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

12 In the Matter of the Accusation Against:

Case No. 5612

13 **ALVARADO MEDICAL PLAZA PHARMACY INC.,**
14 **DBA ALVARADO MEDICAL PLAZA PHARMACY**
15 **5555 Reservoir Drive, Ste. 114**
16 **San Diego, CA 92120**

**FIRST AMENDED
ACCUSATION**

17 **Pharmacy Permit No. PHY 38199**
18 **Sterile Compounding License No. LSC 99270,**

19 **and**

20 **WILLIAM NICHOLAS BURDINE**
21 **10831 Del Rio Road**
22 **Spring Valley, CA 91978**

23 **Pharmacist License No. RPH 31975**

24 Respondents.

25 Complainant alleges:

26 **PARTIES**

27 1. Virginia K. Herold (Complainant) brings this First Amended Accusation solely in her
28 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer
Affairs (Board).

1 investigation of, or action or disciplinary proceeding against, the licensee or to render
2 a decision suspending or revoking the license.

3 STATUTORY AND REGULATORY PROVISIONS

4 9. Section 482 of the Code states:

5 Each board under the provisions of this code shall develop criteria to evaluate
6 the rehabilitation of a person when:

7 (a) Considering the denial of a license by the board under Section 480; or

8 (b) Considering suspension or revocation of a license under Section 490.

9 Each board shall take into account all competent evidence of rehabilitation
10 furnished by the applicant or licensee.

11 10. Section 490 of the Code provides, in pertinent part, that a board may suspend or
12 revoke a license on the ground that the licensee has been convicted of a crime substantially
13 related to the qualifications, functions, or duties of the business or profession for which the
14 license was issued.

15 11. Section 493 of the Code states:

16 Notwithstanding any other provision of law, in a proceeding conducted by a
17 board within the department pursuant to law to deny an application for a license or to
18 suspend or revoke a license or otherwise take disciplinary action against a person who
19 holds a license, upon the ground that the applicant or the licensee has been convicted
20 of a crime substantially related to the qualifications, functions, and duties of the
21 licensee in question, the record of conviction of the crime shall be conclusive
22 evidence of the fact that the conviction occurred, but only of that fact, and the board
23 may inquire into the circumstances surrounding the commission of the crime in order
24 to fix the degree of discipline or to determine if the conviction is substantially related
25 to the qualifications, functions, and duties of the licensee in question.

26 As used in this section, "license" includes "certificate," "permit," "authority,"
27 and "registration."

28 12. Section 4113(c) of the Code states:

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.

13. Section 4169, subdivision (a)(1) of the Code states:

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

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous
drugs or dangerous devices at wholesale with a person or entity that is not licensed
with the board as a wholesaler, third-party logistics provider, or pharmacy.

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14. Section 4301 of the Code states:

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

....

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

....

(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.

....

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

....

(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. . . .

15. Section 4306.5 of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership,

1 management, administration, or operation of a pharmacy or other entity licensed by
2 the board.

3 Acts or omissions that involve, in whole or in part, the failure to consult
4 appropriate patient, prescription, and other records pertaining to the performance of
5 any pharmacy function.

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11 16. Section 4307 of the Code states:

12 (a) Any person who has been denied a license or whose license has been
13 revoked or is under suspension, or who has failed to renew his or her license while it
14 was under suspension, or who has been a manager, administrator, owner, member,
15 officer, director, associate, or partner of any partnership, corporation, firm, or
16 association whose application for a license has been denied or revoked, is under
17 suspension or has been placed on probation, and while acting as the manager,
18 administrator, owner, member, officer, director, associate, or partner had knowledge
19 of or knowingly participated in any conduct for which the license was denied,
20 revoked, suspended, or placed on probation, shall be prohibited from serving as a
21 manager, administrator, owner, member, officer, director, associate, or partner of a
22 licensee as follows:

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

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

28 (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. . . .

17 17. Health and Safety Code section 11153(a) states:

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

....

18 18. United States Code, title 21, section 331 states:

The following acts and the causing thereof are prohibited:

1 (d) The introduction or delivery for introduction into interstate commerce of
2 any article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

3 19. California Code of Regulations, title 16, section 1716 states:

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

7 Nothing in this regulation is intended to prohibit a pharmacist from exercising
8 commonly-accepted pharmaceutical practice in the compounding or dispensing of a
9 prescription.

10 20. California Code of Regulations, title 16, section 1769, subdivision (b) states:

11 (b) When considering the suspension or revocation of a facility or a personal
12 License on the ground that the licensee or the registrant has been convicted of a
13 crime, the board, in evaluating the rehabilitation of such person and his present
14 eligibility for a license will consider the following criteria:

15 (1) Nature and severity of the act(s) or offense(s).

16 (2) Total criminal record.

17 (3) The time that has elapsed since commission of the act(s) or offense(s).

18 (4) Whether the licensee has complied with all terms of parole, probation,
19 restitution or any other sanctions lawfully imposed against the licensee.

20 (5) Evidence, if any, of rehabilitation submitted by the licensee.

21 21. California Code of Regulations, title 16, section 1770 states:

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

29 22. Section 1761 of title 16, California Code of Regulations states:

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

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

1 **COSTS**

2 23. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
3 administrative law judge to direct a licentiate found to have committed a violation or violations of
4 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
5 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
6 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
7 included in a stipulated settlement.

8 **DRUGS**

9 24. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code
10 section 11054(b)(M) and a dangerous drug pursuant to Business and Professions Code section
11 4022.

12 25. Phenergan with Codeine is the brand name for promethazine with codeine, a
13 Schedule V controlled substance pursuant to Health and Safety Code section 111058(c)(1) and is
14 a dangerous drug pursuant to Business and Professions Code section 4022.

15 26. Xanax is the brand name for alprazolam, a Schedule IV controlled substance pursuant
16 to Health and Safety Code section 11057(d)(1) and a dangerous drug pursuant to Business and
17 Professions Code section 4022.

18 **FACTUAL ALLEGATIONS**

19 27. At all times relevant herein, William Burdine was the Pharmacist-in-Charge of
20 Alvarado Medical Plaza Pharmacy.

21 28. On or between May 2010 and June 2011, William Burdine, in the capacity of
22 President, owner, and pharmacist-in-charge of Alvarado Medical Plaza Pharmacy, purchased
23 approximately \$750,000.00 of prescription oncology drugs not approved by the Food and Drug
24 Administration (FDA), and not approved by Medicare for reimbursement. Respondents then sold
25 these unapproved drugs to doctors pre-mixed in infusion bags (compounded) without advising the
26 doctors of their true origin. Respondents knew the doctors would bill Medicare over \$1 million
27 dollars for these drugs. Respondents purchased approximately 278 FDA unapproved drugs from
28

1 Quality Specialty Products, a Canadian pharmaceutical wholesaler that is not licensed by the
2 Board.

3 29. From August 18, 2011 through January 24, 2012, Respondents filled 132
4 prescriptions for 10,350 tablets of alprazolam 2mg, 200 prescriptions for 39,300 tablets of
5 oxycodone 30mg, 45 prescriptions for 20,866 mls of promethazine with codeine and one
6 prescription for 60 tablets of alprazolam 1mg which were written by Dr. C.A. Dr. C.A.'s address
7 was listed on the prescriptions filled by Respondents as being 126 miles away from Alvarado
8 Medical Plaza Pharmacy. Alvarado Medical Plaza Pharmacy was a lengthy distance (typically
9 over 100 miles) from the patients' addresses listed on prescriptions written by Dr. C.A. who did
10 not specialize in pain management, respiratory diseases or anxiety disorders. Patients paid for the
11 majority of the controlled substance prescriptions in cash at Alvarado Medical Plaza Pharmacy
12 and did not seek reimbursement from an insurance company or government agency. Multiple
13 prescriptions were picked up by drivers. Multiple patients were receiving drugs written by
14 multiple prescribers filled at multiple pharmacies during the same time frame.

15 30. Dr. C.A.'s prescriptions for controlled substances were written in an identical fashion
16 for multiple patients as follows: One prescription for oxycodone 30mg with directions to take 2
17 tablets three times a day in a quantity of 180 and a second prescription for (a) alprazolam 2 mg
18 with directions to take 1 tablet twice a day in a quantity of 90; and (b) promethazine with codeine
19 with directions to take 1 teaspoon every 6 hours in a quantity of 16 ounces. This combination of
20 drugs can be lethal. There was no adjustments in the prescribing pattern for sex, age, weight,
21 renal or hepatic function, race, diagnosis, past medications used or any other patient related
22 factor. None of the "chronic pain patients" being treated by Dr. C.A. were receiving a long acting
23 pain medication to control their baseline pain. Initial prescriptions were written for oxycodone
24 30mg which is not a "starting dose" for pain management.

25 31. On or about October 8, 2014, criminal charges were filed against Dr. C.A. in *The*
26 *People of the State of California v. Clyde Arnold*, Los Angeles County Superior Court Case No.
27 BA425640, alleging Dr. C.A.'s violations of drug statutes for improper prescribing practices. On
28 or about December 15, 2014, The Medical Board of California filed an accusation against Dr.

1 C.A. for gross negligence, repeated negligent acts, incompetence, dishonest or corrupt acts,
2 prescribing to addicts, prescribing without performing physical examination or medical indication
3 or both, record keeping violations, excessive prescribing, violation of drug statutes and
4 unprofessional conduct.

5 **FIRST CAUSE FOR DISCIPLINE**

6 **(December 4, 2013 Criminal Convictions for Improper Importation of Merchandise**
7 **& Aiding an Abetting Against William Burdine)**

8 32. William Burdine has subjected his pharmacist license to discipline under sections 490
9 and 4301, subdivision (l) of the Code in that he was convicted of crimes that are substantially
10 related to the qualifications, duties, and functions of a pharmacist. The circumstances are as
11 follows:

12 a. On or about December 4, 2013, in a criminal proceeding entitled *United States*
13 *of America v. William Nicholas Burdine*, in United States District Court, Southern District of
14 California, case number 13cr4295-JLS, he was convicted on his plea of guilty to violating 18
15 U.S.C. section 545 – knowingly importing merchandise, to wit: prescription oncology drugs not
16 approved for use in the United States, and 18 U.S.C. section 2, aiding and abetting a felony.

17 b. As a result of the convictions, on February 21, 2014, William Burdine was
18 sentenced to probation for a term of five years on standard terms of supervised probation, and
19 special conditions that require that he submit to a Fourth Amendment waiver, complete 240 hours
20 of community service, provide complete disclosure of personal and business financial records,
21 comply with the orders and conditions as set forth by California Board of Pharmacy, submit to
22 electronic monitoring (home detention) for a period of eight months, and pay restitution in the
23 amount of \$1,004,282.04.

24 **SECOND CAUSE FOR DISCIPLINE**

25 **(December 4, 2013 Criminal Convictions for Healthcare Fraud & Aiding an Abetting**
26 **Against Alvarado Medical Plaza Pharmacy)**

27 33. Alvarado Medical Plaza Pharmacy has subjected its Pharmacy Permit and Licensed
28 Sterile Compounding License to discipline under sections 490 and 4301, subdivision (l) of the

1 Code in that it was convicted of crimes that are substantially related to the qualifications, duties,
2 and functions of a pharmacy. The circumstances are as follows:

3 a. On or about December 4, 2013, in a criminal proceeding entitled *United States*
4 *of America v. Alvarado Medical Plaza Pharmacy Inc.* (as a defendant organization), in United
5 States District Court, Southern District of California, case number 13cr4295-JLS, it was
6 convicted on its plea of guilty to violating 18 U.S.C. section 1347 – knowingly and willfully
7 executing a material scheme to defraud a healthcare benefit program, to wit: Medicare, in
8 connection with the delivery of and payment for health care benefits and services, by purchasing
9 approximately \$750,000.00 of prescription oncology drugs not approved by the FDA for use in
10 the United States, and not approved by Medicare for reimbursement from sources abroad, at
11 significant cost savings, and selling these unapproved drugs to doctors knowing that the doctors
12 would bill Medicare over \$1 million for these drugs as if they were actually drugs approved for
13 use in the United States, and approved for reimbursement by Medicare; and 18 U.S.C. section 2,
14 aiding and abetting a felony.

15 b. As a result of the convictions, on February 21, 2014, Alvarado Medical Plaza
16 Pharmacy was sentenced to probation for a term of five years on standard terms of supervised
17 probation, and special conditions that require it provide complete disclosure of personal and
18 business financial records, subject corporate records and premises to search by probation officer,
19 have an effective program to prevent and detect violations of law, and pay a fine of \$10,000.00.

20 THIRD CAUSE FOR DISCIPLINE

21 (Commission of Acts Involving Dishonesty, Fraud, Deceit & Corruption)

22 34. Respondents, jointly and severally, have subjected their licenses and permit to
23 discipline under section 4301, subdivision (f) of the Code for acts involving dishonesty, fraud,
24 deceit or corruption in that on or between May 2010 and June 2011, as described in paragraphs
25 27-28 and 32-33, above, they knowingly purchased unapproved by the FDA and not approved by
26 Medicare for reimbursement prescription oncology drugs, then sold these unapproved drugs to
27 doctors without advising the physicians of the true origin of the drugs and knowing the physicians
28 would bill Medicare over \$1 million dollars.

1 **FOURTH CAUSE FOR DISCIPLINE**

2 **(Violations of Federal & State Laws & Regulations Governing Pharmacy)**

3 35. Respondents, jointly and severally, have subjected their licenses and permit to
4 discipline under section 4301, subdivisions (j) and (o) of the Code for unprofessional conduct in
5 that on or on or between, May 2010 and June 2011, as described in paragraphs 27-28 and 32-33,
6 above, Respondents violated, and aided and abetted in the violation of section 4169, subdivision
7 (a)(1) of the Code by purchasing dangerous drugs at wholesale with a person or entity that is not
8 licensed with the Board as a wholesaler; California Code of Regulations, title 16, section 1716 by
9 deviating from the requirements of a prescription; United States Code, title 21, section 331 by
10 improper importation of merchandise; United States Code, title 18, section 1347 for healthcare
11 fraud; United States Code, title 18, section 545 for knowingly importing prescription oncology
12 drugs not approved for use in the United States; and United States Code, title 18, section 2 for
13 aiding and abetting felonious criminal offenses.

14 **FIFTH CAUSE FOR DISCIPLINE**

15 **(Failing to Comply with Corresponding Responsibility**
16 **for Legitimate Controlled Substance Prescriptions)**

17 36. Respondents, jointly and severally, have subjected their licenses and permit to
18 discipline under Code section 4301(j), for violating Health and Safety Code section 11153(a), in
19 that they failed to comply with their corresponding responsibility to ensure that controlled
20 substances were dispensed for a legitimate medical purpose when Respondents furnished
21 prescriptions for controlled substances even though "red flags" were present, indicating those
22 prescriptions were not issued for a legitimate medical purpose, as set forth in paragraphs 27 and
23 29 through 31 above, which are incorporated herein by reference.

24 **SIXTH CAUSE FOR DISCIPLINE**

25 **(Dispensing Controlled Substance Prescriptions with Significant Errors, Omissions,**
26 **Irregularities, Uncertainties, Ambiguities or Alterations)**

27 37. Respondents, jointly and severally, have subjected their licenses and permit to
28 discipline under Code section 4301(o), for violating title 16, California Code of Regulations,

1 sections 1761(a) and (b) in that they dispensed prescriptions for controlled substances, which
2 contained significant errors, omissions, irregularities, uncertainties, ambiguities or alterations, as
3 set forth in paragraphs 27 and 29 through 31 above, which are incorporated herein by reference.

4 **SEVENTH CAUSE FOR DISCIPLINE**

5 **(Failure to Exercise or Implement Best Professional Judgment or Corresponding**
6 **Responsibility when Dispensing Controlled Substances**
7 **against Respondent William Burdine)**

8 38. William Burdine has subjected his license to disciplinary action under Code section
9 4301(o), for violating Business and Professions Code section 4306.5(a) and (b), in that he failed
10 to exercise or implement his best professional judgment or corresponding responsibility when
11 dispensing controlled substances and purchasing and selling unapproved prescription oncology
12 drugs, as set forth in paragraphs 27 through 33 above, which are incorporated herein by reference.

13 **EIGHTH CAUSE FOR DISCIPLINE**

14 **(Unprofessional Conduct)**

15 39. Respondents, jointly and severally, have subjected their licenses and permit to
16 discipline action under Code section 4301 for unprofessional conduct in that they engaged in the
17 activities described in paragraphs 27 through 33 above, which are incorporated herein by
18 reference.

19 **OTHER MATTERS**

20 40. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY
21 38199 and/or Sterile Compounding License No. LSC 99270, issued to Alvarado Medical Plaza
22 Pharmacy Inc., doing business as Alvarado Medical Plaza Pharmacy, Alvarado Medical Plaza
23 Pharmacy Inc. shall be prohibited from serving as a manager, administrator, owner, member,
24 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
25 PHY 38199 and/or Sterile Compounding License No. LSC 99270 are placed on probation or until
26 Pharmacy Permit Number PHY 38199 and/or Sterile Compounding License No. LSC 99270 are
27 reinstated if they are revoked.

28

1 until Pharmacy Permit Number PHY 38199 and/or Sterile Compounding License Number LSC
2 99270 are reinstated if Pharmacy Permit Number PHY 38199 and/or Sterile Compounding
3 License Number LSC 99270 issued to Alvarado Medical Plaza Pharmacy Inc., doing business as
4 Alvarado Medical Plaza Pharmacy are revoked;

5 5. Prohibiting William Nicholas Burdine from serving as a manager, administrator,
6 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy
7 Permit Number PHY 38199 and Sterile Compounding License Number LSC 99270 are placed
8 on probation or until Pharmacy Permit Number PHY 38199 and/or Sterile Compounding License
9 Number LSC 99270 are reinstated if Pharmacy Permit Number PHY 38199 and/or Sterile
10 Compounding License Number LSC 99270 issued to Alvarado Medical Plaza Pharmacy Inc.,
11 doing business as Alvarado Medical Plaza Pharmacy are revoked;

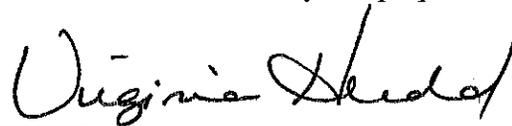
12 6. Prohibiting William Nicholas Burdine from serving as a manager, administrator,
13 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist
14 License Number RPH 31975 is placed on probation or until Pharmacist License Number RPH
15 31975 is reinstated if Pharmacist License Number RPH 31975 issued to William Nicholas
16 Burdine is revoked;

17 7. Ordering Alvarado Medical Plaza Pharmacy Inc., doing business as Alvarado
18 Medical Plaza Pharmacy and/or William Nicholas Burdine to pay the Board of Pharmacy the
19 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
20 Professions Code section 125.3;

21 8. Taking such other and further action as deemed necessary and proper.

22
23 DATED: _____

7/14/16



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

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

12 In the Matter of the Accusation Against:

Case No. 5612

13 **ALVARADO MEDICAL PLAZA PHARMACY INC.,**
14 **DBA ALVARADO MEDICAL PLAZA PHARMACY**
15 **WILLIAM N. BURDINE, PRESIDENT**
16 **SANDRA L. BURDINE, VICE PRESIDENT**
17 **5555 Reservoir Drive, Ste. 114**
18 **San Diego, CA 92120**

A C C U S A T I O N

19 **Pharmacy Permit No. PHY 38199**
20 **Licensed Sterile Compounding Permit No. LCS 99270,**

21 **and**

22 **WILLIAM NICHOLAS BURDINE**
23 **10831 Del Rio Road**
24 **Spring Valley, CA 91978**

25 **Pharmacist License No. RPH 31975**

26 Respondents.

27 Complainant alleges:

28 **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 (Board).

///

1 (c) Any other drug or device that by federal or state law can be lawfully dispensed
2 only on prescription or furnished pursuant to Section 4006.

3 13. Section 4169, subdivision (a)(1) of the Code states:

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

5 (1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or
6 dangerous devices at wholesale with a person or entity that is not licensed with the board
7 as a wholesaler, third-party logistics provider, or pharmacy.

8 14. Section 4301 of the Code states:

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

13

14 (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit,
15 or corruption, whether the act is committed in the course of relations as a licensee or
16 otherwise, and whether the act is a felony or misdemeanor or not.

17

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

20

21 (l) The conviction of a crime substantially related to the qualifications, functions,
22 and duties of a licensee under this chapter. The record of conviction of a violation of
23 Chapter 13 (commencing with Section 801) of Title 21 of the United States Code
24 regulating controlled substances or of a violation of the statutes of this state regulating
25 controlled substances or dangerous drugs shall be conclusive evidence of unprofessional
26 conduct. In all other cases, the record of conviction shall be conclusive evidence only of
27 the fact that the conviction occurred. The board may inquire into the circumstances
28 surrounding the commission of the crime, in order to fix the degree of discipline or, in
the case of a conviction not involving controlled substances or dangerous drugs, to
determine if the conviction is of an offense substantially related to the qualifications,
functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a
conviction following a plea of nolo contendere is deemed to be a conviction within the
meaning of this provision. The board may take action when the time for appeal has
elapsed, or the judgment of conviction has been affirmed on appeal or when an order
granting probation is made suspending the imposition of sentence, irrespective of a
subsequent order under Section 1203.4 of the Penal Code allowing the person to
withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the
verdict of guilty, or dismissing the accusation, information, or indictment.

///

///

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

5 15. Section 4307 of the Code states:

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

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

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

20 (b) "Manager, administrator, owner, member, officer, director, associate, or
21 partner," as used in this section and Section 4308, may refer to a pharmacist or to any
22 other person who serves in that capacity in or for a licensee. . . .

23 REGULATORY PROVISIONS

24 16. California Code of Regulations, title 16, section 1716 states:

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

28 Nothing in this regulation is intended to prohibit a pharmacist from exercising
commonly-accepted pharmaceutical practice in the compounding or dispensing of a
prescription.

17. California Code of Regulations, title 16, section 1769, subdivision (b) states:

(b) When considering the suspension or revocation of a facility or a personal
License on the ground that the licensee or the registrant has been convicted of a crime,
the board, in evaluating the rehabilitation of such person and his present eligibility for a
license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

1 (4) Whether the licensee has complied with all terms of parole, probation,
2 restitution or any other sanctions lawfully imposed against the licensee.

3 (5) Evidence, if any, of rehabilitation submitted by the licensee.

4 18. California Code of Regulations, title 16, section 1770 states:

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

12 19. United States Code, title 21, section 331 states:

13 The following acts and the causing thereof are prohibited:

14 (d) The introduction or delivery for introduction into interstate commerce of any
15 article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

16 COSTS

17 20. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
18 administrative law judge to direct a licentiate found to have committed a violation or violations of
19 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
20 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
21 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
22 included in a stipulated settlement.

23 FACTUAL ALLEGATIONS

24 21. On or between May 2010 and June 2011, Respondent Burdine, in the capacity of
25 President, owner, and pharmacist-in-charge of Respondent AMPP, purchased approximately
26 \$750,000.00 of prescription oncology drugs not approved by the Food and Drug Administration
27 (FDA), and not approved by Medicare for reimbursement. Respondents Burdine and AMPP then
28 sold these unapproved drugs to doctors pre-mixed in infusion bags without advising the doctors of
their true origin. Respondents Burdine and AMPP knew the doctors would bill Medicare over \$1
million dollars for these drugs. Respondents Burdine, through Respondent AMPP, purchased
approximately 278 FDA unapproved drugs from Quality Specialty Products (QSP), a Canadian

1 pharmaceutical wholesaler that is not licensed by the Board. Respondent Burdine and
2 Respondent AMPP compounded the unapproved drugs, and furnished the final compound to
3 physicians knowing that the medical providers would be billing third party payers. The drugs
4 were used to treat cancer patients who were unaware of the origin of the drugs, or that they were
5 not approved for use in the United States.

6 **FIRST CAUSE FOR DISCIPLINE (RESPONDENT BURDINE)**

7 **(December 4, 2013 Criminal Convictions for Improper Importation of Merchandise**
8 **& Aiding an Abetting)**

9 22. Respondent Burdine has subjected his pharmacist license to discipline under sections
10 490 and 4301, subdivision (l) of the Code in that he was convicted of crimes that are substantially
11 related to the qualifications, duties, and functions of a pharmacist. The circumstances are as
12 follows:

13 a. On or about December 4, 2013, in a criminal proceeding entitled *United States*
14 *of America v. William Nicholas Burdine*, in U.S. District Court, Southern District of California,
15 case number 13cr4295-JLS, he was convicted on his plea of guilty to violating 18 U.S.C. section
16 545 – knowingly importing merchandise, to wit: prescription oncology drugs not approved for use
17 in the United States, and 18 U.S.C. section 2, aiding and abetting a felony.

18 b. As a result of the convictions, on February 21, 2014, Respondent Burdine was
19 sentenced to probation for a term of five years on standard terms of supervised probation, and
20 special conditions that require that he submit to a Fourth Amendment waiver, complete 240 hours
21 of community service, provide complete disclosure of personal and business financial records,
22 comply with the orders and conditions as set forth by California Board of Pharmacy, submit to
23 electronic monitoring (home detention) for a period of eight months, and pay restitution in the
24 amount of \$1,004,282.04.

25 **SECOND CAUSE FOR DISCIPLINE (RESPONDENT AMPP)**

26 **(December 4, 2013 Criminal Convictions for Healthcare Fraud & Aiding an Abetting)**

27 23. Respondent AMPP has subjected its Pharmacy Permit to discipline under sections
28 490 and 4301, subdivision (l) of the Code in that it was convicted of crimes that are substantially

1 related to the qualifications, duties, and functions of a pharmacy. The circumstances are as
2 follows:

3 a. On or about December 4, 2013, in a criminal proceeding entitled *United States*
4 *of America v. Alvarado Medical Plaza Pharmacy Inc.* (as a defendant organization), in U.S.
5 District Court, Southern District of California, case number 13cr4295-JLS, it was convicted on its
6 plea of guilty to violating 18 U.S.C. section 1347 – knowingly and willfully executing a material
7 scheme to defraud a healthcare benefit program, to wit: Medicare, in connection with the delivery
8 of and payment for health care benefits and services, by purchasing approximately \$750,000.00 of
9 prescription oncology drugs not approved by the FDA for use in the United States, and not
10 approved by Medicare for reimbursement from sources abroad, at significant cost savings, and
11 selling these unapproved drugs to doctors knowing that the doctors would bill Medicare over \$1
12 million for these drugs as if they were actually drugs approved for use in the United States, and
13 approved for reimbursement by Medicare; and 18 U.S.C. section 2, aiding and abetting a felony.

14 b. As a result of the convictions, on February 21, 2014, Respondent AMPP was
15 sentenced to probation for a term of five years on standard terms of supervised probation, and
16 special conditions that require it provide complete disclosure of personal and business financial
17 records, subject corporate records and premises to search by probation officer, have an effective
18 program to prevent and detect violations of law, and pay a fine of \$10,000.00.

19 **THIRD CAUSE FOR DISCIPLINE**

20 **(Commission of Acts Involving Dishonesty, Fraud, Deceit & Corruption)**

21 24. Respondents Burdine and AMPP, jointly and severally, have subjected their license
22 and permit to discipline under section 4301, subdivision (f) of the Code for acts involving
23 dishonesty, fraud, deceit or corruption in that on or between May 2010 and June 2011, as
24 described in paragraphs 21-23, above, they knowingly purchased unapproved prescription
25 oncology drugs for approximately \$750,000.00, then sold these unapproved drugs to doctors
26 knowing the doctors would bill Medicare over \$1 million dollars. The drugs were used to treat
27 cancer patients who were unaware of the origin of the drugs, or that they were not approved for
28 use in the United States.

1 **FOURTH CAUSE FOR DISCIPLINE**

2 **(Violation of Federal & State Laws & Regulations Governing Pharmacy)**

3 25. Respondents Burdine and AMPP, jointly and severally, have subjected their license
4 and permit to discipline under section 4301, subdivisions (j) and (o) of the Code for
5 unprofessional conduct in that on or on or between, May 2010 and June 2011, as described in
6 paragraphs 21-23, above, Respondents Burdine and AMPP violated, and aided and abetted in the
7 violation of section 4169, subdivision (a)(1) of the Code by purchasing dangerous drugs at
8 wholesale with a person or entity that is not licensed with the Board as a wholesaler; California
9 Code of Regulations, title 16, section 1716 by deviating from the requirements of a prescription;
10 United States Code, title 21, section 331 by improper importation of merchandise; United States
11 Code, title 18, section 1347 for healthcare fraud; United States Code, title 18, section 545 for
12 knowingly importing prescription oncology drugs not approved for use in the United States; and
13 United States Code, title 18, section 2 for aiding and abetting felonious criminal offenses.

14 **OTHER MATTERS**

15 26. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY
16 38199, issued to Alvarado Medical Plaza Pharmacy Inc., doing business as Alvarado Medical
17 Plaza Pharmacy, Alvarado Medical Plaza Pharmacy Inc. shall be prohibited from serving as a
18 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
19 five years if Pharmacy Permit Number PHY 38199 is placed on probation or until Pharmacy
20 Permit Number PHY 38199 is reinstated if it is revoked.

21 27. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No.
22 PHY 38199, issued to Alvarado Medical Plaza Pharmacy Inc., doing business as Alvarado
23 Medical Plaza Pharmacy, while William N. Burdine and/or Sandra L. Burdine have been an
24 officer, and had knowledge of or knowingly participated in any conduct for which the permit was
25 disciplined, William N. Burdine and/or Sandra L. Burdine shall be prohibited from serving as a
26 manager, administrator, owner, member, officer, director, associate, or partner of any licensed or
27 permitted entity for five (5) years if Pharmacy Permit Number PHY 38199 is placed on
28 probation, or until Pharmacy Permit Number PHY 38199 is reinstated, if revoked.

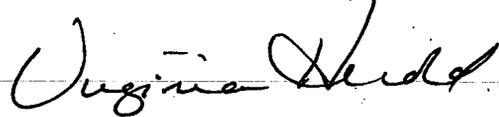
1 **PRAYER**

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

- 4 1. Revoking or suspending Pharmacy Permit Number PHY 38199, issued to Alvarado
5 Medical Plaza Pharmacy Inc., to do business as Alvarado Medical Plaza Pharmacy;
6 2. Revoking or suspending Pharmacist License Number RPH 31975, issued to William
7 Nicholas Burdine;
8 3. Ordering Alvarado Medical Plaza Pharmacy and/or William Nicholas Burdine to pay
9 the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
10 pursuant to Business and Professions Code section 125.3;
11 4. Taking such other and further action as deemed necessary and proper.

12
13 DATED: _____

5/2/16



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

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