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

In the Matter of the Accusation Against: **NOR-CAL PHARMACIES INC.** **DBA LOCKEFORD DRUG;** **LAWRENCE WALTER HOWEN, PRES.** **14090 E. Highway 88** **Lockeford, CA 95237** **Pharmacy Permit No. PHY 39960,** **and** **LAWRENCE WALTER HOWEN** **P.O. 364** **Wallace, CA 95254** **Pharmacist License No. RPH 26598** Respondents.	Case No. 6781 **DEFAULT DECISION AND ORDER** [Gov. Code, §11520]

FINDINGS OF FACT

1. On or about April 30, 2020, Complainant Anne Sodergren, in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board), filed Accusation No. 6781 against Nor-Cal Pharmacies Inc. dba Lockeford Drug; Lawrence Walter Howen, President (Respondent Pharmacy) and Lawrence Walter Howen (Respondent Howen) before the Board of Pharmacy. (Accusation attached as Exhibit A.)

2. On or about April 28, 1994, the Board issued Pharmacy Permit No. PHY 39960 to Respondent Pharmacy. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 6781 and expired on April 1, 2020, and has not yet been renewed. This lapse in licensure, however, pursuant to Business and Professions Code sections 118(b) and 4300.1 does not deprive the Board of its authority to institute or continue this disciplinary proceeding.

3. On or about July 16, 1970, the Board issued Pharmacist License number RPH 26598 to Respondent Howen. The Pharmacist License was in full force and effect at all times relevant

to the charges brought in Accusation No. 6781 and will expire on February 28, 2021, unless renewed.

4. On or about May 4, 2020, Respondents were served by Certified and First Class Mail copies of the Accusation No. 6781, Statement to Respondent, Notice of Defense, Request for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6, and 11507.7) at Respondents' addresses of record which, pursuant to Business and Professions Code section 4100, are required to be reported and maintained with the Board. Respondent Pharmacy's address of record was and is: 14090 E. Highway 88, Lockeford, CA 95237. Respondent Howen's address of record was and is: P.O. Box 364 Wallace, CA 95254.

5. Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505(c) and/or Business and Professions Code section 124.

6. Government Code section 11506(c) states, in pertinent part:

> (c) The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense . . . and the notice shall be deemed a specific denial of all parts of the accusation . . . not expressly admitted. Failure to file a notice of defense . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

7. The Board takes official notice of its records and the fact that Respondents failed to file any Notice of Defense within 15 days after service upon them of the Accusation, and therefore waived their rights to a hearing on the merits of Accusation No. 6781.

8. California Government Code section 11520(a) states, in pertinent part:

> (a) If the respondent either fails to file a notice of defense . . . or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without any notice to respondent . . . .

9. Pursuant to its authority under Government Code section 11520, the Board finds Respondents are in default. The Board will take action without further hearing and, based on the relevant evidence contained in the Default Decision Investigatory Evidence Packet in this matter, as well as taking official notice of all the investigatory reports, exhibits and statements contained therein on file at the Board's offices regarding the allegations contained in Accusation No. 6781,

finds that the charges and allegations in Accusation No. 6781, are separately and severally, found to be true and correct by clear and convincing evidence.

10. The Board finds that the actual costs for Investigation and Enforcement are $29,739.50 as of August 23, 2020.

DETERMINATION OF ISSUES

1. Based on the foregoing findings of fact Respondent Nor-Cal Pharmacies Inc. dba Lockeford Drug; Lawrence Walter Howen, President has subjected its Pharmacy Permit No. PHY 39960 to discipline.

2. Based on the foregoing findings of fact Respondent Lawrence Walter Howen has subjected his Pharmacist License number RPH 26598 to discipline.

3. The agency has jurisdiction to adjudicate this case by default.

4. The Board of Pharmacy is authorized to revoke Respondent Pharmacy's Pharmacy Permit and Respondent Howen's Pharmacist License based upon the following violations alleged in the Accusation which are supported by the evidence contained in the Default Decision Investigatory Evidence Packet in this case:

a. Respondents failed to maintain operational standards and security in violation of Code section 4301, subdivisions (j), and (o), and Regulation section 1714, subdivision (b), in that Respondent Pharmacy's facilities, space, fixtures, and equipment were dirty, dusty, and contained spider webs, a refrigerator contained food items intermingled with drug stock, there were numerous expired drugs in active inventory, and overflowing trash and recycle bins.

b. Code section 4301, subdivisions (j) and (o), and Regulations section 1757, subdivision (a), in that Respondent failed to complete self-assessments prior to July 1 of every odd numbered year. The last self-assessment completed prior to the inspection on March 26, 2019, was dated June 19, 2009.

c. Code section 4301, subdivisions (j) and (o), and Regulations section 1715.65, subdivision (c)(1), in that Respondents failed to perform a physical count of federal Schedule II Controlled Substances.

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d. Code section 4301, subdivisions (j) and (o), and Regulations section 1715.65, subdivision (c)(5), in that Respondents failed to identify possible causes of overages in writing and incorporate that information into the October 1, 2018, to December 31, 2018, quarterly federal Controlled Substance Schedule II reconciliation report.

e. Code section 4301, subdivisions (j) and (o), and Regulations section 1715.65, subdivision (d), in that Respondents failed to report identified losses of controlled substances to the Board within the mandated time frames, to identify the cause of the losses, and to document an investigation of the cause of the losses and actions necessary to prevent additional losses.

f. Code section 4301, subdivisions (j) and (o), and Code of Federal Regulations (CFR) section 1301.75, subdivision (b), in that Respondents failed to store controlled substances either in a securely locked, substantially constructed cabinet or dispersed throughout the stock of non-controlled substances in such a manner as to obstruct theft or diversion. In fact, controlled substances were stored together in a non-locking cardboard box.

g. Code section 4301, subdivisions (j) and (o), and CFR section 1304.04,subdivision (h)(2), in that Respondents failed to maintain paper prescriptions for Schedule III-V and non-controlled medications.

h. Code section 4301 subdivision (o), in that Respondent Howen did not have a nametag stating his name and that he is a pharmacist.

i. Code section 4301, subdivision (o), in that Pharmacy Technician A.R. did not have a name tag identifying A.R. by name and as a pharmacy technician.

j. Code section 4301, subdivision (o), in that Respondents allowed a pharmacy technician to work without the direct supervision of a pharmacist.

k. Code section 4301, subdivisions (j) and (o), and Code section 4169, subdivision (a)(3), in that Respondents intermingled misbranded drugs with active inventory, several of which were expired but still being used to fill prescriptions, and had three (3) prescription vials containing tablets but without any labeling as to drug name, strength, manufacturer, lot number, or expiration date.

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l. Code section 4301, subdivision (o), violating laws governing pharmacy in that Respondents failed to have a written policy and procedure regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods.

m. Code section 4301, subdivision (o), in that Respondents failed to have a written policy and procedure in place to help patients with limited or no English proficiency understand the information on the label in the patient's own language.

n. Code section 4301, subdivisions (j) and (o), and Regulations section 1715.6, in that Respondents failed to report to the Board in writing within thirty (30) days of a theft of controlled substances from the pharmacy including Norco, Xanax, and promethazine with codeine.

o. Code section 4301, subdivisions (j) and (o), and CFR section 1301.74, subdivision (c), in that Respondents failed to report to the DEA that Respondents had suffered a theft of controlled substances including Norcor, Xanax, and promethazine with codeine.

p. Code section 4301, subdivisions (j) and (o), and Code section 4076, subdivisions (a)(2) and (a)(5), in that Respondents failed to include mandatory information on prescription drug labels.

q. Code section 4301, subdivisions (j) and (o), and Regulations 1707.5, subdivision (a), in that Respondents labeled a prescription improperly since the patient's name, the drug's name and strength, directions for using the drug, and the condition for which the drug was prescribed did not comprise 50% of the label.

r. Code section 4301, subdivisions (j) and (o), and Health and Safety Code section 11165, in that during a three (3) year period, Respondents dispensed 427 prescriptions comprising in total 36,149 units of controlled substance and failed to report these prescriptions to CURES.

s. Code section 4301, subdivisions (j) and (o), and Code section 4332, 4333, 4081, 4105, and Health and Safety Code section 11205, in that Respondents failed to maintain prescription records as required. Respondents failed to provide 441 controlled substances prescription documents when requested.

t. Code section 4301, subdivisions (j) and (o), CFR, title 21, section 1306.04, subdivision (a), Health and Safety Code section 11153, subdivision (a), and Regulations section

1761, subdivisions (a) and (b), by dispensing more than 700 prescriptions that had significant irregularities and red flags for abuse or illegitimacy.

u. Code section 4301, subdivision (c), gross negligence, in that Respondents ignored numerous red flags showing diversion when filling more than 700 prescriptions and dispensing more than 100,000 dosages of controlled substances, and Respondents failed to report dispensing more than 30,000 dosage units of controlled units to CURES.

v. Code section 4301, subdivision (d), clearly excessively furnishing controlled substances, in that Respondents failed to resolve or attempt to resolve numerous red flags showing diversion when filling more than 700 prescriptions and dispensing more than 100,000 dosages of controlled substances.

w. Code section 4301, subdivision (o), in that Respondents incorrectly filled and sold a prescription for Zoloft (sertraline hydrochloride) with trazodone.

x. Code section 4301, subdivision (o), and Regulations section 1711, in that Respondents failed to complete or make available a quality assurance report after incorrectly filling and selling a prescription for Zoloft with trazodone.

y. Code section 4301, subdivision (o), and Code sections 4081 and 4333, and Regulations section 1708.2, in that Respondents failed to submit a discontinuance of business form to the Board when closing the pharmacy, failed to identify for the Board where Respondent's drug products would be transferred, failed to provide a final inventory, and failed to notify the Board where the records of drug acquisition and disposition would be held for the required three (3) year period.

ORDER

IT IS SO ORDERED that Pharmacy Permit No. PHY 39960 issued to Respondent Nor-Cal Pharmacies Inc. dba Lockeford Drug; Lawrence Walter Howen, President is revoked.

IT IS SO ORDERED that Pharmacist License No. RPH 26598 issued to Lawrence Walter Howen is revoked.

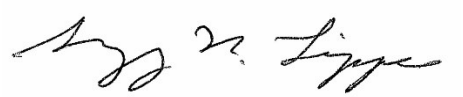
Pursuant to Government Code section 11520, subdivision (c), Respondents may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within

seven (7) days after service of the Decision on Respondents. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

This Decision shall become effective on November 4, 2020 at 5:00 p.m.

It is so ORDERED October 5, 2020

FOR THE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

By 

Greg Lippe
Board President

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Attachment:
Exhibit A: Accusation

Exhibit A

Accusation

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BEFORE THE
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In the Matter of the Accusation Against**:** **NOR-CAL PHARMACIES INC.** **DBA LOCKEFORD DRUG;** **LAWRENCE WALTER HOWEN, PRES.** **14090 E. Highway 88** **Lockeford, CA 95237** **Pharmacy Permit No. PHY 39960,** **and** **LAWRENCE WALTER HOWEN** **P.O. Box 364** **Wallace, CA 95254** **Pharmacist License No. RPH 26598** Respondents.	Case No. 6781 **ACCUSATION**

PARTIES

1. Anne Sodergren (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 April 28, 1994, the Board of Pharmacy issued Pharmacy Permit Number PHY 39960 to Nor-Cal Pharmacies Inc. dba Lockeford Drug; Lawrence Walter Howen, President

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(Respondent Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2020, unless renewed.

3. On or about July 16, 1970, the Board of Pharmacy issued Pharmacist License Number RPH 26598 to Lawrence Walter Howen (Respondent Howen). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2021, 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 (Code) unless otherwise indicated

5. 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.
>
> …
>
> (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

6. 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.

STATUTORY PROVISIONS

7. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

…

(j) The violation of any of the statutes of this state, of 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.

…

8. Section 680 of the Code states in pertinent part:

(a) Except as otherwise provided in this section, a health care practitioner shall disclose, while working, his or her name and practitioner's license status, as granted by this state, on a name tag in at least 18-point type…

9. 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.

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10. Section 4073 of the Code states in pertinent part:

(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients…

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

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

…

(2) The directions for the use of the drug.

…

(5) The date of issue…

12. Section 4081 of the Code states:

(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.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

13. 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.

…

(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.

…

14. Section 4169 of the Code states in pertinent part:

(a) A person or entity shall not do any of the following:

…

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code…

15. 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.

HEALTH AND SAFETY CODE

16. Health and Safety Code section 11153 states in pertinent part:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use…

17. Health and Safety Code section 11165 states in pertinent part:

…

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, and respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed.

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18. Health and Safety Code section 11205 states:

The owner of a pharmacy or any person who purchases a controlled substance upon federal order forms as required pursuant to the provisions of the Federal "Comprehensive Drug Abuse Prevention and Control Act of 1970," (P.L. 91-513, 84 Stat. 1236), relating to the importation, exportation, manufacture, production, compounding, distribution, dispensing, and control of controlled substances, and who sells controlled substances obtained upon such federal order forms in response to prescriptions shall maintain and file such prescriptions in a separate file apart from noncontrolled substances prescriptions. Such files shall be preserved for a period of three years.

19. Health and Safety Code section 111330 states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

20. Health and Safety Code section 111335 states:

Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

21. Health and Safety Code section 111440 states:

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

REGULATORY PROVISIONS

22. California Code of Regulations, title 16, (Regulations) section 1707.5 states in pertinent part:

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted and the name of the manufacturer. In the professional judgment of the pharmacist:

(i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and

(ii) The manufacturer's name may be listed outside of the patient-centered area.

(C) The directions for the use of the drug.

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(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

…

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter…

23. Regulations section 1708.2 states:

Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings and shall follow official instructions given by the board applicable to the transaction.

24. Regulations 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.

…

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created…

25. Regulations 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…

26. Regulations section 1714.1 states in pertinent part:

…

(f) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of

ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours…

27. Regulations 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…

28. Regulations section 1715.6 states:

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

29. Regulations section 1715.65 states in pertinent part:

…

(c) A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require:

(1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;

…

(5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances…

30. Regulations section 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

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31. Regulations section 1761 states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

32. Regulations section 1793.7 states in pertinent part:

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

CODE OF FEDERAL REGULATIONS

33. Code of Federal Regulations, title 21, (CFR) section 1301.74, states in pertinent part:

(c) The registrant must notify the Field Division Office of the Administration in his or her area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. Unless the theft or loss occurs during an import or export transaction, the supplier is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. In an import transaction, once a shipment has been released by the customs officer at the port of entry, the importer is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. In an export transaction, the exporter is responsible for reporting all in-transit losses of controlled substances by their agent or the common or contract carrier selected pursuant to paragraph (e) of this section within one business day of discovery of such theft or loss, until the shipment has been released by the customs officer at the port of export. The registrant must also complete, and submit to the Field Division Office in his or her area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance…

34. CFR section 1301.75, states in pertinent part:

…

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances…

35. CFR section 1304.04 states in pertinent part:

…

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

…

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file…

36. CFR section 1306.04 states in pertinent part:

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances…

COST RECOVERY

37. 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.

DRUGS

38. *Zoloft* is the brand name for the drug *sertraline* and is a dangerous drug pursuant to Code section 4022.

39. *Trazodone* is the generic name for a drug that is sold under the brand names *Oleptro* and *Desyrel*, and is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS – JUNE 13, 2019 INVESTIGATION REPORT

40. On or about March 26, 2019, Board inspectors S.K. and D.D. inspected Respondent Pharmacy due to a complaint received by the Board of Pharmacy. Respondent Howen was present.

41. Inspector D.D. focused on allegations that the pharmacy was dirty, disorganized, had expired drugs in their active inventory and other similar allegations.

42. Inspector D.D. observed dirty dishes in a sink, and the sink itself was dirty. There were bottles of medications on the counter near the sink indicating the sink is used both for drug preparations and for personal use of the pharmacy staff. Similarly, there was a standard food refrigerator containing food items intermingled with medication. There was no temperature log for the refrigerator.

43. Inspector D.D. observed approximately twenty-six (26) expired drugs in active inventory, including drugs which Respondent Howen stated had just been returned to the pharmacy by a patient. The dates of expiration for two of these drugs were February 2017, twenty-eight (28) months prior to the inspection, and April 2018, fourteen (14) months prior to the inspection. The oldest expired drug held in active inventory expired in 1991, approximately twenty-eight (28) years prior to the inspection.

44. Inspector D.D. observed empty bubble/blister packs[1] from a different pharmacy, along with medi-sets[2] with expired drugs that had been filled in the year 2000 inside large garbage bags stored under a desk and on shelves.

[1] A bubble or blister pack is a sheet of plastic with bubbles in it where the drugs are located, and the back is covered with paper or tinfoil. Each pill or dose is then pushed through the backing separately.

[2] A Medi-Set is a medication container that has separate chambers for the days of the week or for different times of day so that the patient can track when to take each medication.

45. Inspector D.D. observed empty stock bottles, garbage bags overflowing with trash or recycling, spider webs, dust, a crack in the ceiling, and boxes of expired drugs laying around the pharmacy.

46. Inspector D.D. observed that neither Respondent Howen nor his pharmacy technician were wearing nametags, and when asked if they had nametags they had neglected to wear during the inspection, they both stated they did not have name tags at all.

47. Inspector D.D. observed that Respondent Howen and his pharmacy technician were both working in different rooms, with walls between their work areas so that Respondent Howen could not observe what the technician was doing. Additionally, Respondent Howen left the computer near where the pharmacy technician was working logged in with Respondent Howen's log in information.

48. Inspector D.D. requested Respondents' most recent self-assessments of the pharmacy's compliance with pharmacy law, which is required to be completed by July 1 of every odd-numbered year. Respondent Howen provided the most recent self-assessment, which was dated June 19, 2009, approximately ten (10) years prior to the inspection.

49. Inspector D.D. reviewed Respondents' biennial inventory and quarterly schedule II controlled substances reconciliation report. The biennial inventory was dated July 13, 2017. The quarterly schedule II controlled substances reconciliation report was dated December 31, 2018, and did not contain an actual physical count of the schedule II controlled substances. Additionally, the quarterly schedule II controlled substances reconciliation report failed to include possible causes of overages, and failed to report identified losses.

50. Inspector D.D. observed that Respondent stored controlled substances together, separately from the rest of the drug stock, but in a non-locking cardboard box on the breakroom shelf. Additionally, Respondent failed to maintain paper prescriptions for Schedule II controlled substances in a separate file from all other prescriptions.

51. Inspector D.D. observed approximately eleven (11) drug prescription vials without adequate labeling, three (3) of which contained tablets but lacked any labeling as to drug name, strength, manufacturer, lot number, or expiration date.

52. Inspector D.D. observed and was informed by Respondent Howen's pharmacy technician that drugs would be taken from an in-date stock bottle and poured into a stock bottle that was empty and expired. Then, the in-date stock bottle would be kept up front to fill prescriptions, and the other would be taken to the back to fill bubble/blister packs.

53. Inspector D.D. observed bubble/blister packs with incorrect labeling in that the labeling did not include the directions for use of the drugs. Additionally, approximately thirty-four (34) bubble/blister packs did not contain the expiration date of the dispensed drug. Respondent Howen provided a sample prescription label which would be affixed to a prescription vial which was also inappropriate in that it did not have the name of the patient, name of the drug, directions for use, and the condition or purpose of the prescription comprising 50% of the label.

54. Inspector D.D. obtained and reviewed Respondents' policies and procedures, and noted that a written policy and procedure for the temporary absence of a pharmacist was not provided, nor was there a policy for the pharmacy to provide interpretive services. Inspector D.D. asked Respondent Howen to provide these policies and procedures, but Respondent Howen failed to do so.

55. Respondent Howen informed Inspector D.D. that the pharmacy had suffered a theft on or about February 26, 2019, which he reported to the Sheriff. Respondent Howen did not notify either the Board of Pharmacy or the DEA of the theft.

56. Inspector D.D. requested Respondent Howen correct issues outlined in the inspection report and provide the corrections no later than April 8, 2019, approximately two (2) weeks after the inspection. Respondent Howen obtained name tags for himself and his staff and provided a few pictures showing a marginally cleaner and more organized sink, counter, and shelving area, but failed to respond in any other respect.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards and Security)

57. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent Pharmacy failed to comply with Regulations section 1714, subdivision (b),

maintaining its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured, and distributed. The circumstances are as set forth in paragraphs 40 through 45, above, and as follows:

58. During an inspection on or about March 26, 2019, Inspector D.D. observed the following violations:

a. A dirty sink containing dirty dishes in need of washing in an area where drugs were stored and prepared.

b. A refrigerator containing food items intermingled with medication.

c. Numerous expired drugs in the active inventory.

d. Overflowing trash, plastic garbage bags full of plastic bottles and aluminum cans, boxes of paper, empty stock bottles, and assorted items everywhere with little to no discernable organization.

e. Empty bubble packs from other pharmacies in plastic garbage bags.

f. Medi-sets with expired drugs from the year 2000 in plastic garbage bags.

g. Spider webs and dust on shelving units used to store drugs.

h. A crack in the ceiling above where drugs are stored.

SECOND CAUSE FOR DISCIPLINE

(Failure to Complete Self-Assessment)

59. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for violating Regulations section 1757, subdivision (a), in that Respondent failed to complete self-assessments of the pharmacy's compliance with federal and state pharmacy law prior to July 1 of every odd numbered year. The circumstances are that during an inspection on or about March 26, 2019, it was discovered that no self-assessment had been completed since June 19, 2009, as set forth in paragraph 48, above.

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THIRD CAUSE FOR DISCIPLINE

(Failure to Perform Physical County of Schedule II Controlled Substances)

60. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for violating Regulations section 1715.65, subdivision (c)(1), in that Respondents failed to perform a physical count of federal Schedule II Controlled Substances for the October 1, 2018 to December 31, 2018, quarterly inventory, as set forth in paragraph 49, above.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Complete Inventory Reconciliation Report)

61. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for violating Regulations section 1715.65, subdivision (c)(5), in that Respondent failed to identify possible causes of overages in writing, and incorporate that information into the October 1, 2018, to December 31, 2018, quarterly federal Controlled Substance Schedule II reconciliation report, as set forth in paragraph 49, above.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Report Identified Losses to Board)

62. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), for violating Regulations section 1715.65, subdivision (d), in that Respondents failed to report in writing identified losses to the Board within the mandated time frames. Additionally, Respondents failed to identify the cause of the losses and no investigation was documented to identify the cause and actions necessary to prevent additional losses of controlled substances. These losses were identified on the October 1, 2018, to December 31, 2018, quarterly federal Controlled Substances, Schedule II reconciliation report, as set forth in paragraph 49, above.

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SIXTH CAUSE FOR DISCIPLINE

(Failure to Comply with Physical Security Controls)

63. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated CFR section 1301.75, subdivision (b), in that Respondent failed to store controlled substances either in a securely locked, substantially constructed cabinet or dispersed throughout the stock of non-controlled substances in such a manner as to obstruct theft or diversion. The circumstances are that Respondents stored controlled substances together in a non-locking cardboard box on the breakroom shelf, as set forth in paragraph 50, above.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Appropriately Maintain Records and Inventories)

64. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated CFR 1304.04, subdivision (h)(2), in that Respondents failed to maintain paper prescriptions for Schedule II controlled substances in a separate file from paper prescriptions for Schedule III-V and non-controlled medications, as set forth in paragraph 50, above.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Have Name Tag for Pharmacist)

65. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated Code section 680, subdivision (a), when during an inspection of the pharmacy on or about March 26, 2019, Respondent Howen did not have a name tag identifying his name and practitioner's license status, as set forth in paragraph 46, above.

NINTH CAUSE FOR DISCIPLINE

(Failure to Have Name Tag for Pharmacy Technician)

66. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents

violated Regulation section 1793.7, subdivision (c), when during an inspection of the pharmacy on or about March 26, 2019, Pharmacy Technician A.R. did not have a name tag identifying A.R. as a pharmacy technician, as set forth in paragraph 46, above.

TENTH CAUSE FOR DISCIPLINE

(Failure to Have Direct Supervision of Pharmacy Technician by Pharmacist)

67. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated Regulation section 1793.7, subdivision (b), by allowing a pharmacy technician to work in a pharmacy without the direct supervision of a pharmacist. The circumstances are that during the inspection on or about March 26, 2019, Inspector D.D. observed a pharmacy technician filling bubble packs of medication while the only pharmacist, Respondent Howen, was filling prescriptions on the other side of the pharmacy, at least thirty (30) feet away and with walls obscuring Respondent's Howen's line of sight and ability to monitor the pharmacy technician, as set forth in paragraph 47, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Exclude Misbranded Drugs from Active Inventory)

68. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated Code section 4169, subdivision (a)(3) by intermingling misbranded drugs with active inventory. The circumstances are that during an inspection on or about March 26, 2019, inspector D.D. observed eight (8) misbranded drugs in active inventory, and three (3) prescription vials containing tablets but without any labeling as to drug name, strength, manufacturer, lot number, or expiration date. Several of the misbranded drugs were expired and were still being used to fill prescriptions, as set forth in paragraph 51, above.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Have Written Policy and Procedure for Absence of Pharmacist)

69. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents

violated Regulation section 1714.1, subdivision (f), for failing to have a written policy and procedure regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The circumstances are that during an inspection on or about March 26, 2019, Respondents failed to have a written policy and procedure for temporary absences of a pharmacist. Inspector D.D. requested Respondent Howen provide such a policy and procedure after the inspection no later than April 8, 2019. Respondent Howen failed to provide any written policy and procedure to Inspector D.D. since the date of the inspection, as set forth in paragraph 54, above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Have Written Policy and Procedure for Interpretive Services)

70. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated Regulation section 1707.5, subdivision (d), by failing to have written policies and procedures in place to help patients with limited or no English proficiency. The circumstances are that during the inspection on or about March 26, 2019, Inspector D.D. reviewed the pharmacy's written policies and procedures and there was no such policy or procedure. Inspector D.D. requested Respondent Howen to provide such a policy and procedure after the inspection and no later than April 8, 2019. Respondent Howen failed to provide any written policy and procedure to Inspector D.D. since the date of the inspection, as set forth in paragraph 54, above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Report Theft or Loss of Controlled Substances to Board)

71. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated Regulation section 1715.6, in that on or about February 26, 2019, Respondents suffered a theft of Norco, Xanax, and promethazine with codeine. Respondents failed to report this theft in writing to the Board within thirty (30) days of discovery of the theft, as set forth in paragraph 55, above.

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FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Report Theft or Loss of Controlled Substances to the DEA)

72. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated CFR section 1301.74, subdivision (c), in that on or about February 26, 2019, Respondents suffered a theft of Norco, Xanax, and promethazine with codeine. Respondents failed to report this theft in writing to the Drug Enforcement Administration (DEA) within one (1) business day of the discovery of the theft, as set forth in paragraph 55, above.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Correctly Label Dispensed Prescriptions)

73. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated Code section 4076, subdivisions (a)(2) and (a)(5), by failing to include mandatory information on prescription drug labels. The circumstances are as set forth in paragraph 53, above, and as follows:

a. During the March 26, 2019, inspection, at lease thirty-four (34) bubble packs of prescriptions were labeled with prescription labels which did not state the directions for use of the drug.

b. During the March 26, 2019, inspection, at lease thirty-four (34) bubble packs of prescriptions were labeled with prescription labels which did not state the date of issue of the prescription.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Comply with Regulations for Prescription Labels)

74. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated Regulations section 1707.5, subdivision (a), in that on during the inspection on March 26, 2019, Respondents labeled prescription number 997703 with an improper label. The circumstances are that the patient name, name and strength of the drug, directions for use of

the drug, and the condition or purpose for which the drug was prescribed did not comprise 50% of the label, as set forth in paragraph 53, above.

FACTUAL ALLEGATIONS – JUNE 24, 2019 INVESTIGATION REPORT

75. On or about March 26, 2019, Board inspectors S.K. and D.D. inspected Respondent Pharmacy due to a complaint received by the Board of Pharmacy. Respondent Howen was present.

76. Inspector S.K. focused on CURES and corresponding responsibility issues.

77. The Controlled Substance Utilization Review and Evaluation System (CURES) is California's Prescription Drug Monitoring Program (PDMP), and requires weekly reporting by all pharmacies of all dispensed Schedule II-IV controlled substances prescriptions. Pharmacies and health care practitioners can then review their patients' CURES reports to assess whether the patient is using the controlled substance correctly, or if the patient is using multiple prescribers or pharmacies to fill controlled substance prescriptions.

78. Inspector S.K. reviewed Respondent's CURES data and found gaps of time where no CURES data was reported, which amounted to approximately eighty (80) days where Respondent Pharmacy was open for business but failed to report CURES data as required. This included approximately 427 prescriptions, and 36,129 total quantity of medications dispensed by Respondent and not reported to CURES.

79. Inspector S.K. requested all of the original prescription documents issued by prescriber Dr. D.C. for review. Respondent was unable to provide 441 original prescriptions issued by Dr. D.C. within the three years prior to this inspection.

80. Respondent ignored red flags on the prescriptions that were filled, specifically:

a. There was a higher percentage of cash payments for controlled substances than for non-controlled substances.

b. Dr. D.C. was Respondent's top prescriber. Dr. D.C.'s office was in Salinas[3], approximately 150 miles from Respondent.

[3] This prescriber also had an office in Stockton, but prescriptions are required to indicate the address of the prescriber and over 500 prescriptions indicated Salinas. There were an additional 155 prescriptions from the Stockton office.

c. Over 95% of Dr. D.C.'s prescriptions were for controlled substances. This contrasts to approximately 14% for other prescribers filled by Respondent. Additionally, Dr. D.C. indicated a specialty in complementary and alternative medicine. It is inconsistent for this specialty to have a high level of controlled substance prescriptions.

d. A majority of Dr. D.C.'s prescriptions had more than one opioid drugs prescribed concurrently, including hydrocodone/APAP, oxycodone, and methadone. This is an indication of diversion.

e. Normal use for pain medications is to start at a low dose and then increase the dose as tolerance increases. Additionally, patients have different age, weight, renal or hepatic function, diagnosis, or other factors which would require the controlled substance strength to be tailored to them. Nearly all of Dr. D.C.'s patients started at the highest dose of the controlled substance available.

f. Over 80% of all controlled substance prescriptions filled by Respondent came from Dr. D.C.

g. The patients obtaining controlled substances from Dr. D.C. all lived south of Respondent, and all passed dozens of other pharmacies in order to fill their prescriptions at Respondent pharmacy. Many patients were in Modesto, which required them to drive from Modesto south to Salinas, then north past Modesto to Respondent pharmacy, before returning to Modesto.

h. Multiple patients received similar if not identical treatment, many filled on the same day after allegedly traveling more than 150 miles to fill their prescriptions at Respondent pharmacy.

i. Some prescriptions were filled more than one month after being written.

j. Some prescriptions were antedated, having a date written on the prescription that had not yet occurred.

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EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Report Prescriptions to CURES)

81. The allegations set forth in paragraphs 70 through 73, are realleged as though fully set forth herein. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated Health and Safety Code section 11165, in that from approximately January 14, 2016, to March 26, 2019, Respondents dispensed 427 prescriptions with a total quantity of 36,149 units of controlled substance to patients without reporting the prescriptions to CURES.

NINTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Prescription Records)

82. The allegations set forth in paragraphs 70 and 74, are realleged as though fully set forth herein. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated Code sections 4332, 4333, 4081, and 4105, and Health and Safety Code section 11205, in that from approximately January 14, 2016, to March 26, 2019, Respondents failed to maintain prescription records as required. Respondents were unable to provide 441 controlled substances prescription documents when requested by a Board Inspector.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Exercise Corresponding Responsibility)

83. The allegations set forth in paragraphs 70 and 75, are realleged as though fully set forth herein. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondents violated CFR, title 21, section 1306.04, subdivision (a), Health and Safety Code section 11153, subdivision (a), and Regulations section 1761, subdivisions (a) and (b), by dispensing more than 700 controlled substances prescriptions with irregularities and red flags for abuse or illegitimacy without ensuring the prescriptions were issued for a legitimate medical purpose.

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TWENTY-FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

84. The allegations set forth in paragraphs 70 through 75, are realleged as though fully set forth herein. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (c), in that Respondents acted with gross negligence as follows:

a. Respondents filled over 700 prescriptions and dispensed over 100,000 dosage units of controlled substances without resolving or attempting to resolve numerous red flags of diversion.

b. Respondents failed to report the dispensing of over 30,000 dosage units of controlled substances to CURES.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Clearly Excessive Furnishing of Controlled Substances)

85. The allegations set forth in paragraphs 70 through 75, are realleged as though fully set forth herein. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (d), in that Respondents filled over 700 prescriptions and dispensed over 100,000 dosage units of controlled substances without resolving or attempting to resolve numerous red flags of diversion.

FACTUAL ALLEGATIONS – SEPTEMBER 26, 2019 INVESTIGATION REPORT

86. On or about August 24, 2019, the Board of Pharmacy received a complaint about a refill medication error against Respondent Pharmacy from consumer K.T.

87. Board Inspector D.D. conducted an investigation including receiving information from K.T. and requesting information from Respondent Howen.

88. K.T. alleged Respondents filled her prescription for Zoloft with the incorrect medication trazodone. K.T. took the medication once, which caused her to become mentally and physically incapacitated, unable to drive, unable to work, and required her to sleep for approximately 19 hours.

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89. When K.T. went back to the pharmacy, Respondent Howen opened the bottle and removed the trazodone, then refilled the same bottle with Zoloft, and gave K.T. the bottle back.

90. On or about September 9, 2019, Inspector D.D. sent a letter to Respondents requesting specific documents related to the medication error by September 23, 2019.

91. On or about September 25, 2019, Inspector D.D. telephoned Respondent Howen and spoke to him. Respondent Howen acknowledged receiving the request for records and stated he would fax them to Inspector D.D.

92. On or about September 25, 2019, Respondent Howen faxed some of the documents requested by Inspector D.D. but failed to provide a Quality Assurance report on the medication error.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Variation from Prescriptions)

93. The allegations set forth in paragraphs 81 through 84, are realleged as though fully set forth herein. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated Regulations section 1716 when they incorrectly filled and sold a prescription for Zoloft with the drug trazodone.

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Failing to Make Available Quality Assurance Report)

94. The allegations set forth in paragraphs 81 through 87, are realleged as though fully set forth herein. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated Regulations section 1711 when they failed to provide a quality assurance report for the medication error described in paragraph 88, above, to the Board upon request.

FACTUAL ALLEGATIONS – February 14, 2020 INVESTIGATION REPORT

95. On or about September 25, 2019, the Board Inspector D.D. attempted to contact Respondent Pharmacy through their main telephone number, and the call was forwarded to another pharmacy. Board Inspector D.D. then called a back-line telephone number and spoke to

Respondent Howen who informed Inspector D.D. that he was closing the pharmacy as soon as possible.

96. Board Inspector D.D. notified Respondent Howen of the proper procedures to close the pharmacy, including filing a discontinuance of business (DOB) form, doing a final inventory, and transferring the drug inventory and records to another board-licensed pharmacy.

97. On or about September 25, 2019, Board Inspector D.D. sent a letter to Respondent Howen confirming the information provided via telephone as set forth in paragraph 96.

98. On or about January 28, 2020, Board Inspector S.K. visited Respondent Pharmacy to ascertain whether Respondent Pharmacy was still open. Board Inspector S.K. observed that the sign on the business stating "Lockeford Drug" had been removed and the only signage was a closed sign and a notice stating Respondent Pharmacy had closed as of September 21, 2019.

99. Board Inspector S.K. observed through the windows of Respondent Pharmacy that the shelves that had previously held drug stock were empty and there was no indication of any remaining drugs or records within the business.

100. On or about January 31, 2020, Board Inspector S.K. sent Respondent Howen an email requesting the DOB form, final inventory, and information regarding the disposition of drug stock and the last three years of drug acquisition and disposition records. To date, Respondent Howen has not responded to this email, or filed the DOB form with the Board and provided other required information.

TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Properly Discontinue Business of Pharmacy)

101. The allegations set forth in paragraphs 95 through 100, are realleged as though fully set forth herein. Respondents Pharmacy and Howen are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondents violated Code sections 4081 and 4333 as well as Regulations section 1708.2 when they failed to follow official instructions given by the Board applicable to the discontinuance of the business of pharmacy. Specifically, Respondents failed to submit a discontinuance of business form, failed to identify for the Board where Respondents drug product would be transferred, failed to provide a

final inventory, and failed to notify the Board where the records of drug acquisition and disposition would be held for three required three (3) year period.

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 39960, issued to Nor-Cal Pharmacies Inc. dba Lockeford Drug; Lawrence Walter Howen, President;

2. Revoking or suspending Pharmacist License Number RPH 26598, issued to Lawrence Walter Howen;

3. Prohibiting Lawrence Walter Howen from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of any Pharmacy licensee;

4. Ordering Nor-Cal Pharmacies Inc. dba Lockeford Drug; Lawrence Walter Howen, President and Lawrence Walter Howen 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,

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

DATED: April 30, 2020

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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