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8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
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11	In the Matter of the Accusation Against:	Case No. 6041	
12	NEWHALL PHARMACY, INC., DBA		
13	NEWHALL PHARMACY; JENISA NUSRAT CHOWDHURY, SOLE OWNER	ACCUSATION	·
1	AND CORPORATE OFFICER		
14	24239 Main Street Newhall, CA 91321		
15	Pharmacy Permit No. PHY 54078		٠
16	23768 Newhall Avenue Newhall, CA 91321		
17	Pharmacy Permit No. PHY 51015 (Canceled),		
18	(~~~~,		•
19	CHARLES M. ZANDBERG 11840 Babbitt		
20	Grenada Hills, CA 91344	·	
21	Pharmacist License No. RPH 22274,		
22	and		
23	JENISA NUSRAT CHOWDHURY	·	
24	28419 N. Horeshoe Circle Santa Clarita, CA 91390-5708		
25	Pharmacist Intern Registration No. INT 35196,		
26		·	
27	Respondents.		
28	·		

Complainant alleges:

#### **PARTIES**

- 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 2. On or about September 7, 2012, the Board of Pharmacy issued Pharmacy Permit Number PHY 51015 to Jenisa Nusrat Chowdhury, dba Newhall Pharmacy. On or about July 20, 2015, Newhall Pharmacy was converted from an unincorporated sole proprietorship into a corporation and became Newhall Pharmacy, Inc., dba Newhall Pharmacy. Respondent Jenisa Nusrat Chowdhury was and is the corporation's sole owner and corporate officer. On or about March 9, 2016, Respondent Newhall Pharmacy Inc., relocated to a different location, and Pharmacy Permit Number PHY 51015 was canceled.
- 3. On or about May 9, 2016, the Board of Pharmacy issued Pharmacy Permit Number PHY 54078 to Newhall Pharmacy, Inc., dba Newhall Pharmacy, Jenisa Nusrat Chowdhury, sole owner and corporate officer. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2018, unless renewed.
- 4. On or about August 10, 1961, the Board of Pharmacy issued Pharmacist License Number RPH 22274 to Charles M. Zandberg. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2018, unless renewed.
- 5. On or about December 17, 2014, the Board of Pharmacy issued Pharmacist Intern Registration Number INT 35196 to Jenisa Nusrat Chowdhury. The Pharmacist Intern Registration was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2018, unless renewed.

## JURISDICTION FOR ACCUSATION

6. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

### 11. 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.
- 12. 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.
  - 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.

4. 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

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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."

- 15. 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.

- 16. Section 4113, subdivision (c) of the Code states, in pertinent part:
- "(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."
  - 17. Health and Safety Code section 11164 states, in pertinent part:

"Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

- "(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
- "(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name 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; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed."
  - 18. 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:

control of controlled substances, and who sells controlled substances obtained upon such federal

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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."

21. 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."

22. 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."

- 23. 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.

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(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.

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#### Pertinent Federal Law

24. United States Code, title 21, section 829, subdivision (a), provides:

"Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], may be dispensed without the written prescription of a practitioner . . . ."

- 25. 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."

#### COST RECOVERY

26. 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.

# FACTUAL BACKGROUND

- 27. Between September 7, 2012, and July 20, 2015, Respondent Newhall Pharmacy was an unincorporated business owned by Respondent Chowdhury as a sole proprietorship. On or about July 20, 2015, the pharmacy incorporated and became Newhall Pharmacy, Inc. Respondent Chowdhury was and is the corporation's sole owner and corporate officer. At all times relevant to the allegations set forth herein, Respondent Zandberg was designated as Newhall Pharmacy's pharmacist-in- charge.<sup>1</sup>
- 28. 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."
- 29. 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.

<sup>&</sup>lt;sup>1</sup> At all times relevant to the allegations set forth herein, Respondent Chowdhury's father, Moazzem Chowdhury, served as Newhall Pharmacy's manager. Moazzem Chowdhury is a registered pharmacist whose license is currently on probation 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).

- 30. 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.
- 31. 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.
- 32. 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.)<sup>2</sup>

<sup>&</sup>lt;sup>22</sup> 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.

- 33. 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.
- 34. 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 DISCIPLINE

#### (Unprofessional Conduct)

35. Respondents Newhall Pharmacy, Zandberg, and Chowdhury are subject to disciplinary action under section 4301 in that Respondents engaged in unprofessional conduct. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 27 through 34, inclusive, as though set forth fully herein.

## SECOND CAUSE FOR DISCIPLINE

#### (Violation of Pharmacy Law: Acquisition & Disposition Records)

36. Respondents Newhall Pharmacy, Zandberg, and Chowdhury are subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4081 and section 4105 in that Respondents failed to maintain acquisition, sale and/or disposition records

related to thousands of oxycodone pills and hundreds of bottles of promethazine with codeine missing form 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 27 through 34, inclusive, as though set forth fully herein.

### THIRD CAUSE FOR DISCIPLINE

# (Violation of Pharmacy Law: Operational Standards)

37. Respondents Newhall Pharmacy, Zandberg, and Chowdhury are subject to disciplinary action under section 4301, subdivision (o), in conjunction with section California Code of Regulations, title 16, section 1714, in that Respondents failed maintain Newhall Pharmacy's facilities, space, fixtures, and equipment such that 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 dispensing records. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 27 through 34, inclusive, as though set forth fully herein.

# FOURTH CAUSE FOR DISCIPLINE

### (Violation of Pharmacy Law: Original Prescriptions)

38. Respondents Newhall Pharmacy, Zandberg, and Chowdhury are subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4333 in that Respondents 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 27 through 34, inclusive, as though set forth fully herein.

#### FIFTH CAUSE FOR DISCIPLINE

# (Misconduct by Owner and/or Persons with Management or Control)

39. Respondent Newhall Pharmacy is subject to disciplinary action under section 4302 in that grounds for disciplinary action exist with respect to a person holding 10 percent or more of the ownership interest in the pharmacy and/or a person with management or control of the pharmacy. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 27 through 34, inclusive, as though set forth fully herein.

# SIXTH CAUSE FOR DISCIPLINE

# (Violation Drug Law: Controlled Substance Prescriptions)

40. Respondents Newhall Pharmacy, Zandberg, and Chowdhury are subject to disciplinary action under section 4301, subdivision (j), in conjunction with Health and Safety Code section 11205 and section 11179 in that Respondents 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 27 through 34, inclusive, as though set forth fully herein.

# SEVENTH CAUSE FOR DISCIPLINE

# (Violation of Drug Law: Dispensing Controlled Substances Without a Prescription)

41. Respondents Newhall Pharmacy, Zandberg, and Chowdhury are subject to disciplinary action under section 4301, subdivision (j), in conjunction with California Health and Safety Code section 11164 and U.S. Code, title 21, section 829, in that Respondents dispensed oxycodone/apap to patients without a prescription. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 27 through 34, inclusive, as though set forth fully herein.

#### EIGHTH CAUSE FOR DISCIPLINE

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

42. Respondents Newhall Pharmacy, Zandberg, and Chowdhury are subject to disciplinary action under section 4301, subdivision (j), in conjunction with California Health and Safety Code section 11165, in that Respondents failed to report information to the Department of Justice regarding Newhall 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 27 through 34, inclusive, as though set forth fully herein.

# NINTH CAUSE FOR DISCIPLINE

#### (Violation of Drug Law: Controlled Substance Inventories)

43. Respondents Newhall Pharmacy, Charles, and Chowdhury are subject to disciplinary action under section 4301, subdivision (j), in conjunction with Code of Federal Regulations, title

21, section 1304.11, in that Respondents 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 27 through 34, 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:

- Revoking or suspending Pharmacy Permit Number PHY 51015 issued to Jenisa
   Nusrat Chowdhury, dba Newhall Pharmacy;
- 2. Revoking or suspending Pharmacy Permit Number PHY 54078 issued to Newhall Pharmacy, Inc., dba Newhall Pharmacy, Jenisa Nusrat Chowdhury, sole owner and corporate officer;
- Revoking or suspending Pharmacist License Number RPH 22274 issued to Charles
   M. Zandberg;
- 4. Revoking or suspending Pharmacist Intern Registration Number INT 35196, issued to Jenisa Nusrat Chowdhury;
- 5. Prohibiting Jenisa Chowdhury from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51015 is placed on probation or until Pharmacy Permit Number PHY 51015 is reinstated if Pharmacy Permit Number PHY 51015 issued to Jenisa Nusrat Chowdhury, dba Newhall Pharmacy is revoked;
- 6. Prohibiting Jenisa Chowdhury from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54078 is placed on probation or until Pharmacy Permit Number PHY 54078 is reinstated if Pharmacy Permit Number 42891 issued to Newhall Pharmacy, Inc. is revoked;
- 7. Prohibiting Newhall Pharmacy, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54078 is placed on probation or until Pharmacy Permit Number PHY 54078 is