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

In the Matter of the Statement of Issues Against**:**	Case No. 7127
MOAZZEM HOSSAIN CHOWDHURY **DBA CROWN VALLEY PHARMACY**	**STATEMENT OF ISSUES**
Pharmacy License Applicant	
Respondent.	

PARTIES

1. Anne Sodergren (Complainant) brings this Statement of Issues solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about September 10, 2020, the Board of Pharmacy, Department of Consumer Affairs received an application for a Pharmacy License from Moazzem Hossain Chowdhury (Respondent) dba Crown Pharmacy. On or about August 1, 2020, Respondent certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. The Board denied the application on February 10, 2021.

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Respondent's License History

3. On or about September 16, 1993, the Board of Pharmacy issued Pharmacist License Number RPH 46737 to Respondent. Pursuant to the decision and order in the disciplinary action entitled *In the Matter of the Accusation Against Moazzem H. Chowdhury, dba Desert Drugs, et al*, Case No. 3917 (OAH No. 2014010146), effective October 22, 2014, the Pharmacist License was placed on probation for a period of four (4) years. Respondent's Pharmacist License will expire on February 28, 2023, unless renewed.

JURISDICTION

4. This Statement of Issues is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code ("Code") unless otherwise indicated.

STATUTORY PROVISIONS

5. Section 4300, subdivision (c), of the Code provides, in pertinent part, that the Board "may refuse a license to any applicant guilty of unprofessional conduct."

6. 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:

. . .

"(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

. . .

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

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7. Section 4302 of the Code states:

"The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee."

8. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been

given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

Pertinent State Regulatory Law

9. 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.

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

"(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

. . .

"(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.

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11. Health and Safety Code section 11165, subdivision (d), provides:

"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, 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, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription."

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12. Health and Safety Code section 11205 provides:

"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),1 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."

13. Health and Safety Code section 11208 provides:

"In a prosecution under this division, proof that a defendant received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substances possessed by the defendant is a lesser amount than is accounted for by any record required by law is prima facie evidence of guilt."

14. Health and Safety Code section 11209, subdivision (a), provides in pertinent part:

"No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received."

15. California Code of Regulations, title 16, section 1714, states in pertinent part:

"(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

. . .

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous

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

. . .

Pertinent Federal Regulatory Law

16. Federal Code of Regulations, title 21, section 1304.04, subdivision (h), provides in pertinent part:

"Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

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

. . .

17. Federal Code of Regulations, title 21, section 1304.11, provides:

"(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.

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"(b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial 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."

FACTUAL BACKGROUND

18. Pursuant to the decision and order in the matter titled "*In the Matter of the Accusation Against Crown Valley Pharmacy, et al.* (Case No. 6042), Crown Valley Pharmacy's Permit No.PHY 51552 was placed on probation for a period of three (3) years, effective February 27, 2019, for the same violations alleged herein. Crown Valley Pharmacy has been in operation since September 2013. At all times relevant to the allegations set forth herein, Crown Valley Pharmacy was owned by Respondent's daughter, Jenisa Chowdhury (49% owner), and Willon Henderson (51% owner). At all times relevant to the allegations set forth herein, Respondent served as Crown Valley Pharmacy's manager and exercised control over the pharmacy. At all times relevant to allegations set forth herein, Respondent's pharmacist license was on probation and subject to a variety of restrictions. During the relevant time period in which Respondent was managing and exercising control over Crown Valley Pharmacy, pharmacy owner Jenisa Chowdhury was residing out of state. Among other things, Respondent controlled the bank account for the pharmacy, maintained control over the ordering and acquisition of the pharmacy's controlled substance inventories, determined which pharmaceutical wholesalers the pharmacy used, controlled the types of security systems and procedures used by the pharmacy, and had unfettered access to the entire inventory of the pharmacy.

19. On or about April 14, 2015, the Board received an anonymous online complaint involving Crown Valley Pharmacy's acquisition and dispensing of certain controlled substances.

Among other things, the complaint alleged that Respondent, Crown Valley's manager, was selling oxycodone pills and a codeine-laced cough syrup (i.e., promethazine with codeine) to people without a prescription. Oxycodone and promethazine with codeine are commonly abused controlled substances with significant street values.

20. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M) and is a dangerous drug pursuant to Code section 4022.

21. Promethazine with codeine is a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c) and is a dangerous drug pursuant to Code section 4022.

22. On or about August 13, 2015, a Board inspector performed an inspection of Crown Valley Pharmacy. Federal law requires pharmacies to complete and maintain an "initial inventory" of any and all controlled substances in its stock as of the first day on which the pharmacy begins dispensing controlled substances and also requires that subsequent "biennial inventories" be performed at least every two (2) years thereafter. (See 21 CFR § 1304.) Among other things, the inspector asked to review Crown Valley's initial controlled substance inventory. Although Crown Valley had been in operation and dispensed controlled substances prior to January 30, 2014, the initial controlled substance inventory was not performed and/or completed until January 30, 2014. In addition, the inventory for Schedule II controlled substances was not maintained separately from all other records of the pharmacy as required by federal law. The inspector advised Respondent, as Crown Valley Pharmacy's manager, that a complete and compliant inventory should be performed and provided to the Board. The Board received a copy of the newly completed controlled substance inventory the following day.

23. The inspector also obtained a variety of records related to Crown Valley Pharmacy's acquisition and dispensing of: (1) oxycodone; (2) oxycodone with acetaminophen (hereinafter, "oxycodone/apap"); and (3) promethazine with codeine between September 2013 and August 2015. Those documents included acquisition records from pharmaceutical wholesalers used by Crown Valley Pharmacy, the pharmacy's own dispensing records, records related to the

pharmacy's transactions with a reverse distributor, original prescriptions, and reports from the Controlled Substance Utilization Review and Evaluation System ("CURES.)[1]

24. These records revealed a vast disparity between the pharmacy's actual inventory of certain controlled substances and the legally documented inventory that should have been present. Specifically, the records demonstrated that Crown Valley was short in its inventory of oxycodone 30 mg by 3,666 pills, short in its inventory of oxycodone 10 mg by 326 pills, and short in its inventory of promethazine with codeine by 63 bottles (i.e. approximately 30,000 ml). Moreover, the records revealed that Crown Valley Pharmacy also could not account for the presence of massive amounts of other controlled substances in its inventory. For example, Crown Valley's inventory included 5,196 oxycodone/apap 5-325 mg pills for which there were no acquisition records, 22,579 oxycodone/apap 10-325 mg pills for which there were no acquisition records, 1,233 oxycodone 5 mg pills for which there were no acquisition records, 433 oxycodone/apap 7.5-325 mg pills for which there were no acquisition records, 148 oxycodone 20 mg pills for which there were no acquisition records, and 34 oxycodone 15 mg pills for which there were no acquisition records.

25. The inspector's analysis of the records also revealed multiple discrepancies between the quantities of oxycodone and oxycodone/apap dispensed pursuant to actual prescriptions versus the quantity dispensed pursuant to the pharmacy's dispensing records and the number of prescriptions and quantity dispensed as reported to CURES. In addition, Crown Valley Pharmacy could not produce the original prescriptions for six (6) purported prescriptions of oxycodone and oxycodone/apap that it had filled and fifteen (15) purported prescriptions of promethazine with codeine, indicating that the pharmacy had dispensed the drugs without prescriptions. The inspector also obtained a variety of records related to Crown Valley Pharmacy's acquisition and dispensing of: (1) oxycodone; (2) oxycodone with acetaminophen (hereinafter,

[11] CURES is a system for monitoring patient controlled substance history information. California Health and Safety Code section 11165 requires pharmacies to report within 7 days to the California Department of Justice every schedule II, III and IV drug prescription that is written or dispensed, and the information provided establishes the CURES database, which includes information about the drug dispensed, drug quantity and strength, patient name, address, prescriber name, and prescriber authorization number including DEA number and prescription number.

"oxycodone/apap"); and (3) promethazine with codeine between September 2013 and August 2015. Those documents included acquisition records from pharmaceutical wholesalers used by Crown Valley Pharmacy, the pharmacy's own dispensing records, records related to the pharmacy's transactions with a reverse distributor, original prescriptions, and reports from CURES.

26. These records revealed a vast disparity between the pharmacy's actual inventory of certain controlled substances and the legally documented inventory that should have been present. Specifically, the records demonstrated that Crown Valley was short in its inventory of oxycodone 30 mg by 3,666 pills, short in its inventory of oxycodone 10 mg by 326 pills, and short in its inventory of promethazine with codeine by 63 bottles (i.e. approximately 30,000 ml). Moreover, the records revealed that Crown Valley Pharmacy also could not account for the presence of massive amounts of other controlled substances in its inventory. For example, Crown Valley's inventory included 5,196 oxycodone/apap 5-325 mg pills for which there were no acquisition records, 22,579 oxycodone/apap 10-325 mg pills for which there were no acquisition records, 1,233 oxycodone 5 mg pills for which there were no acquisition records, 433 oxycodone/apap 7.5-325 mg pills for which there were no acquisition records, 148 oxycodone 20 mg pills for which there were no acquisition records, and 34 oxycodone 15 mg pills for which there were no acquisition records.

27. The inspector's analysis of the records also revealed multiple discrepancies between the quantities of oxycodone and oxycodone/apap dispensed pursuant to actual prescriptions versus the quantity dispensed pursuant to the pharmacy's dispensing records and the number of prescriptions and quantity dispensed as reported to CURES.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Prohibited Pursuant to B&P Section 4307)

28. Respondent's application is subject to denial under Code section 4307 in that while serving as the manager of Crown Valley Pharmacy and/or as someone exercising control over the pharmacy, Respondent had knowledge of or knowingly participated in conduct for which Crown Valley Pharmacy's license was placed on probation. Complainant refers to, and by this reference

incorporates, the allegations set forth above in paragraphs 18 through 27, inclusive, as though set forth fully herein.

SECOND CAUSE FOR DENIAL

(Unprofessional Conduct)

29. Respondent's application is subject to denial under Code section 4300, subdivision (c), and Code section 4302, in that Respondent engaged in unprofessional conduct while serving as the manager of Crown Valley Pharmacy and/or as someone exercising control over the pharmacy. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 27, inclusive, as though set forth fully herein.

THIRD CAUSE FOR DENIAL

(Violation of Pharmacy Law: Acquisition & Disposition Records)

30. Respondent's application is subject to denial under Code sections 4300, subdivision (c), and 4302, in conjunction with Code sections 4301, subdivision (o), and 4105 in that, while serving the manager of Crown Valley Pharmacy and/or as someone exercising control over the pharmacy, Crown Valley Pharmacy failed to maintain acquisition, sale and/or disposition records related to thousands of oxycodone and oxycodone/apap pills as well as dozens of bottles of promethazine with codeine. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 27, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DENIAL

(Violation of Pharmacy Law: Operational Standards)

31. Respondent's application is subject to denial under Code sections 4300, subdivision (c), and 4302, in conjunction with Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1714, in that, while serving as the manager of Crown Valley Pharmacy and/or as someone exercising control over the pharmacy, Crown Valley Pharmacy's facilities, space, fixtures, and equipment were not maintained such that the pharmacy's drugs were safely and properly maintained, secured and distributed as evidenced by the vast discrepancies between its in-stock inventory and the inventory denoted by its acquisition and

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dispensing records. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 27, inclusive, as though set forth fully herein.

FIFTH CAUSE FOR DENIAL

(Violation of Drug Law: Failure to Report to CURES)

32. Respondent's application is subject to denial under Code sections 4300, subdivision (c), and 4302, in conjunction with section 4301, subdivision (j), and California Health and Safety Code section 11165, in that , while serving as the manager of Crown Valley Pharmacy and/or as someone exercising control over the pharmacy, Crown Valley Pharmacy failed to report information to the Department of Justice regarding Crown Valley Pharmacy's dispensing of Schedule II controlled substances as required by state and federal law. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 27, inclusive, as though set forth fully herein.

SIXTH CAUSE FOR DENIAL

(Violation of Drug Law: Controlled Substance Inventories)

33. Respondent's application is subject to denial under Code sections 4300, subdivision (c), and 4302, in conjunction with section 4301, subdivision (j), and Code of Federal Regulations, title 21, section 1304.11, in that, while serving as the manager of Crown Valley Pharmacy and/or as someone exercising control over the pharmacy, Crown Valley Pharmacy failed to maintain separate inventory records for its Schedule II controlled substances as required under federal law. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 27, inclusive, as though set forth fully herein.

SEVENTH CAUSE FOR DENIAL

(Violation Drug Law: Controlled Substance Prescriptions)

34. Respondent's application is subject to denial under Code sections 4300, subdivision (c), and 4302, in conjunction with section 4301, subdivision (j), in conjunction with Health and Safety Code section 11205 in that, while serving as the manager of Crown Valley Pharmacy and/or as someone exercising control over the pharmacy, Crown Valley Pharmacy failed to maintain the original prescriptions for six (6) purported prescriptions of oxycodone and

oxycodone/apap and fifteen (15) purported prescriptions of promethazine with codeine that it filled. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 27, inclusive, as though set forth fully herein.

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. Denying the application of Moazzem Hossain Chowdhury dba Crown Pharmacy for a Pharmacy License;

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

DATED: 7/1/2021

Signature on File

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

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