KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General
JONATHAN D. COOPER
Deputy Attorney General
State Bar No. 141461
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 703-1404
Facsimile: (415) 703-5480
*Attorneys for Complainant*

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

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>**DANIELS PHARMACY**<br>**943 Geneva Avenue**<br>**San Francisco, CA 94112**<br><br>**Pharmacy License No. PHY 36740**<br><br>**and**<br><br>**IYAD I. NASRAH**<br>**488 Gellert Drive**<br>**San Francisco, CA 94132**<br><br>**Pharmacist License No. RPH 40241**<br><br>Respondents. | Case No. 4125<br><br>**FIRST AMENDED ACCUSATION** |

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 October 24, 1990, the Board of Pharmacy issued Pharmacy License No. PHY 36740 to Daniels Pharmacy (Respondent Daniels). The License was in full force and effect at all times relevant to the charges herein, and will expire on October 1, 2014, unless renewed.

3. On or about August 20, 1986, the Board of Pharmacy issued Pharmacist License No. RPH 40241 to Iyad I. Nasrah (Respondent Nasrah). The License was in full force and effect at all

times relevant to the charges herein and will expire on October 31, 2014, unless renewed. Since on or about October 24, 1990, Respondent Nasrah has served and/or has been reflected in Board records as the Pharmacist in Charge (PIC) for Respondent Daniels.

## JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section **4011** of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section **4300(a)** of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section **4300.1** of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

## STATUTORY AND REGULATORY PROVISIONS

**Business and Professions Code:**

8. Section **4043(a)** of the Code states:

"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

9. Section **4059** of the Code, in pertinent part, prohibits furnishing of any dangerous drug or dangerous device except upon the prescription of an authorized prescriber.

10. Section **4059.5** of the Code, in pertinent part, permits ordering/delivery of dangerous drugs or devices only by and to entities licensed by the board and authorized prescribers, and requires that all deliveries to a licensed premises shall be signed for and received by a pharmacist.

11. Section **4061** of the Code provides, in pertinent part, that manufacturers' sales representatives may distribute complimentary samples of drugs only to and pursuant to a written request from an authorized prescriber that specifies the name and quantity of drug desired.

12. Section **4063** of the Code states:

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

13. Section **4064** of the Code states:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

14. Section **4076**, subdivision (a), of the Code provides, in pertinent part, that a

pharmacist shall not dispense any prescription except in a container meeting the requirements of state and federal law that is correctly labeled with information including the following:

(1) Except where ordered otherwise by the prescriber, the manufacturer's trade name of the drug or the generic name and the name of the manufacturer;

(2) The directions for use of the drug;

(3) The name of the patient or patients;

(4) The name(s) of the prescriber(s);

(5) The date of dispensing;

(6) The name and address of the pharmacy, and prescription number;

(7) The strength of the drug(s) dispensed;

(8) The quantity of the drug(s) dispensed;

(9) The expiration date of the drug(s) dispensed;

(10) If on the prescription, the condition or purpose for which the drug was prescribed;

(11) A physical description of the dispensed medication.

15. Section **4081** of the Code states, in pertinent part:

(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 a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

. . .

16. Section **4105** of the Code requires, in pertinent part, that unless a waiver is granted by the board, all records and other documentation of the acquisition and disposition of dangerous drugs and devices by any entity licensed by the board be retained on the licensed premises, in a readily retrievable form, for three years from the date of making.

17. 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.

18. Section **4115(e)** of the Code states:

No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

19. Section **4125(a)** of the Code states:

Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

20. Section **4160(a)** of the Code states:

(a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

21. 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 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.

(g) Knowingly making or signing any certificate or other document that falsely represents

the existence or nonexistence of a state of facts.

. . .

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

. . .

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

. . .

(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.

. . .

22. Section **4324** of the Code states:

(a) Every person who signs the name of another, or of a fictitious person, or falsely makes, alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail for not more than one year.

(b) Every person who has in his or her possession any drugs secured by a forged prescription shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in the county jail for not more than one year.

23. Section **4332** of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or

refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

24. Section **4342** of the Code states:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

**Health and Safety Code**:

25. Health and Safety Code section **11165** provides, in pertinent part, for establishment and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV controlled substance, the dispensing pharmacy or clinic transmit a report with certain information on the patient, prescriber, controlled substance, and prescription, to the California Department of Justice, on a weekly basis in a format prescribed by the California Department of Justice. [1]

26. Health and Safety Code section **111340** states:

Any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

---

[1] Health and Safety Code section 11165 was first amended to impose CURES reporting requirements effective January 1, 2005; as of that date, prescriptions for Schedule II and III drugs had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

27. Health and Safety Code section **111440** states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

**California Code of Regulations**:

28. California Code of Regulations, title 16, section **1707.2** states, in pertinent part:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a

health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

. . .

29. California Code of Regulations, title 16, section **1707.3** states:

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

30. California Code of Regulations, title 16, section **1711** states:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in

paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

31. 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.

. . .

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

. . .

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

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

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

33. California Code of Regulations, title 16, section **1717** states, in pertinent part:

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

. . .

(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

34. California Code of Regulations, title 16, section **1718**, states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

35. California Code of Regulations, title 16, section **1793.7** states, in pertinent part:

. . .

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

. . .

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

. . .

**Code of Federal Regulations**:

36. Title 21, Code of Federal Regulations, section **1304.04(f)** requires, in pertinent part, that inventories and records of Schedule I and II controlled substances shall be kept separate from all other records, and that inventories and records of Schedule III-V controlled substances shall be either kept separate from other records, or be immediately retrievable from the business records.

**Controlled Substances/Dangerous Drugs**:

37. Section **4021** of the Code provides that a "controlled substance" means any substance listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

38. Section **4022** of the Code states, in pertinent part:

"Dangerous drug: or "dangerous device" means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import. . . .

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

39. **Klonopin** is a brand name for **clonazepam**, a Schedule IV controlled substance as designated by Health and Safety Code section 11057(d) and a dangerous drug as designated by Business and Professions Code section 4022. It is used to treat mental health symptoms.

40. **Celexa** is a brand name for **citalopram**, a dangerous drug as designated by Business and Professions Code section 4022. It is used to treat mental health symptoms.

41. **Zyprexa** is a brand name for **olanzapine**, a dangerous drug as designated by Business

and Professions Code section 4022. It is used to treat mental health symptoms.

**COST RECOVERY**

42. Section **125.3** of the Code provides, 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.

**2011 INSPECTIONS AND INVESTIGATION**

43. Between in or about January and April 2011, Respondents were the subject(s) of investigation(s) by the Board of Pharmacy. The investigation(s) revealed record-keeping, dispensing, and furnishing practices that failed to comply with the law.

44. During January 12 and January 27, 2011 inspections by Board Inspector(s), each of the following deviations from pharmacy requirements was/were noted by the Inspector(s):

a. Included in the active drug inventory for the pharmacy were: (i) a prescription bottle for patient SM, labeled by a Safeway Pharmacy, prescription number 6448294 dispensed on January 4, 2009, that expired in October 2010, with some of the labeled drug quantity missing; (ii) several boxes of prescription bottles containing professional drug samples; and (iii) one or more bubble packs or strip packs containing drugs returned from board and care homes. There were no records of acquisition maintained by Respondents with regard to any of these items.

b. Respondents used a prescription dispensing software and system to create pre-filled bubble packs or strip packs for board and care homes, subdivided by patient and dose. The software and system did not make note of the identity of the dispensing pharmacist, nor was this information recorded anywhere on the label or in Respondents' records. Respondent Nasrah said that he had no record of and/or it was not possible to identify the dispensing pharmacist for any of the thousands of prescriptions dispensed using this system during the previous nine (9) years.

c. The software and system used to generate the bubble/strip packs for board and care homes also did not include required information on the label(s) generated during this nine (9) year period, including: dispense date; drug manufacturer; and/or address of the pharmacy.

d. In various places in the pharmacy, including in the active inventory, were

prescription bottles containing quantities of dangerous drugs, with either no labels or incomplete labels affixed. Respondent asserted that these were returned from assisted living facilities.

e. Since at least October 21, 2009, Respondents had not successfully transmitted data regarding controlled substances dispensed by the pharmacy to the Controlled Substances Utilization Review (CURES) database maintained by the California Department of Justice.

f. Controlled substance invoices for at least the two months prior to the inspection were grouped and filed together, and there was no separation of Schedule II invoices.

g. On at least one occasion, including on or about July 17, 2010, a non-pharmacist (store clerk) signed a wholesaler's proof of delivery form to accept delivery of dangerous drugs.

45. Between on or about July 10, 2009 and on or about January 10, 2011, Respondents dispensed dangerous drugs and/or controlled substances to patient DC pursuant to unauthorized prescriptions and/or refills, including:

a. On at least ten (10) occasions between on or about December 14, 2009 and on or about January 10, 2011, Respondents filled new prescriptions for DC for controlled substances and/or dangerous drugs without prescriber authorization, including: two (2) prescriptions for controlled substance/dangerous drug **clonazepam 0.5mg (Klonopin)**; six (6) prescriptions for the dangerous drug **Celexa 40mg**; and two (2) prescriptions for the dangerous drug **Zyprexa 20mg**.

b. On at least twenty-nine (29) occasions between on or about August 2, 2009 and on or about September 1, 2010, Respondents furnished refill prescriptions to DC for controlled substances and/or dangerous drugs without prescriber authorization, including: five (5) refills for controlled substance/dangerous drug **clonazepam 0.5mg (Klonopin)**; fourteen (14) refills for the dangerous drug **Zyprexa 20mg**; and ten (10) refills for the dangerous drug **Celexa 40mg**.

c. On at least seven (7) occasions between on or about July 10, 2009 and on or about January 19, 2010, Respondents created and/or signed prescription documents for DC that falsely stated authorization by the prescriber, including: one (1) prescription for controlled substance/dangerous drug **clonazepam 0.5mg (Klonopin)**; five (5) prescriptions for the dangerous drug **Celexa 40mg**; and one (1) prescription for the dangerous drug **Zyprexa 20mg**.

///

**FIRST CAUSE FOR DISCIPLINE**

(Incomplete Inventory and/or Records of Acquisition and/or Disposition)

46. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section(s) 4081, 4105, 4332 and/or 4342 of the Code, and/or California Code of Regulations, title 16, section 1718, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents failed to maintain an accurate, complete, and readily retrievable inventory and/or records of acquisition and disposition of all dangerous drugs in the pharmacy inventory.

**SECOND CAUSE FOR DISCIPLINE**

(Possessing and/or Dispensing/Furnishing Drug Samples)

47. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4061 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents had in their inventory, and/or had previously dispensed or furnished, manufacturer drug samples.

**THIRD CAUSE FOR DISCIPLINE**

(Failure to Identify Dispensing Pharmacist)

48. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1717, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents dispensed medications without a means of identifying the dispensing pharmacist.

///

**FOURTH CAUSE FOR DISCIPLINE**

(Inadequately Labeled Prescription Containers)

49. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4076 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents dispensed medications in prescription containers which failed to include required information.

**FIFTH CAUSE FOR DISCIPLINE**

(Possession of Misbranded Drug Containers)

50. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340 and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents possessed drug containers that were misbranded inasmuch as they had affixed to them no or incomplete labels describing the contents, the manufacturer, and other required data.

**SIXTH CAUSE FOR DISCIPLINE**

(Failure to Report Controlled Substance Prescriptions to CURES)

51. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 11165, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, in the period prior to January 12, 2011, the pharmacy had not successfully transmitted any dispensing data to CURES for controlled substances that were dispensed since at least October 21, 2009.

**SEVENTH CAUSE FOR DISCIPLINE**

(Failure to Segregate Schedule II Records)

52. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Title 21, Code of Federal Regulations, section 1304.04(f), for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, on or about January 12, 2011, Schedule II records were not segregated.

**EIGHTH CAUSE FOR DISCIPLINE**

(Receipt and Acknowledgment of Delivery by Non-Pharmacist)

53. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section(s) 4059 and/or 4059.5 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, a non-pharmacist received and/or signed for a delivery of a dangerous drug or device.

**NINTH CAUSE FOR DISCIPLINE**

(Furnishing/Dispensing Prescriptions Without Prescriber Authorization)

54. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4059 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 45 above, Respondents furnished ten (10) new prescriptions to patient DC that were not authorized by a prescriber.

**TENTH CAUSE FOR DISCIPLINE**

(Furnishing/Dispensing Refills Without Prescriber Authorization)

55. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4063 of the Code, for violating

statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 45 above, Respondents furnished twenty nine (29) refills to patient DC that were not authorized by a prescriber.

**ELEVENTH CAUSE FOR DISCIPLINE**

(Dishonesty/Creation of False Prescription Document(s))

56. Respondents are each and severally subject to discipline under section 4301(f) and/or (g) and/or section 4113(c) and/or section 4324 of the Code, for acts involving moral turpitude, dishonesty, fraud, deceit, corruption and forgery, and/or for knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts in that, as described in paragraph 45 above, Respondents created seven (7) false prescriptions for patient DC.

**TWELFTH CAUSE FOR DISCIPLINE**

(Failure to Maintain Records of Acquisition of Drugs)

57. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about January 12, 2011, Respondents' facility contained a prescription bottle containing 180 Premarin 1.25 tablets, Safeway prescription number 6448294, issue to patient SM on January 4, 2009. Respondents had no record of the acquisition of this item.

**THIRTEENTH CAUSE FOR DISCIPLINE**

(Unprofessional Conduct)

58. are each and severally subject to discipline under section 4301 of the Code in that Respondents, as described in paragraphs 43-45 above, engaged in unprofessional conduct.

///

///

**CASH COMPROMISE OF MEDI-CAL CHARGES**

59. On or about June, 2010, the California Department of Health Care Services (hereinafter "Department") audited Respondents' premises and records pertaining to the period of March 1, 2009 through March 31, 2010.

60. Based on this audit, on or about July 16, 2010, the Department took formal action against Respondents by withholding all Medi-Cal payments to Respondents and by suspending and deactivating Respondents' Medi-Cal provider number and National Provider Identifier number. The Department charged Respondents with having violated California Welfare and Institutions Code section 14107(b) (false and fraudulent claims) and California Code of Regulations, Title 22, sections 51470(a) (false billing) and 51485 (submission of false information), based on to the following misconduct:

a) Overbilling for medications;

b) Billing for prescriptions that had not actually been provided to beneficiaries;

c) Falsification of a telephone prescription; and

d) Failure to purchase sufficient quantities of drugs to fill claims made for orders filled.

61. On or about October 13, 2010, Respondents entered into a cash compromise of the above-described charges by signing a document entitled "Stipulation And Settlement Agreement Between The California Department of Health Care Services And Daniel's Pharmacy." The agreement provided for settlement of the charges in exchange for Respondents' agreement to pay approximately $1,000,000.00 to the Department.

**FOURTEENTH CAUSE FOR DISCIPLINE**

(Cash Compromise of Medi-Cal Charges)

62. Respondents are each and severally subject to discipline under section 4301(m) and/or section 4113(c) of the Code, in that they engaged in a cash compromise of a charge of violation of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program, as described above in paragraphs 59-61.

///

///

**2013 INSPECTION**

63. On or about August 1, 2013, Pharmacy Board inspectors inspected Respondents' pharmacy in order to ascertain whether Respondents continued to be in violation of law. The Inspectors observed numerous violations, as set forth below in the following Causes for Discipline.

**FIFTEENTH CAUSE FOR DISCIPLINE**

(Failure to Consult with On-Premises Patient)

64. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1707.2(b)(1)(A), for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents dispensed a prescription to patient DV, which had not previously been dispensed to patient DV, without providing a consultation by a pharmacist. Respondents failed to have a policy or procedure identifying medications for which a consultation should be provided.

**SIXTEENTH CAUSE FOR DISCIPLINE**

(Failure to Consult with Off-Premises Patient)

65. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1707.2(b)(2), for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents prepared prescription medication for delivery to a patient, which medication had not previously been dispensed to said patient, without providing any notification to the patient regarding the patient's right to request a consultation.

**SEVENTEENTH CAUSE FOR DISCIPLINE**

(Possession of Misbranded Drug Containers)

66. Respondents are each and severally subject to discipline under section 4301(j) and/or

(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340 and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Respondents possessed numerous misbranded/unlabeled prescription vials with dangerous drugs and outdated products in current inventory. Respondents also had in its possession previously-dispensed bubble packs of medications which had been returned by board-and-care homes.

**EIGHTEENTH CAUSE FOR DISCIPLINE**

(Failure to Initiate Quality Assurance Review)

67. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4125(a) and California Code of Regulations, Title 16, section 1711, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents admitted to Board Inspectors that they had failed to complete quality assurance reviews, procedures and related forms in the aftermath of dispensing errors.

**NINETEENTH CAUSE FOR DISCIPLINE**

(Variation from Prescription)

68. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1716, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Board Inspectors identified two prescriptions, RX numbers N9878911 and N9879201, which contained erroneous directions for use and/or identified the wrong prescriber.

**TWENTIETH CAUSE FOR DISCIPLINE**

(Improper Supervision of Pharmacy Technician)

69. Respondents are each and severally subject to discipline under section 4301(j) and/or

(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1793.7, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' pharmacy technician worked unsupervised in the basement of the facility, and had the ability to override the automated dispensing unit SynMed's scan features when replenishing the dispensing unit.

**TWENTY-FIRST CAUSE FOR DISCIPLINE**

(Failure to Maintain Operational Standards -- Drugs)

70. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' pharmacy premises contained dangerous drugs on stock shelves in unlabeled containers without drug name, strength, lot numbers and expiration dates. The premises also contained automated dispensing units without accurate lot numbers and expiration dates. Loose pills were sitting in on various counters in various locations.

**TWENTY-SECOND CAUSE FOR DISCIPLINE**

(Failure to Maintain Records of Acquisition of Drugs)

71. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Respondents' facility contained numerous full bubble packs which had been acquired from board-and-care homes, the receipt/acquisition of which had not been memorialized in any record. Similarly, Respondents were in possession of a Walgreens prescription bottle containing amlodipine-benzapril capsules

which had evidently previously been issued to patient PL. Respondents had no record of the acquisition of this item.

**TWENTY-THIRD CAUSE FOR DISCIPLINE**

(Unlicensed Wholesale Activity)

72. Respondents are each and severally subject to discipline under section 4301(f) and/or (j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4060, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 13, 2013, Respondents were found to be in possession of medications which had been returned to them by board-and-care homes, thus constituting wholesaling activity, when Respondents were not licensed as wholesalers. Respondents evidently intended to reuse the medications.

**TWENTY-FOURTH CAUSE FOR DISCIPLINE**

(False Statements on Certificates or Documents)

73. Respondents are each and severally subject to discipline under section 4301(g) and/or (j) and/or (o) and/or section 4113(c) of the Code, for making a false statement on a certificate or document and for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Board Inspectors located documents showing that Respondents had filled a prescription for divalproex by Wockhardt by utilizing Mylan divalproex, but billed insurance as if they had provided divalproex by Wockhardt.

**TWENTY-FIFTH CAUSE FOR DISCIPLINE**

(Failure to Maintain Operational Standards -- Key)

74. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of

laws or regulations governing the practice of pharmacy, in that on or about August 2, 2013, Respondents admitted that the key to the pharmacy was in the possession of a family member, and was not in a tamper-proof container.

**2014 INSPECTION**

75. On or about August 5, 2014, Pharmacy Board inspectors inspected Respondents' pharmacy. At that time, the inspectors observed an individual, Lydia Dean, acting as a pharmacy technician, and filling prescriptions, when that individual was not licensed as a pharmacy technician.

**TWENTY-SIXTH CAUSE FOR DISCIPLINE**

(Employment of Unlicensed Pharmacy Technician)

76. Respondents are each and severally subject to discipline under Code section 4301, subsections (j) and/or (o), and under Code sections 4113, subsection (c), and 4115, subsection (e), in that Respondents employed an unlicensed individual, Lydia Dean, to act as a pharmacy technician, as set forth above in paragraph 75.

**DISCIPLINE CONSIDERATIONS**

77. To determine the level of discipline, if any, to be imposed on Respondent Daniels and/or Respondent Nasrah (collectively, Respondents), Complainant further alleges that:

a. On or about October 21, 2009, Citation No. CI 2008 38553, with a fine of $4,000.00, was issued to Respondent Daniels for failure(s) to comply with its obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV controlled substance prescriptions dispensed by the pharmacy to the Controlled Substance Utilization Review and Evaluation System (CURES), in and/or between December 2004 and December 2008. That citation is now final and is incorporated by reference as if fully set forth herein.

b. On or about October 21, 2009, Citation No. CI 2008 41785, with a fine of $4,000.00, was issued to Respondent Nasrah, as PIC, for Daniels Pharmacy's failure(s) to comply with its obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV controlled substance prescriptions dispensed to the Controlled Substance Utilization Review and Evaluation System (CURES), in and/or between December 2004 and December 2008. That

citation is now final and is incorporated by reference as if fully set forth 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. Revoking or suspending Pharmacy License No. PHY 36740, issued to Daniels Pharmacy (Respondent Daniels);

2. Revoking or suspending Pharmacist License No. RPH 40241, issued to Iyad Nasrah (Respondent Nasrah);

3. Ordering Respondent Daniels and Respondent Nasrah to jointly and severally be responsible to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Taking such other and further action as is deemed necessary and proper.

DATED: 1/23/15

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

KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General
JONATHAN D. COOPER
Deputy Attorney General
State Bar No. 141461
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 703-1404
Facsimile: (415) 703-5480
*Attorneys for Complainant*

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

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>**DANIELS PHARMACY**<br>**943 Geneva Avenue**<br>**San Francisco, CA 94112**<br><br>**Pharmacy License No. PHY 36740**<br><br>**and**<br><br>**IYAD I. NASRAH**<br>**488 Gellert Drive**<br>**San Francisco, CA 94132**<br><br>**Pharmacist License No. RPH 40241**<br><br>Respondents. | Case No. 4125<br><br>**A C C U S A T I O N** |

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 October 24, 1990, the Board of Pharmacy issued Pharmacy License No. PHY 36740 to Daniels Pharmacy (Respondent Daniels). The License was in full force and effect at all times relevant to the charges herein, and will expire on October 1, 2014, unless renewed.

3. On or about August 20, 1986, the Board of Pharmacy issued Pharmacist License No. RPH 40241 to Iyad I. Nasrah (Respondent Nasrah). The License was in full force and effect at all

times relevant to the charges herein and will expire on October 31, 2014, unless renewed. Since on or about October 24, 1990, Respondent Nasrah has served and/or has been reflected in Board records as the Pharmacist in Charge (PIC) for Respondent Daniels.

## JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section **4011** of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section **4300(a)** of the Code provides that every license issued by the Board may be suspended or revoked.

7. Section **4300.1** of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

## STATUTORY AND REGULATORY PROVISIONS

**Business and Professions Code:**

8. Section **4043(a)** of the Code states:

"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

9. Section **4059** of the Code, in pertinent part, prohibits furnishing of any dangerous drug or dangerous device except upon the prescription of an authorized prescriber.

10. Section **4059.5** of the Code, in pertinent part, permits ordering/delivery of dangerous drugs or devices only by and to entities licensed by the board and authorized prescribers, and requires that all deliveries to a licensed premises shall be signed for and received by a pharmacist.

11. Section **4061** of the Code provides, in pertinent part, that manufacturers' sales representatives may distribute complimentary samples of drugs only to and pursuant to a written request from an authorized prescriber that specifies the name and quantity of drug desired.

12. Section **4063** of the Code states:

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

13. Section **4064** of the Code states:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

14. Section **4076**, subdivision (a), of the Code provides, in pertinent part, that a

pharmacist shall not dispense any prescription except in a container meeting the requirements of state and federal law that is correctly labeled with information including the following:

(1) Except where ordered otherwise by the prescriber, the manufacturer's trade name of the drug or the generic name and the name of the manufacturer;

(2) The directions for use of the drug;

(3) The name of the patient or patients;

(4) The name(s) of the prescriber(s);

(5) The date of dispensing;

(6) The name and address of the pharmacy, and prescription number;

(7) The strength of the drug(s) dispensed;

(8) The quantity of the drug(s) dispensed;

(9) The expiration date of the drug(s) dispensed;

(10) If on the prescription, the condition or purpose for which the drug was prescribed;

(11) A physical description of the dispensed medication.

15. Section **4081** of the Code states, in pertinent part:

(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 a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

. . .

16. Section **4105** of the Code requires, in pertinent part, that unless a waiver is granted by the board, all records and other documentation of the acquisition and disposition of dangerous drugs and devices by any entity licensed by the board be retained on the licensed premises, in a readily retrievable form, for three years from the date of making.

17. 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.

18. Section **4125(a)** of the Code states:

Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

19. Section **4160(a)** of the Code states:

(a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

20. 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 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.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

. . .

(j) The violation of any of the statutes of this state, of any other state, or of the United

States regulating controlled substances and dangerous drugs.

. . .

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

. . .

(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.

. . .

21. Section **4324** of the Code states:

(a) Every person who signs the name of another, or of a fictitious person, or falsely makes, alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county jail for not more than one year.

(b) Every person who has in his or her possession any drugs secured by a forged prescription shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in the county jail for not more than one year.

22. Section **4332** of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

///

23. Section **4342** of the Code states:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

**Health and Safety Code**:

24. Health and Safety Code section **11165** provides, in pertinent part, for establishment and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV controlled substance, the dispensing pharmacy or clinic transmit a report with certain information on the patient, prescriber, controlled substance, and prescription, to the California Department of Justice, on a weekly basis in a format prescribed by the California Department of Justice. [1]

25. Health and Safety Code section **111340** states:

Any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small

[1] Health and Safety Code section 11165 was first amended to impose CURES reporting requirements effective January 1, 2005; as of that date, prescriptions for Schedule II and III drugs had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

packages shall be established in accordance with regulations adopted pursuant to Section 110380.

26. Health and Safety Code section **111440** states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

**California Code of Regulations**:

27. California Code of Regulations, title 16, section **1707.2** states, in pertinent part:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of

Business and Professions Code Section 4074.

. . .

28. California Code of Regulations, title 16, section **1707.3** states:

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

29. California Code of Regulations, title 16, section **1711** states:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop

pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

30. 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.

. . .

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

. . .

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

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

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

32. California Code of Regulations, title 16, section **1717** states, in pertinent part:

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code section 4040, the

following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

. . .

(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

33. California Code of Regulations, title 16, section **1718**, states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

34. California Code of Regulations, title 16, section **1793.7** states, in pertinent part:

. . .

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the

preparation and dispensing of medications, including the maintenance of appropriate records.

. . .

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

. . .

**Code of Federal Regulations**:

35. Title 21, Code of Federal Regulations, section **1304.04(f)** requires, in pertinent part, that inventories and records of Schedule I and II controlled substances shall be kept separate from all other records, and that inventories and records of Schedule III-V controlled substances shall be either kept separate from other records, or be immediately retrievable from the business records.

**Controlled Substances/Dangerous Drugs**:

36. Section **4021** of the Code provides that a "controlled substance" means any substance listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

37. Section **4022** of the Code states, in pertinent part:

"Dangerous drug: or "dangerous device" means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import. . . .

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

38. **Klonopin** is a brand name for **clonazepam**, a Schedule IV controlled substance as designated by Health and Safety Code section 11057(d) and a dangerous drug as designated by Business and Professions Code section 4022. It is used to treat mental health symptoms.

39. **Celexa** is a brand name for **citalopram**, a dangerous drug as designated by Business and Professions Code section 4022. It is used to treat mental health symptoms.

40. **Zyprexa** is a brand name for **olanzapine**, a dangerous drug as designated by Business and Professions Code section 4022. It is used to treat mental health symptoms.

///

## COST RECOVERY

41. Section **125.3** of the Code provides, 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.

## 2011 INSPECTIONS AND INVESTIGATION

42. Between in or about January and April 2011, Respondents were the subject(s) of investigation(s) by the Board of Pharmacy. The investigation(s) revealed record-keeping, dispensing, and furnishing practices that failed to comply with the law.

43. During January 12 and January 27, 2011 inspections by Board Inspector(s), each of the following deviations from pharmacy requirements was/were noted by the Inspector(s):

a. Included in the active drug inventory for the pharmacy were: (i) a prescription bottle for patient SM, labeled by a Safeway Pharmacy, prescription number 6448294 dispensed on January 4, 2009, that expired in October 2010, with some of the labeled drug quantity missing; (ii) several boxes of prescription bottles containing professional drug samples; and (iii) one or more bubble packs or strip packs containing drugs returned from board and care homes. There were no records of acquisition maintained by Respondents with regard to any of these items.

b. Respondents used a prescription dispensing software and system to create pre-filled bubble packs or strip packs for board and care homes, subdivided by patient and dose. The software and system did not make note of the identity of the dispensing pharmacist, nor was this information recorded anywhere on the label or in Respondents' records. Respondent Nasrah said that he had no record of and/or it was not possible to identify the dispensing pharmacist for any of the thousands of prescriptions dispensed using this system during the previous nine (9) years.

c. The software and system used to generate the bubble/strip packs for board and care homes also did not include required information on the label(s) generated during this nine (9) year period, including: dispense date; drug manufacturer; and/or address of the pharmacy.

d. In various places in the pharmacy, including in the active inventory, were prescription bottles containing quantities of dangerous drugs, with either no labels or incomplete

labels affixed. Respondent asserted that these were returned from assisted living facilities.

e. Since at least October 21, 2009, Respondents had not successfully transmitted data regarding controlled substances dispensed by the pharmacy to the Controlled Substances Utilization Review (CURES) database maintained by the California Department of Justice.

f. Controlled substance invoices for at least the two months prior to the inspection were grouped and filed together, and there was no separation of Schedule II invoices.

g. On at least one occasion, including on or about July 17, 2010, a non-pharmacist (store clerk) signed a wholesaler's proof of delivery form to accept delivery of dangerous drugs.

44. Between on or about July 10, 2009 and on or about January 10, 2011, Respondents dispensed dangerous drugs and/or controlled substances to patient DC pursuant to unauthorized prescriptions and/or refills, including:

a. On at least ten (10) occasions between on or about December 14, 2009 and on or about January 10, 2011, Respondents filled new prescriptions for DC for controlled substances and/or dangerous drugs without prescriber authorization, including: two (2) prescriptions for controlled substance/dangerous drug **clonazepam 0.5mg (Klonopin)**; six (6) prescriptions for the dangerous drug **Celexa 40mg**; and two (2) prescriptions for the dangerous drug **Zyprexa 20mg**.

b. On at least twenty-nine (29) occasions between on or about August 2, 2009 and on or about September 1, 2010, Respondents furnished refill prescriptions to DC for controlled substances and/or dangerous drugs without prescriber authorization, including: five (5) refills for controlled substance/dangerous drug **clonazepam 0.5mg (Klonopin)**; fourteen (14) refills for the dangerous drug **Zyprexa 20mg**; and ten (10) refills for the dangerous drug **Celexa 40mg**.

c. On at least seven (7) occasions between on or about July 10, 2009 and on or about January 19, 2010, Respondents created and/or signed prescription documents for DC that falsely stated authorization by the prescriber, including: one (1) prescription for controlled substance/dangerous drug **clonazepam 0.5mg (Klonopin)**; five (5) prescriptions for the dangerous drug **Celexa 40mg**; and one (1) prescription for the dangerous drug **Zyprexa 20mg**.

///

///

**FIRST CAUSE FOR DISCIPLINE**

(Incomplete Inventory and/or Records of Acquisition and/or Disposition)

45. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section(s) 4081, 4105, 4332 and/or 4342 of the Code, and/or California Code of Regulations, title 16, section 1718, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents failed to maintain an accurate, complete, and readily retrievable inventory and/or records of acquisition and disposition of all dangerous drugs in the pharmacy inventory.

**SECOND CAUSE FOR DISCIPLINE**

(Possessing and/or Dispensing/Furnishing Drug Samples)

46. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4061 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents had in their inventory, and/or had previously dispensed or furnished, manufacturer drug samples.

**THIRD CAUSE FOR DISCIPLINE**

(Failure to Identify Dispensing Pharmacist)

47. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1717, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents dispensed medications without a means of identifying the dispensing pharmacist.

///

///

**FOURTH CAUSE FOR DISCIPLINE**

(Inadequately Labeled Prescription Containers)

48. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4076 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents dispensed medications in prescription containers which failed to include required information.

**FIFTH CAUSE FOR DISCIPLINE**

(Possession of Misbranded Drug Containers)

49. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340 and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents possessed drug containers that were misbranded inasmuch as they had affixed to them no or incomplete labels describing the contents, the manufacturer, and other required data.

**SIXTH CAUSE FOR DISCIPLINE**

(Failure to Report Controlled Substance Prescriptions to CURES)

50. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 11165, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, in the period prior to January 12, 2011, the pharmacy had not successfully transmitted any dispensing data to CURES for controlled substances that were dispensed since at least October 21, 2009.

///

///

**SEVENTH CAUSE FOR DISCIPLINE**

(Failure to Segregate Schedule II Records)

51. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Title 21, Code of Federal Regulations, section 1304.04(f), for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, on or about January 12, 2011, Schedule II records were not segregated.

**EIGHTH CAUSE FOR DISCIPLINE**

(Receipt and Acknowledgment of Delivery by Non-Pharmacist)

52. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section(s) 4059 and/or 4059.5 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, a non-pharmacist received and/or signed for a delivery of a dangerous drug or device.

**NINTH CAUSE FOR DISCIPLINE**

(Furnishing/Dispensing Prescriptions Without Prescriber Authorization)

53. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4059 of the Code, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 44 above, Respondents furnished ten (10) new prescriptions to patient DC that were not authorized by a prescriber.

**TENTH CAUSE FOR DISCIPLINE**

(Furnishing/Dispensing Refills Without Prescriber Authorization)

54. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to section 4063 of the Code, for violating

statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that, as described in paragraph 44 above, Respondents furnished twenty nine (29) refills to patient DC that were not authorized by a prescriber.

**ELEVENTH CAUSE FOR DISCIPLINE**

(Dishonesty/Creation of False Prescription Document(s))

55. Respondents are each and severally subject to discipline under section 4301(f) and/or (g) and/or section 4113(c) and/or section 4324 of the Code, for acts involving moral turpitude, dishonesty, fraud, deceit, corruption and forgery, and/or for knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts in that, as described in paragraph 44 above, Respondents created seven (7) false prescriptions for patient DC.

**TWELFTH CAUSE FOR DISCIPLINE**

(Failure to Maintain Records of Acquisition of Drugs)

56. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about January 12, 2011, Respondents' facility contained a prescription bottle containing 180 Premarin 1.25 tablets, Safeway prescription number 6448294, issue to patient SM on January 4, 2009. Respondents had no record of the acquisition of this item.

**THIRTEENTH CAUSE FOR DISCIPLINE**

(Unprofessional Conduct)

57. Respondent is subject to discipline under section 4301 of the Code in that Respondents, as described in paragraphs 42-44 above, engaged in unprofessional conduct.

///

///

**CASH COMPROMISE OF MEDI-CAL CHARGES**

58. On or about June, 2010, the California Department of Health Care Services (hereinafter "Department") audited Respondents' premises and records pertaining to the period of March 1, 2009 through March 31, 2010.

59. Based on this audit, on or about July 16, 2010, the Department took formal action against Respondents by withholding all Medi-Cal payments to Respondents and by suspending and deactivating Respondents' Medi-Cal provider number and National Provider Identifier number. The Department charged Respondents with having violated California Welfare and Institutions Code section 14107(b) (false and fraudulent claims) and California Code of Regulations, Title 22, sections 51470(a) (false billing) and 51485 (submission of false information), based on to the following misconduct:

a) Overbilling for medications;

b) Billing for prescriptions that had not actually been provided to beneficiaries;

c) Falsification of a telephone prescription; and

d) Failure to purchase sufficient quantities of drugs to fill claims made for orders filled.

60. On or about October 13, 2010, Respondents entered into a cash compromise of the above-described charges by signing a document entitled "Stipulation And Settlement Agreement Between The California Department of Health Care Services And Daniel's Pharmacy." The agreement provided for settlement of the charges in exchange for Respondents' agreement to pay approximately $1,000,000.00 to the Department.

**FOURTEENTH CAUSE FOR DISCIPLINE**

(Cash Compromise of Medi-Cal Charges)

61. Respondents are each and severally subject to discipline under section 4301(m) and/or section 4113(c) of the Code, in that they engaged in a cash compromise of a charge of violation of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program, as described above in paragraphs 55-57.

///

///

**2013 INSPECTION**

62. On or about August 1, 2013, Pharmacy Board inspectors inspected Respondents' pharmacy in order to ascertain whether Respondents continued to be in violation of law. The Inspectors observed numerous violations, as set forth below in the following Causes for Discipline.

**FIFTEENTH CAUSE FOR DISCIPLINE**

(Failure to Consult with On-Premises Patient)

63. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1707.2(b)(1)(A), for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents dispensed a prescription to patient DV, which had not previously been dispensed to patient DV, without providing a consultation by a pharmacist. Respondents failed to have a policy or procedure identifying medications for which a consultation should be provided.

**SIXTEENTH CAUSE FOR DISCIPLINE**

(Failure to Consult with Off-Premises Patient)

64. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1707.2(b)(2), for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents prepared prescription medication for delivery to a patient, which medication had not previously been dispensed to said patient, without providing any notification to the patient regarding the patient's right to request a consultation.

**SEVENTEENTH CAUSE FOR DISCIPLINE**

(Possession of Misbranded Drug Containers)

65. Respondents are each and severally subject to discipline under section 4301(j) and/or

(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340 and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Respondents possessed numerous misbranded/unlabeled prescription vials with dangerous drugs and outdated products in current inventory. Respondents also had in its possession previously-dispensed bubble packs of medications which had been returned by board-and-care homes.

**EIGHTEENTH CAUSE FOR DISCIPLINE**

(Failure to Initiate Quality Assurance Review)

66. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4125(a) and California Code of Regulations, Title 16, section 1711, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents admitted to Board Inspectors that they had failed to complete quality assurance reviews, procedures and related forms in the aftermath of dispensing errors.

**NINETEENTH CAUSE FOR DISCIPLINE**

(Variation from Prescription)

67. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1716, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Board Inspectors identified two prescriptions, RX numbers N9878911 and N9879201, which contained erroneous directions for use and/or identified the wrong prescriber.

**TWENTIETH CAUSE FOR DISCIPLINE**

(Improper Supervision of Pharmacy Technician)

68. Respondents are each and severally subject to discipline under section 4301(j) and/or

(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1793.7, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' pharmacy technician worked unsupervised in the basement of the facility, and had the ability to override the automated dispensing unit SynMed's scan features when replenishing the dispensing unit.

**TWENTY-FIRST CAUSE FOR DISCIPLINE**

(Failure to Maintain Operational Standards -- Drugs)

69. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' pharmacy premises contained dangerous drugs on stock shelves in unlabeled containers without drug name, strength, lot numbers and expiration dates. The premises also contained automated dispensing units without accurate lot numbers and expiration dates. Loose pills were sitting in on various counters in various locations.

**TWENTY-SECOND CAUSE FOR DISCIPLINE**

(Failure to Maintain Records of Acquisition of Drugs)

70. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Respondents' facility contained numerous full bubble packs which had been acquired from board-and-care homes, the receipt/acquisition of which had not been memorialized in any record. Similarly, Respondents were in possession of a Walgreens prescription bottle containing amlodipine-benzapril capsules

which had evidently previously been issued to patient PL. Respondents had no record of the acquisition of this item.

**TWENTY-THIRD CAUSE FOR DISCIPLINE**

(Unlicensed Wholesale Activity)

71. Respondents are each and severally subject to discipline under section 4301(f) and/or (j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4060, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 13, 2013, Respondents were found to be in possession of medications which had been returned to them by board-and-care homes, thus constituting wholesaling activity, when Respondents were not licensed as wholesalers. Respondents evidently intended to reuse the medications.

**TWENTY-FOURTH CAUSE FOR DISCIPLINE**

(False Statements on Certificates or Documents)

72. Respondents are each and severally subject to discipline under section 4301(g) and/or (j) and/or (o) and/or section 4113(c) of the Code, for making a false statement on a certificate or document and for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Board Inspectors located documents showing that Respondents had filled a prescription for divalproex by Wockhardt by utilizing Mylan divalproex, but billed insurance as if they had provided divalproex by Wockhardt.

**TWENTY-FIFTH CAUSE FOR DISCIPLINE**

(Failure to Maintain Operational Standards -- Key)

73. Respondents are each and severally subject to discipline under section 4301(j) and/or (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of

laws or regulations governing the practice of pharmacy, in that on or about August 2, 2013, Respondents admitted that the key to the pharmacy was in the possession of a family member, and was not in a tamper-proof container.

**DISCIPLINE CONSIDERATIONS**

74. To determine the level of discipline, if any, to be imposed on Respondent Daniels and/or Respondent Nasrah (collectively, Respondents), Complainant further alleges that:

a. On or about October 21, 2009, Citation No. CI 2008 38553, with a fine of $4,000.00, was issued to Respondent Daniels for failure(s) to comply with its obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV controlled substance prescriptions dispensed by the pharmacy to the Controlled Substance Utilization Review and Evaluation System (CURES), in and/or between December 2004 and December 2008. That citation is now final and is incorporated by reference as if fully set forth herein.

b. On or about October 21, 2009, Citation No. CI 2008 41785, with a fine of $4,000.00, was issued to Respondent Nasrah, as PIC, for Daniels Pharmacy's failure(s) to comply with its obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV controlled substance prescriptions dispensed to the Controlled Substance Utilization Review and Evaluation System (CURES), in and/or between December 2004 and December 2008. That citation is now final and is incorporated by reference as if fully set forth 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. Revoking or suspending Pharmacy License No. PHY 36740, issued to Daniels Pharmacy (Respondent Daniels);

2. Revoking or suspending Pharmacist License No. RPH 40241, issued to Iyad Nasrah (Respondent Nasrah);

3. Ordering Respondent Daniels and Respondent Nasrah to jointly and severally be responsible to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Taking such other and further action as is deemed necessary and proper.

DATED: 5/8/14

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