of the inspection was M.K., who had been PIC for approximately one month. D.F. advised that as a result of the missing hydrocodone/acetaminophen, Respondent Woodland hired outside consultant B.D. and outside company CHAN Healthcare.

25. On April 25, 2014, CHAN issued a report noting Respondent Dallas:

1. Had the ability to reject key controls and processes built into the inventory tracking system;

2. Inadequately placed security cameras in the pharmacy and directed those security camera feeds to his office;

3. Could manipulate the inventory tracking system by deleting National Drug Codes from the inventory history;

4. Allowed staff and others to use his passwords and failed to require staff to not share passwords;

5. Did not implement a pharmacy server back-up procedure; and

6. Allowed untraceable access to the controlled substance inventory.

26. The CHAN report identified six areas of concern needing correction:

1. Respondent Woodland failed to fully utilize the Pharmacy Inventory Management System;

2. Respondent Woodland failed to adequately segregate the duties of the employees;

3. Respondent Dallas was able to delete National Drug Codes, purchase, and dispensing history from the inventory tracking system;

4. Employee passwords were not secure;

5. Respondent Woodland's computer server did not have a back-up; and

6. Respondent Woodland's pharmacy and controlled substances access was not logged.

27. On June 23, 2014, CHAN conducted an unannounced audit at Respondent Woodland to test controlled substance diversion monitoring and reporting. During the audit, two issues were identified:

1. There was an inability to identify discrepancies because Respondent Woodland's inventory was not adjusted after the recently identified loss making it impossible to identify current discrepancies needing to be researched, resolved, and/or reported; and

2. The Controlled Substance Compliance Audit Checklist was incomplete.

28. On March 25, 2015, Inspector J.H. conducted a phone interview of Respondent Dallas.

29. On March 30, 2015, Inspector J.H. completed her audit of Respondent Woodland that covered May 21, 2012 to November 9, 2014. The audit revealed drug losses for 11 of the 18 controlled substances audited. The most significant loss was the hydrocodone/acetaminophen 10/325mg with 21,559 tablets missing followed by methadone 5mg with 2,502 tablets missing and methylphenidate 10mg with 430 tablets missing.

Drug and Dosage	Shortage	Overage
hydrocodone/acetaminophen 10/325mg	21,559 tablets	
Opana ER 20mg	185 tablets	
hydromorphone 2mg	166 tablets	
hydromorphone 4mg	83 tablets	
hydromorphone 8mg	488 tablets	
fentanyl 12mcg	11 patches	
fentanyl 75mcg	3 patches	
fentanyl 100mcg	2 patches	
methylphenidate 10mg	27 tablets	
methylphenidate 20mg	430 tablets	
methadone 5mg	2,502 tablets	
hydrocodone/acetaminophen 5/325mg		1,579 tablets
Opana ER 5mg		20 tablets
Opana ER 40mg		99 tablets
fentanyl 25mcg		35 patches
fentanyl 50mcg		6 patches
methylphenidate 5mg		3 tablets
methadone 10mg		1,424 tablets

30. One source of error was the beginning inventory conducted by Respondent Dallas who did not provide exact counts for each medication. Instead, counts were estimated with full bottles, half bottles, quarter bottles, and tenths of a bottle. The variance could be incorrect depending on how far off the estimation was at the beginning of the inventory.

FIRST CAUSE FOR DISCIPLINE

(Woodland Healthcare Pharmacy – Failure to Provide Consultation)

31. Respondent Woodland's pharmacy permit is subject to disciplinary action under California Code of Regulations, title 16, section 1707.2 in that Woodland failed to ensure patients with new prescriptions were provided with a pharmacist consult. The circumstances are as follows:

32. On or about December 10, 2014, during an inspection of Woodland, Technician G.S. failed to notify a pharmacist of three patients filling new prescriptions as described in Paragraph 23 above.

SECOND CAUSE FOR DISCIPLINE

(Woodland Healthcare Pharmacy – Failure to Maintain Adequate Operational Standards and Security of Controlled Substances)

33. Respondent Woodland's pharmacy permit is subject to disciplinary action under California Code of Regulations, title 16, section 1714(b) in that Woodland failed to maintain its facilities, space, fixtures, and equipment so that drugs are properly prepared, maintained, secured and distributed. The circumstances are as follows:

34. On March 30, 2015, Inspector Hall completed her Woodland audit that covered May 21, 2012 to November 9, 2014. Results of the audit revealed Woodland could not account for shortages in 11 of the 18 controlled substances audited during the inspection period as described in Paragraphs 21-25 above.

THIRD CAUSE FOR DISCIPLINE

(Woodland Healthcare Pharmacy – Failure to Maintain Current Inventory)

35. Respondent Woodland's pharmacy permit is subject to disciplinary action under California Code of Regulations, title 16, section 1718, and Business and Professions Code section 4081, subsection (a), in that Woodland failed to maintain a current inventory that included complete accountability for all controlled substances and dangerous drugs handled by every licensee. Respondent Woodland's pharmacy permit is also subject to disciplinary action under California Code of Regulations, title 16, section 1714, Business and Professions Code section 4301, California Code of Regulations, title 21, sections 1304.03 and 1304.11, and Code of Federal Regulations, title 21, sections 1304.03, 1304.11, and 1304.21, in that Respondent Woodland failed to maintain adequate security and proper inventory records relating to controlled substances. The circumstances are as follows:

36. On March 30, 2015, Inspector Hall completed her Woodland audit that covered May 21, 2012 to November 9, 2014. Results of the audit revealed Woodland could not account for shortages in 11 of the 18 controlled substances audited during the inspection period as described in Paragraphs 21-25 above.

FOURTH CAUSE FOR DISCIPLINE

(PIC Wayne Dallas – Failure to Maintain Adequate Operational Standards and Security of Controlled Substances)

37. Respondent Wayne Dallas's pharmacist license is subject to disciplinary action under Business and Professions Code, section 4113 in that as PIC, Respondent Dallas was responsible for the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy and Respondent Dallas failed to maintain adequate operational standards and security of controlled substances. The circumstances are as follows:

38. Based on Respondent Woodland's own internal audit completed by CHAN and Inspector J.H.'s audit from May 21, 2012 to November 9, 2014, an interview with Respondent Dallas, and an inspection on 12/10/14, it was determined that Respondent Woodland and Respondent Dallas did not have effective controls against theft or diversion of controlled substances including employees sharing passcodes and computers, the ability to delete National Drug Codes from the inventory system, multiple manual adjustments of inventory, and inaccurate or incomplete biennial inventories as described in Paragraphs 21-25 above.

FIFTH CAUSE FOR DISCIPLINE

(PIC Wayne Dallas – Failure to Maintain Current Inventory)

39. Respondent Dallas's pharmacist license is subject to disciplinary action under California Code of Regulations, title 16, section 1718, and Business and Professions Code section 4081, subsection (a), in that as PIC, Respondent Dallas failed to maintain a current inventory that included complete accountability for all controlled substances and dangerous drugs handled by every licensee. Respondent Dallas's pharmacist license is also subject to disciplinary action under California Code of Regulations, title 16, section 1714, Business and Professions Code section 4301, California Code of Regulations, title 21, sections 1304.03 and 1304.11, and Code of Federal Regulations, title 21, sections 1304.03, 1304.11, and 1304.21, in that Respondent Dallas failed to maintain adequate security and proper inventory records relating to controlled substances. The circumstances are as follows:

40. On March 30, 2015, Inspector J.H. completed her audit of Respondent Woodland that covered May 21, 2012 to November 9, 2014, where Respondent Dallas was the PIC at the time. Results of the audit revealed Respondent Woodland could not account for shortages in 11 of the 18 controlled substances audited during the inspection period as described in Paragraphs 21-25 above.

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 Permit Number PHY 45513, issued to Dignity Health dba Woodland Healthcare Pharmacy;

2. Revoking or suspending Original Pharmacist License Number RPH 30680, issued to Wayne Dallas;

3. Ordering Dignity Health dba Woodland Healthcare Pharmacy and Wayne Dallas 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

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

DATED: 4/20/16

Virginia Herold

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

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