

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

In the Matter of the First Amended Accusation Against:

Case No. 5192

**SAN DIMAS PHARMACY &
COMPOUNDING CENTER; KALPANA
PATEL
AKA KALPANA KALPESHKUMAR
PATEL
3805 San Dimas Street, Suite A
Bakersfield, CA 93301**

Pharmacy Permit No. PHY 48922

and

**KALPANA PATEL
AKA KALPANA KALPESHKUMAR
PATEL
5111 Vista Rica Court
Bakersfield, CA 93311**

Pharmacist License No. RPH 49676

Respondents.

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on January 27, 2017.

It is so ORDERED on December 28, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By _____

Amy Gutierrez, Pharm.D.
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 SHEILA J. VASANTHARAM
Deputy Attorney General
4 State Bar No. 289217
1515 Clay Street, 20th Floor
5 P.O. Box 70550
Oakland, CA 94612-0550
6 Telephone: (510) 879-1006
Facsimile: (510) 622-2270
7 E-mail: Sheila.Vasantharam@doj.ca.gov
Attorneys for Complainant

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BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the First Amended Accusation
12 Against:

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13 **SAN DIMAS PHARMACY &**
14 **COMPOUNDING CENTER; KALPANA**
PATEL
15 **AKA KALPANA KALPESHKUMAR**
PATEL
16 **3805 San Dimas Street, Suite A**
Bakersfield, CA 93301

STIPULATED SURRENDER OF
LICENSE AND ORDER

17 **Pharmacy Permit No. PHY 48922**

18 and

19 **KALPANA PATEL**
20 **AKA KALPANA KALPESHKUMAR**
PATEL
21 **5111 Vista Rica Court**
Bakersfield, CA 93311

22 **Pharmacy Permit No. PHY 49676**

23
24 Respondents.

25
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27 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
28 entitled proceedings that the following matters are true:

///

1 PARTIES

2 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
3 (Board). She brought this action solely in her official capacity and is represented in this matter by
4 Kamala D. Harris, Attorney General of the State of California, by Sheila J. Vasantharam, Deputy
5 Attorney General.

6 2. Respondents San Dimas Pharmacy & Compounding Center and Kalpana Patel, also
7 known as Kalpana Kalpeshkumar Patel, are represented in this proceeding by attorney Barry L.
8 Goldner of Klein, DeNatale, Goldner, Cooper, Rosenblid & Kimball, LLP, whose address is
9 4550 California Avenue, Second Floor, Bakersfield, CA 93309.

10 3. On or about January 7, 2008, the Board issued Pharmacy Permit Number PHY 48922
11 to San Dimas Pharmacy & Compounding Center (Respondent San Dimas). The Pharmacy Permit
12 expired on January 1, 2016, and has not been renewed.

13 4. On or about August 22, 1997, the Board issued Pharmacist License Number RPH
14 49676 to Kalpana Patel, also known as Kalpana Kalpeshkumar Patel (Respondent Patel). The
15 Pharmacist License will expire on November 30, 2018, unless renewed.

16 JURISDICTION

17 5. First Amended Accusation No. 5192 was filed before the (Board), and is currently
18 pending against Respondents San Dimas and Patel (Respondents). The First Amended
19 Accusation and all other statutorily required documents were properly served on Respondents on
20 October 13, 2016. Respondents timely filed their Notice of Defense contesting the First
21 Amended Accusation. A copy of First Amended Accusation No. 5192 is attached as Exhibit A
22 and incorporated by reference.

23 ADVISEMENT AND WAIVERS

24 6. Respondents have carefully read, have fully discussed with counsel, and understand
25 the charges and allegations in First Amended Accusation No. 5192. Respondents also have
26 carefully read, have fully discussed with counsel, and understand the effects of this Stipulated
27 Surrender of License and Order.

1 Respondents or their counsel. By signing the stipulation, Respondents understand and agree that
2 they may not withdraw their agreement or seek to rescind the stipulation prior to the time the
3 Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and
4 Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for
5 this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall
6 not be disqualified from further action by having considered this matter.

7 13. The parties understand and agree that Portable Document Format (PDF) and facsimile
8 copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures
9 thereto, shall have the same force and effect as the originals.

10 14. This Stipulated Surrender of License and Order is intended by the parties to be an
11 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
12 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
13 negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order
14 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing
15 executed by an authorized representative of each of the parties.

16 15. In consideration of the foregoing admissions and stipulations, the parties agree that
17 the Board may, without further notice or formal proceeding, issue and enter the following Order:

18 **ORDER**

19 IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 48922, issued to Respondent
20 San Dimas Pharmacy & Compounding Center, and Pharmacist License Number RPH 49676,
21 issued to Kalpana Patel, also known as Kalpana Kalpeshkumar Patel, are surrendered and
22 accepted by the Board of Pharmacy.

23 1. The surrender of Respondent San Dimas Pharmacy Permit and Respondent Patel's
24 Pharmacist License and the acceptance of the surrendered licenses by the Board shall constitute
25 the imposition of discipline against Respondents. This stipulation constitutes a record of the
26 discipline and shall become a part of Respondents' license history with the Board of Pharmacy.

27 2. Respondent San Dimas shall lose all rights and privileges as a Pharmacy in California
28 as of the effective date of the Board's Decision and Order.

1 3. Respondent Patel shall lose all rights and privileges as a Pharmacist in California as
2 of the effective date of the Board's Decision and Order.

3 4. Respondent Patel shall cause to be delivered to the Board her pocket license and, if
4 one was issued, her wall certificate on or before the effective date of the Decision and Order.

5 5. If Respondents ever file an application for licensure or a petition for reinstatement in
6 the State of California, the Board shall treat it as a new application for licensure. Respondents
7 must comply with all the laws, regulations and procedures for licensure in effect at the time the
8 application or petition is filed, and all of the charges and allegations contained in First Amended
9 Accusation No. 5192 shall be deemed to be true, correct and admitted by Respondents when the
10 Board determines whether to grant or deny the application or petition.

11 6. Respondent shall pay the agency its costs of investigation and enforcement in the
12 amount of \$25,394.00, prior to issuance of a new or reinstated license.

13 7. If Respondents should ever apply or reapply for a new license or certification, or
14 petition for reinstatement of license, by any other health care licensing agency in the State of
15 California, all of the charges and allegations contained in the First Amended Accusation No.
16 5192, shall be deemed to be true, correct, and admitted by Respondents for the purpose of any
17 Statement of Issues or any other proceeding seeking to deny or restrict licensure.

18 8. Respondents may not apply, reapply, or petition for any licensure or registration of
19 the Board for three (3) years from the effective date of the Decision and Order.

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ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 11/7/10

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General



SHEILA J. VASANTHARAM
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 5192

1 KAMALA D. HARRIS
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 SHEILA J. VASANTHARAM
Deputy Attorney General
4 State Bar No. 289217
1515 Clay Street, 20th Floor
5 P.O. Box 70550
Oakland, CA 94612-0550
6 Telephone: (510) 879-1006
Facsimile: (510) 622-2270
7 E-mail: Sheila.Vasantharam@doj.ca.gov
Attorneys for Complainant

8
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BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:
12 **SAN DIMAS PHARMACY &**
13 **COMPOUNDING CENTER;**
14 **KALPANA PATEL AKA KALPANA**
KALPESHKUMAR PATEL,
15 **President**
3805 San Dimas Street, Suite A
16 **Bakersfield, CA 93301**

17 **Pharmacy Permit No. PHY 48922**

18 **and**

19 **KALPANA PATEL**
20 **AKA KALPANA KALPESHKUMAR**
PATEL
21 **5111 Vista Rica Court**
Bakersfield, CA 93311

22 **Pharmacist License No. RPH 49676**

23 Respondents.
24

Case No. 5192

FIRST AMENDED
ACCUSATION

25 Complainant alleges:
26
27
28

1 PARTIES

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

5 2. On or about January 7, 2008, the Board of Pharmacy issued Pharmacy Permit
6 Number PHY 48922 to San Dimas Pharmacy & Compounding Center (Respondent San Dimas).
7 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in
8 this First Amended Accusation and will expire on January 1, 2016, unless renewed.

9 3. On or about August 22, 1997, the Board of Pharmacy issued Pharmacist License
10 Number RPH 49676 to Kalpana Patel, also known as Kalpana Kalpeshkumar Patel (Respondent
11 Patel). The Pharmacist License was in full force and effect at all times relevant to the charges
12 brought in this First Amended Accusation and will expire on November 30, 2016, unless
13 renewed.

14 JURISDICTION

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

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

21 6. Section 4300 of the Code states, in pertinent part:

22 "(a) Every license issued may be suspended or revoked.

23 "(b) The board shall discipline the holder of any license issued by the board, whose default
24 has been entered or whose case has been heard by the board and found guilty, by any of the
25 following methods:

26 "(1) Suspending judgment.

27 "(2) Placing him or her upon probation.

28 "(3) Suspending his or her right to practice for a period not exceeding one year.

1 "(4) Revoking his or her license.

2 "(5) Taking any other action in relation to disciplining him or her as the board in its
3 discretion may deem proper.

4 ...

5 "(e) The proceedings under this article shall be conducted in accordance with Chapter 5
6 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
7 shall have all the powers granted therein. The action shall be final, except that the propriety of
8 the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of
9 Civil Procedure."

10 7. Section 4300.1 of the Code states:

11 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by
12 operation of law or by order or decision of the board or a court of law, the placement of a license
13 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
14 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
15 proceeding against, the licensee or to render a decision suspending or revoking the license."

16 **STATUTORY/REGULATORY PROVISIONS**

17
18 8. Section 4040 of the Code states, in pertinent part:

19 "(a) "Prescription" means an oral, written, or electronic transmission order that is both of
20 the following:

21 "(1) Given individually for the person or persons for whom ordered that includes all of the
22 following:

23 "(A) The name or names and address of the patient or patients.

24 "(B) The name and quantity of the drug or device prescribed and the directions for use.

25 "(C) The date of issue.

26 "(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and
27 telephone number of the prescriber, his or her license classification, and his or her federal registry
28 number, if a controlled substance is prescribed.

1 "(E) A legible, clear notice of the condition or purpose for which the drug is being
2 prescribed, if requested by the patient or patients.

3 "(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife,
4 nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to
5 Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug
6 order pursuant to Section 4052.1, 4052.2, or 4052.6."

7 9. Section 4051 of the Code states, in pertinent part:

8 "(a) Except as otherwise provided in this chapter, it is unlawful for any person to
9 manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to
10 dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a
11 pharmacist under this chapter."

12 10. Section 4301 of the Code states, in pertinent part:

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

16 ...

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

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

22 ...

23 "(i) The conviction of a crime substantially related to the qualifications, functions, and
24 duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13
25 (commencing with Section 801) of Title 21 of the United States Code regulating controlled
26 substances or of a violation of the statutes of this state regulating controlled substances or
27 dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the
28 record of conviction shall be conclusive evidence only of the fact that the conviction occurred.

1 The board may inquire into the circumstances surrounding the commission of the crime, in order
2 to fix the degree of discipline or, in the case of a conviction not involving controlled substances
3 or dangerous drugs, to determine if the conviction is of an offense substantially related to the
4 qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or
5 a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning
6 of this provision. The board may take action when the time for appeal has elapsed, or the
7 judgment of conviction has been affirmed on appeal or when an order granting probation is made
8 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of
9 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not
10 guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or
11 indictment."

12 11. Section 4307 of the Code states:

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

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

24 "(2) Where the license is denied or revoked, the prohibition shall continue until the license
25 is issued or reinstated.

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

1 "(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to
2 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code.
3 However, no order may be issued in that case except as to a person who is named in the caption,
4 as to whom the pleading alleges the applicability of this section, and where the person has been
5 given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of
6 Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this
7 subdivision shall be in addition to the board's authority to proceed under Section 4339 or any
8 other provision of law."

9 12. Section 11164 of the Health and Safety Code states, in pertinent part:

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

13 "(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V,
14 except as authorized by subdivision (b), shall be made on a controlled substance prescription
15 form as specified in Section 11162.1 and shall meet the following requirements:

16 "(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the
17 prescriber's address and telephone number; the name of the ultimate user or research subject, or
18 contact information as determined by the Secretary of the United States Department of Health and
19 Human Services; refill information, such as the number of refills ordered and whether the
20 prescription is a first-time request or a refill; and the name, quantity, strength, and directions for
21 use of the controlled substance prescribed."

22 13. Section 11167 of the Health and Safety Code states:

23 "Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue
24 a prescription may result in loss of life or intense suffering, an order for a controlled substance
25 may be dispensed on an oral order, an electronic data transmission order, or a written order not
26 made on a controlled substance form as specified in Section 11162.1, subject to all of the
27 following requirements:

28 "(a) The order contains all information required by subdivision (a) of Section 11164.

1 "(b) Any written order is signed and dated by the prescriber in ink, and the pharmacy
2 reduces any oral or electronic data transmission order to hard copy form prior to dispensing the
3 controlled substance.

4 "(c) The prescriber provides a written prescription on a controlled substance prescription
5 form that meets the requirements of Section 11162.1, by the seventh day following the
6 transmission of the initial order; a postmark by the seventh day following transmission of the
7 initial order shall constitute compliance.

8 "(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the
9 Department of Justice in writing within 144 hours of the prescriber's failure to do so and shall
10 make and retain a hard copy, readily retrievable record of the prescription, including the date and
11 method of notification of the Department of Justice.

12 "(e) This section shall become operative on January 1, 2005."

13 14. Section 11200 of the Health and Safety Code states, in pertinent part:

14 "(b) No prescription for a Schedule III or IV substance may be refilled more than five times
15 and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply."

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

17 "Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it
18 to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is
19 then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription
20 to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by
21 a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in
22 section 4019 of the Business and Professions Code are not subject to the provisions of this
23 subsection."

24 16. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

25 "(f) The pharmacist performing or supervising compounding is responsible for the integrity,
26 potency, quality, and labeled strength of a compounded drug product until it is dispensed.

27 ...

28

1 "(h) Every compounded drug product shall be given an expiration date representing the date
2 beyond which, in the professional judgment of the pharmacist performing or supervising the
3 compounding, it should not be used. This "beyond use date" of the compounded drug product
4 shall not exceed 180 days from preparation or the shortest expiration date of any component in
5 the compounded drug product, unless a longer date is supported by stability studies of finished
6 drugs or compounded drug products using the same components and packaging. Shorter dating
7 than set forth in this subsection may be used if it is deemed appropriate in the professional
8 judgment of the responsible pharmacist."

9 17. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

10 "(a) For each compounded drug product, the pharmacy records shall include:

11 "(1) The master formula record.

12 "(2) The date the drug product was compounded.

13 "(3) The identity of the pharmacy personnel who compounded the drug product.

14 "(4) The identity of the pharmacist reviewing the final drug product.

15 "(5) The quantity of each component used in compounding the drug product.

16 "(6) The manufacturer, expiration date and lot number of each component. If the
17 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.
18 Exempt from the requirements in this paragraph are sterile products compounded on a one-time
19 basis for administration within seventy-two (72) hours and stored in accordance with standards
20 for "Redispensed CSPPS" found in Chapter 797 of the United States Pharmacopeia - National
21 Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference,
22 to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

23 "(7) A pharmacy assigned reference or lot number for the compounded drug product.

24 "(8) The expiration date of the final compounded drug product.

25 "(9) The quantity or amount of drug product compounded."

26 18. Code of Federal Regulations, title 21, section 1304.04 states, in pertinent part:

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FACTUAL STATEMENT

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2 27. From about January 1, 2008, to the present, Respondent San Dimas Pharmacy &
3 Compounding Center (Respondent San Dimas) has been operating as a pharmacy in Bakersfield,
4 California. From about January 7, 2008, to the present, Kalpana Patel (Respondent Patel) has
5 been the pharmacist-in-charge (PIC) at Respondent San Dimas.

6 **2012 Complaint and Investigation**

7
8 28. On or about May 9, 2012, a private individual submitted an online complaint to the
9 Board, alleging that Respondent San Dimas was committing various license violations, including
10 filling faxed copies of prescriptions in non-emergency situations and failing to obtain the original
11 hard copies of the prescriptions until much later; and sometimes submitting invoices to insurance
12 companies for larger quantities of medication than the pharmacy actually dispensed to the
13 insurance companies' customers and never giving the customers their remaining balance of
14 medication.

15
16 29. On or about August 29, 2012, in response to the complaint, a Board inspector
17 (inspector) conducted an inspection at Respondent San Dimas.

18
19 30. While at the pharmacy, the inspector found five prescriptions for Schedule II
20 controlled substances that the pharmacy had filled even though the prescriptions were not signed
21 and dated in ink by the original prescriber. The specifics of the five prescriptions are as follows:

22 a. A prescription dated August 24, 2012, for oxycodone. The prescription was a
23 photocopy of the original prescription. The prescription was not signed and dated in ink by the
24 prescriber.

25 b. A prescription dated March 15, 2012, for methadone. The prescription was on a
26 faxed refill authorization request form. The prescription was not signed and dated in ink by the
27 prescriber.

1 c. A prescription dated March 17, 2012, for morphine. The prescription was on a faxed
2 refill authorization request form. The prescription was not signed and dated in ink by the
3 prescriber.

4 d. A prescription dated April 6, 2012, for oxycodone. The prescription was on a faxed
5 refill authorization request form. The prescription was not signed and dated in ink by the
6 prescriber.

7 e. A prescription dated May 16, 2012, for Vyvanse. The prescription was on a faxed
8 refill authorization request form. The prescription was not signed and dated in ink by the
9 prescriber.

10 31. Respondent Patel told the inspector that she filled these five prescriptions for
11 Schedule II controlled substances without the required signatures because there was a possibility
12 the patients would run out of their medications while their doctors' offices were closed. The
13 inspector informed Respondent Patel that she could not provide Schedule II controlled substances
14 without a properly signed prescription unless there was a true emergency situation, meaning that
15 not providing the medication would result in harm to the patient. The inspector did not believe
16 that the patients with the five prescriptions in question had been in true emergency situations.

17 32. Respondents San Dimas and Patel did not obtain the original prescriptions, signed
18 and dated in ink by the prescriber, within seven days of filling the prescriptions. The investigator
19 asked Respondents San Dimas and Patel to show her the original prescriptions, but they could not
20 produce these documents.

21 33. The inspector found a folder in the pharmacy containing many labels bearing the
22 words "balance owed". The inspector determined that these labels showed the quantity of
23 medications still owed to patients on prescriptions that they had purchased from Respondent San
24 Dimas.

25 34. Respondent Patel did not reverse the insurance claims she submitted for the
26 prescriptions where there was a balanced owed. She also did not resubmit the claims for the
27 actual quantity of medication the pharmacy had provided to the patient. Respondent Patel instead
28

1 waited for the patients who were owed additional medication to return to the pharmacy to request
2 the balance owed.

3 35. From approximately September 24, 2010, to August 15, 2012, Respondents San
4 Dimas and Patel failed to completely fill 178 prescriptions and submit invoices to the insurance
5 companies for the amount of medication the pharmacy actually dispensed. None of the patients
6 for these 178 prescriptions returned to the pharmacy and claimed their owed balances of
7 medication.

8 **2013 Investigation**

9 36. On or about August 28, 2013, Board inspectors (inspectors) conducted another
10 inspection at Respondent San Dimas.

11 37. One of the inspectors found that Respondents had expired and non-expired bulk stock
12 medications intermixed on their active use medication shelving. The inspector reviewed
13 Respondents' completed compounding log sheets and found that several of the expired products
14 had been used to prepare compounded products with an assigned beyond use date greater than the
15 expiration date of at least one of the ingredients.

16 38. The inspectors noticed that a number of entries on Respondents' compounding log
17 sheets were incomplete because Respondents failed to include necessary documentation,
18 including the ingredient lot numbers, manufacturer's name, and/or ingredient expiration dates.
19 Respondents failed to include the generic active ingredients on many of the labels on the
20 compounded drugs.

21 39. The inspectors noticed that Respondents had a number of containers labeled "sample
22 cream" on the premises. Respondents said that occasionally, when their customers had to wait
23 for approval from their insurance companies for payment for a compound drug, Respondents'
24 staff members would ask the patients' physicians for permission to provide "sample creams"
25 during the interim period.

26 40. One of Respondents' pharmacy technicians would speak with patients' physicians'
27 offices to ask for approval to give patients "sample cream". The technicians would write down
28 the order for the "sample cream" on the original prescription copy. The sample creams contained

1 dangerous drugs. The orders were not valid prescriptions because a pharmacist did not orally
2 receive them and a physician did not handwrite or transmit them. The approved prescriptions
3 were incomplete because they did not include the name of the physician's office's staff member
4 who authorized the prescription, the list of ingredients, the quantity or length of time, directions,
5 or the initials of Respondents' staff member who received the oral prescription.

6 41. Many of the compound prescriptions were on pre-printed prescription forms provided
7 by Respondents to the patients' physicians' offices. Respondents' preprinted prescription forms,
8 which included controlled substance prescriptions, were multiple, check-off prescription blank
9 forms. Three of the prescription "formulas" on the preprinted prescription forms contained
10 ketamine, a controlled substance. Prescriptions for controlled substance are required to be
11 written on a secure blank prescription form, faxed with a physician's signature and date, or orally
12 prescribed by the patient's physician to the pharmacist. Respondents' controlled substance pre-
13 printed prescriptions were not on secure blank prescription forms or orally received by
14 Respondents' pharmacists.

15 42. On one of the physician-approved prescriptions for the Schedule III controlled
16 substance ketamine, the physician authorized 11 refills and did not record the date on which s/he
17 approved the prescription.

18 43. Respondents failed to identify ketamine as a Schedule III controlled substance in their
19 compounding software program. Due to this oversight, Respondents did not record prescriptions
20 using or incorporating ketamine as controlled substance prescriptions. Respondents did not
21 ensure that prescriptions using or incorporating ketamine were written on secure blank
22 prescription forms or that oral prescriptions using or incorporating ketamine were only received
23 by the pharmacist. Respondents did not report prescriptions using or incorporating ketamine to
24 the Controlled Substance Utilization Review and Evaluation System (CURES).

25 44. On or about December 17, 2013, Respondents dispensed a prescription for T3/T4
26 Mixture C 20/80 mg capsules. A qualitative analysis report taken on or about February 21, 2014,
27 revealed that the T4 (Levothyroxine Sodium) component of the compounded drug was sub-potent
28 because the T4 was 73.5% of the expected potency.

1 **2016 Criminal Conviction**

2 45. On or about March 26, 2016, in a criminal proceeding entitled *People v. Kalpana*
3 *Kalpeshkumar Patel*, in the Superior Court of the County of Sacramento, Case No. 14F03262,
4 Respondent pled nolo contendere to and the court convicted her of submitting false and
5 fraudulent Medi-Cal claims (Welf. & Inst. Code, § 14107, subd. (b)(1)), a misdemeanor. The
6 court ordered her to pay \$5,667.89, in restitution and \$360.00, in fines. The court also sentenced
7 her to two years of probation and 100 hours of community service. The underlying circumstances
8 are described under the section labeled "2012 Complaint and Investigation", above.

9 **FIRST CAUSE OF ACTION**

10 (Failure to Follow Filling Requirements for Prescriptions for Controlled Substances)
11 (Health & Saf. Code, § 11164, subd. (a)(1))

12 46. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action for
13 filling prescriptions for Schedule II controlled substances that were not signed and dated in ink by
14 the prescribers. (Health & Saf. Code, § 11164, subd. (a)(1).) The circumstances are further
15 explained in paragraphs 30 to 32, above.

16 **SECOND CAUSE OF ACTION**

17 (Failure to Follow Requirements for Dispensing Controlled Substances in Emergency Situations)
18 (Health & Saf. Code, § 11167)

19 47. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action
20 because it filled prescriptions not signed and dated in ink by the prescribers in non-emergency
21 situations. (Health & Saf. Code, § 11167.) Respondent San Dimas also failed to obtain the
22 original prescriptions, signed and dated in ink by the prescribers, within seven days of filling the
23 improperly formatted prescriptions. The circumstances are further explained in paragraphs 30 to
24 33, above.

25 **THIRD CAUSE OF ACTION**

26 (Unprofessional Conduct: Fraud)
27 (Bus. & Prof. Code, § 4301, subd. (f))

28 48. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
engaging in unprofessional conduct because it committed acts involving fraud. (Bus. & Prof.

1 Code, § 4301, subd. (f).) Respondent San Dimas left a balance of medications owing on 178 of
2 the prescriptions it sold. The circumstances are further explained in paragraphs 34 to 35, above.

3 **FOURTH CAUSE OF ACTION**

4 (Unprofessional Conduct: False Representation)
5 (Bus. & Prof. Code, § 4301, subd. (g))

6 49. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
7 engaging in unprofessional conduct by knowingly making or signing certificates or documents
8 that falsely represented the existence or nonexistence of a state of facts. (Bus. & Prof. Code, §
9 4301, subd. (g).) Respondent San Dimas left a balance of medications owing on 178 of the
10 prescriptions it sold. The patients for these 178 prescriptions did not receive their owed
11 quantities of medications and the pharmacy failed to reverse these claims to the patients'
12 insurance companies to reflect the actual quantity dispensed to the patients. The circumstances
13 are further explained in paragraphs 34 to 35, above.

14 **FIFTH CAUSE OF ACTION**

15 (Failure to Follow Compounding Limitations and Requirements)
16 (Cal. Code Regs., tit. 16, § 1735.3, subd. (a))

17 50. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
18 maintaining incomplete pharmacy compounding records. (Cal. Code Regs., tit. 16, § 1735.3,
19 subd. (a).) A number of records were missing required information, including the identity of the
20 manufacturer, the lot number for each ingredient used in the compound, and the expiration date
21 for each ingredient used in the compound. The circumstances are further explained in paragraph
22 38, above.

23 **SIXTH CAUSE OF ACTION**

24 (Failure to Follow Compounding Limitations and Requirements)
25 (Cal. Code Regs., tit. 16, § 1735.2, subd. (h))

26 51. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
27 allowing pharmacy staff to assign beyond use dates to compounded products which exceeded the
28 expiration date of at least one ingredient of the compounded drug. (Cal. Code Regs., tit. 16, §
1735.2, subd. (h).) The circumstances are further explained in paragraphs 37, above.

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SEVENTH CAUSE OF ACTION

(Failure to Follow Content Requirements for Prescriptions)
(Bus. & Prof. Code, § 4040, subd. (a)(1))

52. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by accepting prescriptions for compounded medications that did not contain all of the statutorily required information. (Bus. & Prof. Code, § 4040, subd. (a)(1).) Respondent San Dimas filled prescriptions that did not contain the following required elements: the name, strength, and quantity of the drug prescribed and directions on how to use the medication. The circumstances are further explained in paragraphs 39 to 40, above.

EIGHTH CAUSE OF ACTION

(Prescriptions Furnished or Dispensed by Non-Pharmacist)
(Bus. & Prof. Code, §§ 4040, 4051, subd. (a); Cal. Code Regs., tit. 16, § 1717, subd. (c))

53. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by allowing non-pharmacists to orally receive prescriptions and not requiring the pharmacist to receive, transcribe, and complete the prescription. (Bus. & Prof. Code, §§ 4040, 4051, subd. (a); Cal. Code Regs., tit. 16, § 1717, subd. (c).) The circumstances are further explained in paragraphs 39 to 41, above.

NINTH CAUSE OF ACTION

(Failure to Properly Maintain Records)
(Health & Saf. Code, §§ 11200, subd. (b), 11164; 21 C.F.R. § 1304.04, subd. (f)(2))

54. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by failing to properly maintain records for ketamine powder, a Schedule III controlled substance. (Health & Saf. Code, §§ 11200, subd. (b), 11164; 21 C.F.R. § 1304.04, subd. (f)(2).) Respondent San Dimas did not identify ketamine powder as a Schedule III controlled substance, separate invoices involving ketamine powder from invoices not involving controlled substances, and identify prescriptions for medications containing ketamine as controlled substance prescriptions. In addition, Respondent San Dimas did not require prescriptions involving ketamine powder to be written on secure blank prescription forms or orally received by Respondent San Dimas's pharmacist. Respondent San Dimas did not report prescriptions involving ketamine to CURES

1 and filled one that was authorized for more than five refills. The circumstances are further
2 explained in paragraphs 41 to 43, above.

3 **TENTH CAUSE OF ACTION**

4 (Failure to Follow Compounding Requirements for Potency)
5 (Cal. Code Regs., tit. 16, § 1735.2, subd. (f))

6 55. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
7 failing to meet compounding requirements for potency. (Cal. Code Regs., tit. 16, § 1735.2, subd.
8 (f).) A qualitative analysis report revealed that a prescription compounded by Respondent San
9 Dimas and dispensed to a patient was sub-potent. The circumstances are further explained in
10 paragraph 44, above.

11 **ELEVENTH CAUSE OF ACTION**

12 (Failure to Follow Filling Requirements for Prescriptions for Controlled Substances)
13 (Health & Saf. Code, § 11164, subd. (a)(1))

14 56. Respondent Patel has subjected her Pharmacist License to disciplinary action for
15 filling prescriptions for Schedule II controlled substances that were not signed and dated in by the
16 prescribers. (Health & Saf. Code, § 11164, subd. (a)(1).) The circumstances are further
17 explained in paragraphs 30 to 32, above.

18 **TWELFTH CAUSE OF ACTION**

19 (Failure to Follow Requirements for Dispensing Controlled Substances in Emergency Situations)
20 (Health & Saf. Code, § 11167)

21 57. Respondent Patel has subjected her Pharmacy Permit to disciplinary action because
22 she filled prescriptions not signed and dated in ink by the prescribers in non-emergency
23 situations. (Health & Saf. Code, § 11167.) Respondent Patel also failed to obtain the original
24 prescriptions, signed and dated in ink by the prescribers, within seven days of filling the
25 improperly formatted prescriptions. The circumstances are further explained in paragraphs 30 to
26 33, above.

27 **THIRTEENTH CAUSE OF ACTION**

28 (Unprofessional Conduct; Fraud)
(Bus. & Prof. Code, § 4301, subd. (f))

1 58. Respondent Patel has subjected her Pharmacist License to disciplinary action by
2 engaging in unprofessional conduct because she committed acts involving fraud. (Bus. & Prof.
3 Code, § 4301, subd. (g).) Respondent Patel left a balance of medications owing on 178 of the
4 prescriptions she sold. The circumstances are further explained in paragraphs 34 to 35, above.

5 **FOURTEENTH CAUSE OF ACTION**

6 (Unprofessional Conduct: False Representation)
7 (Bus. & Prof. Code, § 4301, subd. (g)).

8 59. Respondent Patel has subjected her Pharmacist License to disciplinary action by
9 engaging in unprofessional conduct by knowingly making or signing certificates or documents
10 that falsely represented the existence or nonexistence of a state of facts. (Bus. & Prof. Code, §
11 4301, subd. (h).) Respondent Patel left a balance of medications owing on 178 of the
12 prescriptions she sold. The patients for these 178 prescriptions did not receive their owed
13 quantities of medications and she failed to reverse these claims to the patients' insurance
14 companies to reflect the actual quantity dispensed to the patients. The circumstances are further
15 explained in paragraphs 34 to 35, above.

16 **FIFTEENTH CAUSE OF ACTION**

17 (Unprofessional Conduct: Substantially Related Conviction)
18 (Bus. & Prof. Code, § 4301, subd. (l))

19 60. Respondent Patel has subjected her Pharmacist License to disciplinary action by
20 engaging in unprofessional conduct by being convicted of a crime substantially related to the
21 qualifications, functions, and duties of a licensee. (Bus. & Prof. Code, § 4301, subd. (l).)
22 Respondent Patel has been convicted of submitting false and fraudulent Medi-Cal claims. The
23 circumstances are further explained in paragraph 45, above.

24 **SIXTEENTH CAUSE OF ACTION**

25 (Failure to Follow Compounding Limitations and Requirements)
26 (Cal. Code Regs., tit. 16, § 1735.3, subd. (a))

27 61. Respondent Patel has subjected her Pharmacist License to disciplinary action by
28 maintaining incomplete pharmacy compounding records. (Cal. Code Regs., tit. 16, § 1735.3,
subd. (a).) A number of records at the pharmacy were missing required information, including
the identity of the manufacturer, the lot number for each ingredient used in the compound, and the

1 expiration date for each ingredient used in the compound. The circumstances are further
2 explained in paragraph 38, above.

3 **SEVENTEENTH CAUSE OF ACTION**

4 (Failure to Follow Compounding Limitations and Requirements)
5 (Cal. Code Regs., tit. 16, § 1735.2, subd. (h))

6 62. Respondent Patel has subjected her Pharmacist License to disciplinary action by
7 allowing pharmacy staff to assign beyond use dates to compounded products which exceeded the
8 expiration date of at least one ingredient of the compounded product. (Cal. Code Regs., tit. 16, §
9 1735.2, subd. (h).) The circumstances are further explained in paragraph 37, above.

10 **EIGHTEENTH CAUSE OF ACTION**

11 (Failure to Follow Content Requirements for Prescriptions)
12 (Bus. & Prof. Code, § 4040, subd. (a)(1))

13 63. Respondent Patel has subjected her Pharmacist License to disciplinary action by
14 accepting prescriptions for compounded medications that did not contain all of the statutorily
15 required information. (Bus. & Prof. Code, § 4040, subd. (a)(1).) Respondent Patel filled
16 prescriptions that did not contain the following required elements: the name, strength, and
17 quantity of the drug prescribed and directions on how to use the medication. The circumstances
18 are further explained in paragraphs 39 to 40, above.

19 **NINETEENTH CAUSE OF ACTION**

20 (Prescriptions Furnished or Dispensed by Non-Pharmacist)
21 (Bus. & Prof. Code, §§ 4040, 4051, subd. (a); Cal. Code Regs., tit. 16, § 1717, subd. (c))

22 64. Respondent Patel has subjected her Pharmacist License to disciplinary action by
23 allowing non-pharmacists to orally receive prescriptions and not receiving, transcribing, and
24 completing the prescription herself as the pharmacist-in-charge. (Bus. & Prof. Code, §§ 4040,
25 4051, subd. (a); Cal. Code Regs., tit. 16, § 1717, subd. (c).) The circumstances are further
26 explained in paragraphs 39 to 41, above.

27 **TWENTIETH CAUSE OF ACTION**

28 (Failure to Properly Maintain Records)
(Health & Saf. Code, §§ 11200, subd. (b), 11164; 21 C.F.R. § 1304.04, subd. (f)(2))

1 65. Respondent Patel has subjected her Pharmacist License to disciplinary action by
2 failing to properly maintain records for ketamine powder, a Schedule III controlled substance.
3 (Health & Saf. Code, §§ 11200, subd. (b), 11164; 21 C.F.R. § 1304.04, subd. (f)(2).) Respondent
4 Patel did not identify ketamine powder as a Schedule III controlled substance, separate invoices
5 involving ketamine powder from invoices not involving controlled substances, and identify
6 prescriptions for medications containing ketamine as controlled substance prescriptions. In
7 addition, Respondent Patel as did not require prescriptions involving ketamine powder to be
8 written on secure blank prescription forms or orally received by herself as Respondent San
9 Dimas's sole pharmacist. Respondent San Patel did not report prescriptions involving ketamine
10 to CURES and filled one that authorized for more than five refills. The circumstances are further
11 explained in paragraphs 41 to 43, above.

12 **TWENTY-FIRST CAUSE OF ACTION**

13 (Failure to Follow Compounding Requirements for Potency)
14 (Cal. Code Regs., tit. 16, § 1735.2, subd. (f))

15 66. Respondent Patel has subjected her Pharmacist License to disciplinary action by
16 failing to meet compounding requirements for potency. (Cal. Code Regs., tit. 16, § 1735.2, subd.
17 (f).) A qualitative analysis report revealed that a prescription compounded by Respondent Patel
18 had a component that was sub-potent. The circumstances are further explained in paragraph 44,
19 above.

20 **DISCIPLINARY CONSIDERATIONS**

21 67. To determine the degree of discipline, if any, to be imposed on Respondent San
22 Dimas, Complainant alleges that on or about July 3, 2013, in a prior action, the Board of
23 Pharmacy issued Citation Number CI-2011-52726 and ordered Respondent San Dimas to pay a
24 \$250.00 fine for deviating from prescriptions (Cal. Code Regs., tit. 16, § 1716); a \$250.00 fine for
25 not following proper requirements for off-site storage of records (Cal. Code Reg., tit. 16, § 1707,
26 subs. (e), (f)); a \$500.00 fine for engaging in compounding and failing to maintain proper
27 written documentation of its personnel having the necessary skills and training, to maintain an
28 evaluation process for personnel involved in compounding, to ensure that personnel involved in

1 compounding could demonstrate knowledge about processes and procedures used in
2 compounding (Cal. Code Regs., tit. 16, § 1735.7, subds. (a), (b), (c)); a \$250.00 fine for failing to
3 prevent the sale of preparations or drugs that lacked quality or strength (Bus. & Prof. Code, §
4 4342); a \$1,000.00 fine for failing to follow the requirement that a pharmacy with only one
5 pharmacist should have no more than one pharmacy technician performing tasks (Bus. & Prof.
6 Code, § 4115, subd. (f)(1)); a \$500.00 fine for engaging in unprofessional conduct (Bus. & Prof.
7 Code, § 4301, subd. (j); 21 U.S.C §§ 802, 822; 21 C.F.R. § 1307.21 (2013)), and a \$500.00 fine
8 for failing to maintaining proper records for compounded drug products (Cal. Code Regs., tit. 16,
9 § 1735.3, subd. (a)).

10 68. To determine the degree of discipline, if any, to be imposed on Respondent San
11 Dimas, Complainant alleges that on or about December 15, 2010, in a prior action, the Board of
12 Pharmacy issued Citation Number CI-2009-44507 and ordered Respondent San Dimas to pay a
13 \$500.00 fine for failing to ensure that there was proper pharmacy security (Cal. Code Regs., tit.
14 16, § 1714, subd. (b)) and a \$500.00 fine for allowing an unlicensed individual to act as a
15 pharmacy technician (Bus. & Prof. Code, § 4115, subd. (e)).

16 69. To determine the degree of discipline, if any, to be imposed on Respondent Patel,
17 Complainant alleges that on or about July 3, 2013, in a prior action, the Board of Pharmacy
18 issued Citation Number CI-2012-57375 and ordered Respondent Patel to pay a \$500.00 fine for
19 deviating from prescriptions (Cal. Code Reg., tit. 16, § 1716); a \$250.00 fine for not following
20 proper requirements for off-site storage of records (Cal. Code Reg., tit. 16, § 1707, subds. (e),
21 (f)); a \$500.00 fine for engaging in compounding and failing to maintain proper written
22 documentation of its personnel having the necessary skills and training, to maintain an evaluation
23 process for personnel involved in compounding, to ensure that personnel involved in
24 compounding could demonstrate knowledge about processes and procedures used in
25 compounding (Cal. Code Regs., tit. 16, § 1735.7, subds. (a), (b), (c)); a \$250.00 fine for failing to
26 prevent the sale of pharmaceutical preparations or drugs that lacked quality or strength (Bus. &
27 Prof. Code, § 4342); a \$1,000.00 fine for failing to follow the requirement that a pharmacy with
28 only one pharmacist should have no more than one pharmacy technician performing tasks (Bus.

1 & Prof. Code, § 4115, subd. (f)(1)); a \$500.00 fine for engaging in unprofessional conduct (Bus.
2 & Prof. Code, § 4301, subd. (j); 21 U.S.C §§ 802, 822; 21 C.F.R. § 1307.21 (2013)), and a
3 \$500.00 fine for failing to maintaining proper records for compounded drug products (Cal. Code
4 Reg., tit. 16, § 1735.3, subd. (a)).

5 70. To determine the degree of discipline, if any, to be imposed on Respondent Patel,
6 Complainant alleges that on or about December 15, 2010, in a prior action, the Board of
7 Pharmacy issued Citation Number CI-2010-46672 and ordered Respondent Patel to pay a
8 \$500.00 fine for failing to ensure that there was proper pharmacy security (Cal. Code Regs., tit.
9 16, § 1714, subd. (b)) and a \$500.00 fine for allowing an unlicensed individual to act as a
10 pharmacy technician (Bus. & Prof. Code, § 4115, subd. (e)).

11 PRAYER

12 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
13 First Amended Accusation, and that following the hearing, the Board of Pharmacy issue a
14 decision:

15 1.1. Revoking or suspending Pharmacy Permit Number PHY 48922, issued to San Dimas
16 Pharmacy & Compounding Center;

17 1.2. Revoking or suspending Pharmacist License Number RPH 49676, issued to Kalpana
18 Patel, also known as Kalpana Kalpeshkumar Patel;

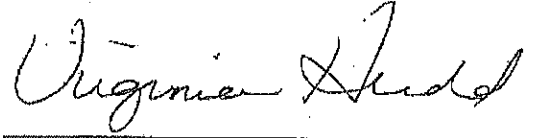
19 1.3. Ordering San Dimas Pharmacy & Compounding Center and Kalpana Patel, also
20 known as Kalpana Kalpeshkumar Patel, to pay the Board of Pharmacy the reasonable costs of the
21 investigation and enforcement of this case, pursuant to Business and Professions Code section
22 125.3;

23 1.4. Pursuant to Business and Professions Code section 4307, if discipline is imposed on
24 Pharmacy Permit Number PHY 48922, issued to San Dimas Pharmacy & Compounding Center,
25 and Kalpana Patel, also known as Kalpana Kalpeshkumar Patel, (Patel) while acting as the
26 manager, administrator, owner, member, officer, director, associate, or partner of San Dimas
27 Pharmacy & Compounding Center, had knowledge of or knowingly participated in any conduct
28 for which Pharmacy Permit Number PHY 48922, issued to San Dimas Pharmacy &

1 Compounding Center, was revoked, suspended, or placed on probation, Patel shall be prohibited
2 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
3 of a licensee for five years if Pharmacy Permit Number PHY 48922, issued to San Dimas
4 Pharmacy & Compounding Center, is placed on probation or until PHY 48922, issued to San
5 Dimas Pharmacy & Compounding Center, is reinstated, if it is revoked; and

6 1.5. Taking such other and further action as deemed necessary and proper.

7
8 DATED: 10/7/16



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

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