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

In the Matter of the Accusation Against: **CLARK'S DRUG STORE PHARMACY, INC.** **2126 Solano Street** **Corning, CA 96021** **Original Permit No. PHY 36175,** **and** **WILLIAM G. MCFADDEN** **2126 Solano Street** **Corning, CA 96021** **Original Pharmacist License No. RPH 29744** Respondents.	Case No. 5038 **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 February 23, 1990, the Board of Pharmacy issued Original Permit Number PHY 36175 to Clark's Drug Store Pharmacy, Inc. (Respondent Clark's). The Original

Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2014, unless renewed.

3. On or about August 4, 1975, the Board of Pharmacy issued Original Pharmacist License Number RPH 29744 to William G. McFadden (Respondent McFadden). The Original Pharmacist License 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. Respondent McFadden is and has been the Pharmacist-in-Charge at Respondent Clark's since July 26, 2010.

JURISDICTION

5. 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.

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

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

STATUTORY PROVISIONS

7. 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.

"(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."

8. 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. . . ."

9. 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."

10. 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. . . ."

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REGULATIONS

11. 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."

12. Code of Federal Regulations, title 21, section 1301.11, states, in pertinent part:

"(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.). . . ."

13. Code of Federal Regulations, title 21, section 1304.03, states, in pertinent part:

"(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to § 1301.22(b) of this chapter or pursuant to §§ 1307.11-1307.13 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered 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. . . ."

14. 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

15. 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

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

17. ***Carisoprodol*** is a Schedule IV controlled substance as designated by Code of Federal Regulations, title 21, section 1308.14, subdivision (c)(5).

18. ***Clonazepam*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(7).

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

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

21. ***Modafinil*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (f)(3).

22. ***Phenobarbital*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(26).

23. ***Phentermine*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (f)(4).

24. ***Zolpidem*** is a Schedule IV controlled substance as designated by Health and Safety Code section 11057, subdivision (d)(32).

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RESPONDENT CLARK'S DRUG STORE PHARMACY, INC.

FIRST CAUSE FOR DISCIPLINE

(Failure to Account for all Controlled Substances)

25. Respondent Clark's Drug Store Pharmacy, Inc. is subject to disciplinary action under section 4081, subdivision (b), of the Code in that Respondent failed to maintain records and a current inventory of its sale, acquisition, or disposition of controlled substances. The circumstances are as follows:

26. On or about June 7, 2013, the Board conducted an audit of the controlled substances that Respondent had sold, acquired, or dispensed from May 1, 2011, through April 23, 2013. The audit revealed the following variances[1]:

a. -222 (1.2%) dosage unit variance for alprazolam 0.25 mg

b. -199 (0.62%) dosage unit variance for alprazolam 0.5 mg

c. -687 (2.07%) dosage unit variance for alprazolam 1 mg

d. +243 (4.58%) dosage unit variance for alprazolam 2 mg

e. -5 dosage unit variance for carisoprodol

f. -713 (4.81%) dosage unit variance for clonazepam 0.5 mg

g. +190 (1.15%) dosage unit variance for clonazepam 1 mg

h. +200 (1.24%) dosage unit variance for hydrocodone/acetaminophen 7.5/325 mg

i. +16,847 (2.83%) dosage unit variance for hydrocodone/acetaminophen 10/325 mg

j. -7 (2.3%) dosage unit variance for hydrocodone/acetaminophen 10/660 mg

k. -25,200 (81.96 %) ml variance for hydrocodone/homatropine 5/1.5 mg/5 ml

l. +83 (25.93%) dosage unit variance for modafinil 100 mg

m. +152 (10.78%) dosage unit variance for modafinil 200 mg

n. -251 (2.48%) dosage unit variance for phenobarbital ½ grain

[1] The variances were calculated by comparing the total amount of each controlled substance that Respondent acquired with the total amount of each controlled substance that Respondent dispensed during the audit period. A negative variance indicates missing and unaccounted for dosage units. A positive variance indicates that Respondent acquired more dosage units than Respondent possesses records for.

o. -44 (22%) dosage unit variance for phentermine 15 mg

p. +8 (0.44%) dosage unit variance for phentermine 30 mg

q. -96 (8%) dosage unit variance for phentermine 37.5 mg

r. -450 (1.08%) dosage unit variance for zolpidem 10 mg

s. -246 (2.39%) dosage unit variance for zolpidem ER 12.5 mg

27. On or about July 2, 2013, the Board requested that Respondent provide a detailed explanation of the variances identified in the audit.

28. On or about September 9, 2013, Respondent provided the Board with its response to the audit, which consisted solely of a handwritten table indicating Respondent's calculation of the variances identified in the audit. Respondent failed to provide an explanation of its calculations, variances, or any supporting documentation used for its calculations such that the Board was unable to verify Respondent's calculations.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records and Inventories of all Controlled Substances)

29. Respondent Clark's Drug Store Pharmacy, Inc. is subject to disciplinary action under Code of Federal Regulations, title 21, sections 1304.03, subdivision (a), and 1304.21, subdivision (a), by and through section 4301(o) of the Code in that Respondent failed to maintain records and a current inventory of its controlled substances. The circumstances are set forth with more particularity in paragraphs 26-28, and all of their subparts.

RESPONDENT WILLIAM G. MCFADDEN

THIRD CAUSE FOR DISCIPLINE

(Failure to Account for all Dangerous Drugs)

30. Respondent William G. McFadden (Respondent McFadden) is subject to disciplinary action under section 4081, subdivision (b) of the Code in that as the pharmacist-in-charge for Respondent Clark's Drug Store Pharmacy, Inc. (Respondent Clark's), Respondent McFadden failed to maintain records and a current inventory of Respondent Clark's sale, acquisition, or disposition of controlled substances. The circumstances are described with more particularity in paragraphs 26-28, and all of their subparts.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records and Inventories of all Controlled Substances)

31. Respondent William G. McFadden (Respondent McFadden) is subject to disciplinary action under Code of Federal Regulations, title 21, sections 1304.03, subdivision (a), and 1304.21, subdivision (a), by and through section 4301(o) of the Code in that as the pharmacist-in-charge for Respondent Clark's Drug Store Pharmacy, Inc. (Respondent Clark's), Respondent McFadden failed to maintain records and a current inventory of Respondent Clark's controlled substances. The circumstances are described with more particularity in paragraphs 26-28, and all of their subparts.

MATTERS IN AGGRAVATION

32. On or about January 17, 2005, In the Matter of the Accusation Against William G. McFadden dba Clark's Drug Store Pharmacy, Case No. 2752, Respondents Clark's Pharmacy Permit No. PHY 36175 was placed on three years probation, and Respondent McFadden's Pharmacist License No. RPH 29744 was placed on five years probation, following the filing of an accusation alleging that McFadden: (1) disclosed medical information without patients' prior authorization; (2) failed to properly dispose of medical records; (3) failed to identify each pharmacist responsible for filling patient prescriptions; (4) furnished controlled substances for himself; (5) dispensed medication while under the influence; (6) failed to maintain pharmacy security; (7) failed to maintain complete accountability for dangerous drug inventory; and (8) was convicted in 1993 of driving with a blood alcohol of .08% or greater.

33. On or about December 22, 2009, Respondent Clark's was issued a citation for: (1) failing to comply with California Code of Regulations, title 16, section 1716, which prohibits a pharmacist from varying from the requirements of a prescription without prescriber authorization; and (2) failing to comply with California Code of Regulations, title 16, section 1707.2(b)(1)(A), which requires a pharmacist to consult on a new, not previously dispensed prescription.

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34. On or about December 22, 2009, Respondent McFadden was issued a citation for failing to comply with California Code of Regulations, title 16, section 1716, which prohibits a pharmacist from varying from the requirements of a prescription without prescriber authorization.

35. On or about March 16, 2010, Respondent McFadden was issued a citation for failing to comply with California Code of Regulations, title 16, section 1716, which prohibits a pharmacist from varying from the requirements of a prescription without prescriber authorization.

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 36175, issued to Clark's Drug Store Pharmacy, Inc.;

2. Revoking or suspending Original Pharmacist License Number RPH 29744, issued to William G. McFadden, Clark's Drug Store Pharmacy, Inc.;

3. Ordering Clark's Drug Store Pharmacy, Inc. and William G. McFadden 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: 4/5/14

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

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