ROB BONTA
Attorney General of California
JAMES M. LEDAKIS
Supervising Deputy Attorney General
ARMANDO ZAMBRANO
Supervising Deputy Attorney General
WILLIAM D. GARDNER
Deputy Attorney General
State Bar No. 244817
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6292
Facsimile: (916) 731-2126
Attorneys for Complainant

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

In the Matter of the Statement of Issues Against**:** **MOAZZEM HOSSAIN CHOWDHURY DBA NEWHALL PHARMACY** **Pharmacy License Applicant** Respondent.	Case No. 7128 **STATEMENT OF ISSUES**

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 Newhall Pharmacy (Respondent). On or about August 1, 2020, Moazzem Hossain Chowdhury 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.

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 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 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.

11. 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.

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"(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.

. . . .

12. 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."

13. 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."

14. 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."

15. 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."

16. 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 Law

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.

"(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 Newhall Pharmacy Inc., et al.* (Case No. 6041), Newhall Pharmacy Inc.'s Permit No.PHY 54078 was surrendered, effective February 27, 2019, for the same violations alleged herein. At all times relevant to the allegations set forth herein, Respondent's daughter, Jenisa Chowdhury, was Newhall Pharmacy Inc.'s (Newhall Pharmacy) sole owner and corporate officer.[1] At all times relevant to the allegations set forth herein, Respondent served as Newhall 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 Newhall 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 Respondent Newhall Pharmacy's acquisition and dispensing of certain controlled substances. Among other things, the complaint alleged that Newhall Pharmacy 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."

[1] Between September 7, 2012, and July 20, 2015, Respondent Newhall Pharmacy was an unincorporated business owned by Jenisa Chowdhury as a sole proprietorship. On or about July 20, 2015, the pharmacy incorporated and became Newhall Pharmacy, Inc.

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 Newhall 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 Newhall Pharmacy's controlled substance inventories. Although Newhall Pharmacy had been in operation since September 2012 and had been dispensing controlled substances since that time, the pharmacy never performed an initial controlled substance inventory, and the only controlled substance inventory available was an *incomplete* inventory dated May 1, 2015. The inspector issued a notice of non-compliance to the pharmacy related to the controlled substance inventory violations and admonished the pharmacy to perform a complete controlled substance inventory immediately and to provide a copy of that inventory to the Board. Newhall Pharmacy provided a complete controlled substance inventory to the Board on August 17, 2015.

23. The inspector also obtained a variety of records related to Newhall Pharmacy's acquisition and dispensing of: (1) oxycodone; (2) oxycodone with acetaminophen (hereinafter, "oxycodone/apap"); and (3) promethazine with codeine between September 2012 and August 2015. Those documents included acquisition records from pharmaceutical wholesalers used by Newhall 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.)[2]

[22] 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

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 Newhall Pharmacy was short in its inventory of oxycodone 30 mg by 2,748 pills, short in its inventory of oxycodone/apap 7.5-325 mg by 400 pills, short in its inventory of oxycodone 10 mg by 85 pills, short in its inventory of oxycodone 15 mg pills by 40 pills, and short in its inventory of promethazine with codeine by 322 bottles (i.e. more than 152,000 ml). Moreover, the records revealed that Newhall Pharmacy also could not account for the presence of large amounts of other controlled substances in its inventory. For example, Newhall Pharmacy's inventory included 1,025 oxycodone/apap 10-325 mg pills for which there were no acquisition records and 828 oxycodone/apap 5-325 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/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, Newhall Pharmacy could not produce the original prescriptions for three (3) purported prescriptions of oxycodone/apap that it had filled, indicating that the pharmacy had dispensed the drugs without prescriptions.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Prohibited Pursuant to B&P Section 4307)

26. Respondent's application is subject to denial under Code section 4307 in that while serving as the manager of Newhall Pharmacy and/or as someone exercising control over the pharmacy, Respondent had knowledge of or knowingly participated in conduct for which Newhall Pharmacy's license was surrendered. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 25, inclusive, as though set forth fully herein.

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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.

SECOND CAUSE FOR DENIAL

(Unprofessional Conduct)

27. 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 Newhall 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 25, inclusive, as though set forth fully herein.

THIRD CAUSE FOR DENIAL

(Violation of Pharmacy Law: Acquisition & Disposition Records)

28. 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 as the manager of Newhall Pharmacy and/or as someone exercising control over the pharmacy, Newhall Pharmacy failed to maintain acquisition, sale and/or disposition records related to thousands of oxycodone pills and hundreds of bottles of promethazine with codeine missing from its inventory and nearly 2000 oxycodone/apap pills present in its inventory. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 25, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DENIAL

(Violation of Pharmacy Law: Operational Standards)

29. 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 Newhall Pharmacy and/or as someone exercising control over the pharmacy, Newhall 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 the pharmacy's in-stock inventory and the inventory denoted by its acquisition and dispensing records. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 25, inclusive, as though set forth fully herein.

FIFTH CAUSE FOR DENIAL

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

30. 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 Newhall Pharmacy and/or as someone exercising control over the pharmacy, Newhall Pharmacy failed to report information to the Department of Justice regarding its 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 25, inclusive, as though set forth fully herein.

SIXTH CAUSE FOR DENIAL

(Violation of Drug Law: Controlled Substance Inventories)

31. 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 Newhall Pharmacy and/or as someone exercising control over the pharmacy, Newhall Pharmacy failed to complete an initial inventory of controlled substances or to timely complete a biennial inventory of controlled substances as required under federal law. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 25, inclusive, as though set forth fully herein.

SEVENTH CAUSE FOR DENIAL

(Violation Drug Law: Controlled Substance Prescriptions)

32. 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 Newhall Pharmacy and/or as someone exercising control over the pharmacy, Newhall Pharmacy failed to maintain the original prescriptions for three (3) purported prescriptions of oxycodone/apap that it filled. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 through 25, 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 Newhall 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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