

1 XAVIER BECERRA
Attorney General of California
2 ANTOINETTE B. CINCOTTA
Supervising Deputy Attorney General
3 MARICHELLE S. TAHIMIC
Deputy Attorney General
4 State Bar No. 147392
600 West Broadway, Suite 1800
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 738-9435
7 Facsimile: (619) 645-2061
Attorneys for Complainant

8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Statement of Issues
Against:

Case No. 6203

12
13 **AURO PHARMACIES, INC.,**
DBA CENTRAL DRUGS; NAYAN PATEL,
14 **Owner; YOGESH PATEL, Owner;**
15 **ASHWIN PATEL, Owner**

STATEMENT OF ISSUES

16 **Instate Outsourcing Facility License**
17 **Applicant**

18 Respondent.

19 Complainant alleges:

20 **PARTIES**

21 1. Virginia Herold (Complainant) brings this Statement of Issues solely in her official
22 capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer
23 Affairs.

24 2. On or about February 6, 2017, the Board received an application for an Instate
25 Outsourcing Facility License from Auro Pharmacies, Inc., dba Central Drugs (Respondent), Nayan
26 Patel, Yogesh Patel and Ashwin Patel, owners. On or about January 31, 2017, Nayan Patel
27
28

1 certified under penalty of perjury to the truthfulness of all statements, answers, and representations
2 in the application. The Board denied the application on May 24, 2017.

3 JURISDICTION

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

7 4. Section 475 of the Code states:

8 (a) Notwithstanding any other provisions of this code, the provisions of this
9 division shall govern the denial of licenses on the grounds of:

10 ...

11 (4) Commission of any act which, if done by a licentiate of the business or
12 profession in question, would be grounds for suspension or revocation of license.

13 ...

14 (c) A license shall not be denied, suspended, or revoked on the grounds of a lack of
15 good moral character or any similar ground relating to an applicant's character,
16 reputation, personality, or habits.

17 5. Section 480 of the Code states:

18 (a) A board may deny a license regulated by this code on the grounds that the
19 applicant has one of the following:

20 ...

21 (3) (A) Done any act that if done by a licentiate of the business or
22 profession in question, would be grounds for suspension or revocation of
23 license.

24 (B) The board may deny a license pursuant to this subdivision only if
25 the crime or act is substantially related to the qualifications, functions, or
26 duties of the business or profession for which application is made.

27 ...

28 6. Section 4115(e) of the Code states in pertinent part, "(e) A person shall not act as a
pharmacy technician without first being licensed by the board as a pharmacy technician."

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:

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

...

(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.

...

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, or partner of any partnership, corporation, 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, or partner 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, or partner 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, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that 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.

///

///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

9. Title 16, California Code of Regulations (CCR), section 1751.7 states in pertinent part:

...

(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

...

10. Title 16, CCR, section 1770, states:

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

CAUSE FOR DENIAL OF APPLICATION

**(Committed An Act Which, If Done by Licentiate,
Would Be Grounds for Suspension or Revocation)**

11. Respondent's application is subject to denial under Code sections 475 and 480, in conjunction with Code sections 4301, 4115, and title 16, CCR, section 1751.7(c) for committing acts which, if done by a licentiate, would be grounds for suspension or revocation.

12. The circumstances are as follows. Accusation No. 5865 is currently pending against Respondent before the Board. Accusation No. 5865 is attached as Exhibit A to this Statement of Issues and is incorporated herein as though set forth in full. The Accusation alleges that Respondent:

- a. aided and abetted unlicensed activity;
- b. failed to document end product testing for sterility and pyrogens for batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients; and,
- c. failed to set forth directions for use on prescription labels for prescriptions RX #6423900, RX #6441577, RX #6449573, RX #6459220, RX #6442478, RX #6454501 and RX #6445321.

1 **OTHER MATTERS**

2 13. Pursuant to Section 4307, if Respondent is denied a license, and if Nayan Patel, while
3 acting as the manager, administrator, owner, member, officer, director, associate, or partner had
4 knowledge of or knowingly participated in any conduct for which the license was denied, revoked,
5 suspended, or placed on probation, shall be prohibited from serving as a manager, administrator,
6 owner, member, officer, director, associate, or partner of a licensee of the Board.

7 14. Pursuant to Section 4307, if Respondent is denied a license, and if Yogesh Patel, while
8 acting as the manager, administrator, owner, member, officer, director, associate, or partner had
9 knowledge of or knowingly participated in any conduct for which the license was denied, revoked,
10 suspended, or placed on probation, shall be prohibited from serving as a manager, administrator,
11 owner, member, officer, director, associate, or partner of a licensee of the Board.

12 15. Pursuant to Section 4307, if Respondent is denied a license, and if Ashwin Patel, while
13 acting as the manager, administrator, owner, member, officer, director, associate, or partner had
14 knowledge of or knowingly participated in any conduct for which the license was denied, revoked,
15 suspended, or placed on probation, shall be prohibited from serving as a manager, administrator,
16 owner, member, officer, director, associate, or partner of a licensee of the Board.

17 **PRAYER**

18 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
19 and that following the hearing, the Board of Pharmacy issue a decision:

20 1. Denying the application of Auro Pharmacies, Inc., dba Central Drugs for an Instate
21 Outsourcing Facility License;

22 2. Prohibiting Nayan Patel from serving as a manager, administrator, owner, member,
23 officer, director, associate, or partner of a licensee of the Board;

24 3. Prohibiting Yogesh Patel from serving as a manager, administrator, owner, member,
25 officer, director, associate, or partner of a licensee of the Board;

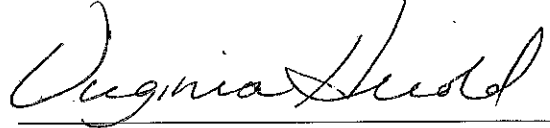
26 4. Prohibiting Ashwin Patel from serving as a manager, administrator, owner, member,
27 officer, director, associate, or partner of a licensee of the Board; and,

28 ///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

DATED: 10/7/17



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

SD2017705647
81831850.doc