1 2 3 4 5 6 7 8 9	BOARD OF	RE THE PHARMACY
10		CONSUMER AFFAIRS CALIFORNIA
11	In the Matter of the Accusation Against:	Case No. 5192
12	SAN DIMAS PHARMACY & COMPOUNDING CENTER;	
13	KALPANA PATEL AKA KALPANA	FIRST AMENDED
14	KALPESHKUMAR PATEL, President	ACCUSATION
15	3805 San Dimas Street, Suite A Bakersfield, CA 93301	ACCUSATION
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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.	
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25	Complainant alleges:	
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	(SAN DIMAS PHARMACY & COMPO	UNDING CENTER) FIRST AMENDED ACCUSATION

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.
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	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

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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.	
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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	8. Section 4040 of the Code states, in pertinent part:	
18	"(a) "Prescription" means an oral, written, or electronic transmission order that is both of	
19	the following:	
20	"(1) Given individually for the person or persons for whom ordered that includes all of the	
21	following:	
22	"(A) The name or names and address of the patient or patients.	
23	"(B) The name and quantity of the drug or device prescribed and the directions for use.	
24 25	"(C) The date of issue.	
26	"(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and	
20	telephone number of the prescriber, his or her license classification, and his or her federal registry	
28	number, if a controlled substance is prescribed.	
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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:
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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	"(1) 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.
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The board may inquire into the circumstances surrounding the commission of the crime, in order 1 to fix the degree of discipline or, in the case of a conviction not involving controlled substances 2 or dangerous drugs, to determine if the conviction is of an offense substantially related to the 3 qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or 4 a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning 5 of this provision. The board may take action when the time for appeal has elapsed, or the 6 judgment of conviction has been affirmed on appeal or when an order granting probation is made 7 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of 8 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not 9 10 guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment." 11

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11. Section 4307 of the Code states:

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

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

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

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

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

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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 shall any person fill, compound, or dispense a prescription for a controlled substance, unless it 11 complies with the requirements of this section. 12

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 form as specified in Section 11162.1 and shall meet the following requirements: 15

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

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

"Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue 23a prescription may result in loss of life or intense suffering, an order for a controlled substance 24 may be dispensed on an oral order, an electronic data transmission order, or a written order not 2526 made on a controlled substance form as specified in Section 11162.1, subject to all of the 27 following requirements:

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

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

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

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

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

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

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

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

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

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

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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 CSPS" 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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	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

1	"(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment
2	program and compounder for narcotic treatment program shall maintain inventories and records
3	of controlled substances as follows:
4	"(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall
5	be maintained either separately from all other records of the registrant or in such form that the
6	information required is readily retrievable from the ordinary business records of the registrant."
7	CONTROLLED SUBSTANCES
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9	19. Section 4021 of the Code states:
10	"Controlled substance' means any substance listed in Chapter 2 (commencing with Section
11	11053) of Division 10 of the Health and Safety Code."
12	20. Oxycodone is a Schedule II controlled substance as designated by Health and Safety
13	Code section 11055, subdivision (b)(1)(M).
14	21. Morphine is a Schedule II controlled substance as designated by Health and Safety
15	Code section 11055, subdivision (b)(1)(L).
16	22. Vyvanase is a Schedule II controlled substance as designated by Health and Safety
17	Code section 11055, subdivision (d)(2).
18	23. Methadone is a Schedule II controlled substance as designated by Health and Safety
19	Code section 11055, subdivision (c)(14).
20	24. Methadone is a Schedule II controlled substance as designated by Health and Safety
21	Code section 11055, subdivision (c)(14).
22	25. Ketamine is a Schedule III controlled substance as designated by Health and Safety
23	Code section 11056, subdivision (g).
24	<u>COST RECOVERY</u>
25	26. Code section 125.3 states, in part, that the Board may request the administrative law
26	judge to direct a licentiate found to have committed a violation or violations of the licensing act
27	to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.
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	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

1	FACTUAL STATEMENT
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 Bakersfiel
	California. From about January 7, 2008, to the present, Kalpana Patel (Respondent Patel) has
	been the pharmacist-in-charge (PIC) at Respondent San Dimas.
	2012 Complaint and Investigation
	28. On or about May 9, 2012, a private individual submitted an online complaint to the
	Board, alleging that Respondent San Dimas was committing various license violations, includi
	filling faxed copies of prescriptions in non-emergency situations and failing to obtain the origi
	hard copies of the prescriptions until much later; and sometimes submitting invoices to insurar
	companies for larger quantities of medication than the pharmacy actually dispensed to the
	insurance companies' customers and never giving the customers their remaining balance of
	medication.
	29. On or about August 29, 2012, in response to the complaint, a Board inspector
	(inspector) conducted an inspection at Respondent San Dimas.
	30. While at the pharmacy, the inspector found five prescriptions for Schedule II
	controlled substances that the pharmacy had filled even though the prescriptions were not sign
	and dated in ink by the original prescriber. The specifics of the five prescriptions are as follow
	a. A prescription dated August 24, 2012, for oxycodone. The prescription was a
	photocopy of the original prescription. The prescription was not signed and dated in ink by th
	prescriber.
	b. A prescription dated March 15, 2012, for methadone. The prescription was on a
	faxed refill authorization request form. The prescription was not signed and dated in ink by th
	prescriber.
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c. A prescription dated March 17, 2012, for morphine. The prescription was on a faxed refill authorization request form. The prescription was not signed and dated in ink by the prescriber.

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

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

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

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

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

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

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

8 2013 Investigation

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

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

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

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

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

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

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

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

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

44. On or about December 17, 2013, Respondents dispensed a prescription for T3/T4 25 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 because the T4 was 73.5% of the expected potency. 28

1	2016 Criminal Conviction
2	45. On or about March 26, 2016, in a criminal proceeding entitled <i>People v. Kalpana</i>
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 10	FIRST CAUSE OF ACTION (Failure to Follow Filling Requirements for Prescriptions for Controlled Substances) (Health & Saf. Code, § 11164, subd. (a)(1))
11	46. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action for
12	filling prescriptions for Schedule II controlled substances that were not signed and dated in ink by
13	the prescribers. (Health & Saf. Code, § 11164, subd. (a)(1).) The circumstances are further
14	explained in paragraphs 30 to 32, above.
15 16 17	SECOND CAUSE OF ACTION (Failure to Follow Requirements for Dispensing Controlled Substances in Emergency Situations) (Health & Saf. Code, § 11167)
18	47. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action
19	because it filled prescriptions not signed and dated in ink by the prescribers in non-emergency
20	situations. (Health & Saf. Code, § 11167.) Respondent San Dimas also failed to obtain the
21	original prescriptions, signed and dated in ink by the prescribers, within seven days of filling the
22	improperly formatted prescriptions. The circumstances are further explained in paragraphs 30 to
23	33, above.
24 25	THIRD CAUSE OF ACTION (Unprofessional Conduct: Fraud) (Bus. & Prof. Code, § 4301, subd. (f))
26	48. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
27	engaging in unprofessional conduct because it committed acts involving fraud. (Bus. & Prof.
	14
	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

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) (Bus. & Prof. Code, § 4301, subd. (g))
5	49. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
6	engaging in unprofessional conduct by knowingly making or signing certificates or documents
7	that falsely represented the existence or nonexistence of a state of facts. (Bus. & Prof. Code, §
8	4301, subd. (g).) Respondent San Dimas left a balance of medications owing on 178 of the
9	prescriptions it sold. The patients for these 178 prescriptions did not receive their owed
10	quantities of medications and the pharmacy failed to reverse these claims to the patients'
11	insurance companies to reflect the actual quantity dispensed to the patients. The circumstances
12	are further explained in paragraphs 34 to 35, above.
13	FIFTH CAUSE OF ACTION
14	(Failure to Follow Compounding Limitations and Requirements) (Cal. Code Regs., tit. 16, § 1735.3, subd. (a))
15 16	50. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
10	maintaining incomplete pharmacy compounding records. (Cal. Code Regs., tit. 16, § 1735.3,
18	subd. (a).) A number of records were missing required information, including the identity of the
19	manufacturer, the lot number for each ingredient used in the compound, and the expiration date
20	for each ingredient used in the compound. The circumstances are further explained in paragraph
21	38, above.
22	SIXTH CAUSE OF ACTION
23	(Failure to Follow Compounding Limitations and Requirements) (Cal. Code Regs., tit. 16, § 1735.2, subd. (h))
24	51. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
25	allowing pharmacy staff to assign beyond use dates to compounded products which exceeded the
26	expiration date of at least one ingredient of the compounded drug. (Cal. Code Regs., tit. 16, §
27	1735.2, subd. (h).) The circumstances are further explained in paragraphs 37, above.
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(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

1 2	SEVENTH CAUSE OF ACTION (Failure to Follow Content Requirements for Prescriptions) (Bus. & Prof. Code, § 4040, subd. (a)(1))
3	52. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
4	accepting prescriptions for compounded medications that did not contain all of the statutorily
5	required information. (Bus. & Prof. Code, § 4040, subd. (a)(1).) Respondent San Dimas filled
6	prescriptions that did not contain the following required elements: the name, strength, and
7	quantity of the drug prescribed and directions on how to use the medication. The circumstances
8	are further explained in paragraphs 39 to 40, above.
9	EIGHTH CAUSE OF ACTION
10	(Prescriptions Furnished or Dispensed by Non-Pharmacist) (Bus. & Prof. Code, §§ 4040, 4051, subd. (a); Cal. Code Regs., tit. 16, § 1717, subd. (c))
11	53. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
12	allowing non-pharmacists to orally receive prescriptions and not requiring the pharmacist to
13	receive, transcribe, and complete the prescription. (Bus. & Prof. Code, §§ 4040, 4051, subd. (a);
14	Cal. Code Regs., tit. 16, § 1717, subd. (c).) The circumstances are further explained in
15	paragraphs 39 to 41, above.
 16 17 18 19 20 21 22 23 24 25 26 27 	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
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	16 (SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION
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(Failure to Follow Filling Requirements for Prescriptions for Controlled Substances)
(Loolth V Vot Voda S 1116/ model (-)(1))
(Health & Saf. Code, § 11164, subd. (a)(1)) 56. Respondent Patel has subjected her Pharmacist License to disciplinary action for
filling prescriptions for Schedule II controlled substances that were not signed and dated in by t
prescribers. (Health & Saf. Code, § 11164, subd. (a)(1).) The circumstances are further
explained in paragraphs 30 to 32, above.
TWELFTH CAUSE OF ACTION (Failure to Follow Requirements for Dispensing Controlled Substances in Emergency Situation (Health & Saf. Code, § 11167)
57. Respondent Patel has subjected her Pharmacy Permit to disciplinary action because
she filled prescriptions not signed and dated in ink by the prescribers in non-emergency
situations. (Health & Saf. Code, § 11167.) Respondent Patel also failed to obtain the original
prescriptions, signed and dated in ink by the prescribers, within seven days of filling the
improperly formatted prescriptions. The circumstances are further explained in paragraphs 30
33, above.
THIRTEENTH CAUSE OF ACTION
(Unprofessional Conduct: Fraud)
(Bus. & Prof. Code, § 4301, subd. (f))
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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) (Bus. & Prof. Code, § 4301, subd. (g))
7	59. Respondent Patel has subjected her Pharmacist License to disciplinary action by
8	engaging in unprofessional conduct by knowingly making or signing certificates or documents
9	that falsely represented the existence or nonexistence of a state of facts. (Bus. & Prof. Code, §
10	4301, subd. (h).) Respondent Patel left a balance of medications owing on 178 of the
11	prescriptions she sold. The patients for these 178 prescriptions did not receive their owed
12	quantities of medications and she failed to reverse these claims to the patients' insurance
13	companies to reflect the actual quantity dispensed to the patients. The circumstances are further
14	explained in paragraphs 34 to 35, above.
15 16	<u>FIFTEENTH CAUSE OF ACTION</u> (Unprofessional Conduct: Substantially Related Conviction) (Bus. & Prof. Code, § 4301, subd. (1))
17	60. Respondent Patel has subjected her Pharmacist License to disciplinary action by
18	engaging in unprofessional conduct by being convicted of a crime substantially related to the
19	qualifications, functions, and duties of a licensee. (Bus. & Prof. Code, § 4301, subd. (1).)
20	Respondent Patel has been convicted of submitting false and fraudulent Medi-Cal claims. The
21	circumstances are further explained in paragraph 45, above.
22	
23 24	SIXTEENTH CAUSE OF ACTION (Failure to Follow Compounding Limitations and Requirements) (Cal. Code Regs., tit. 16, § 1735.3, subd. (a))
25	61. Respondent Patel has subjected her Pharmacist License to disciplinary action by
26	maintaining incomplete pharmacy compounding records. (Cal. Code Regs., tit. 16, § 1735.3,
27	subd. (a).) A number of records at the pharmacy were missing required information, including
28	the identity of the manufacturer, the lot number for each ingredient used in the compound, and the
	18
	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

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) (Cal. Code Regs., tit. 16, § 1735.2, subd. (h))
5	62. Respondent Patel has subjected her Pharmacist License to disciplinary action by
6	allowing pharmacy staff to assign beyond use dates to compounded products which exceeded the
7	expiration date of at least one ingredient of the compounded product. (Cal. Code Regs., tit. 16, §
8	1735.2, subd. (h).) The circumstances are further explained in paragraph 37, above.
9	EIGHTEENTH CAUSE OF ACTION
10 11	(Failure to Follow Content Requirements for Prescriptions) (Bus. & Prof. Code, § 4040, subd. (a)(1))
12	63. Respondent Patel has subjected her Pharmacist License to disciplinary action by
12	accepting prescriptions for compounded medications that did not contain all of the statutorily
14	required information. (Bus. & Prof. Code, § 4040, subd. (a)(1).) Respondent Patel filled
15	prescriptions that did not contain the following required elements: the name, strength, and
16	quantity of the drug prescribed and directions on how to use the medication. The circumstances
17	are further explained in paragraphs 39 to 40, above.
18	NINETEENTH CAUSE OF ACTION
19	(Prescriptions Furnished or Dispensed by Non-Pharmacist) (Bus. & Prof. Code, §§ 4040, 4051, subd. (a); Cal. Code Regs., tit. 16, § 1717, subd. (c))
20	64. Respondent Patel has subjected her Pharmacist License to disciplinary action by
21	allowing non-pharmacists to orally receive prescriptions and not receiving, transcribing, and
22	completing the prescription herself as the pharmacist-in-charge. (Bus. & Prof. Code, §§ 4040,
23	4051, subd. (a); Cal. Code Regs., tit. 16, § 1717, subd. (c).) The circumstances are further
24	explained in paragraphs 39 to 41, above.
25	TWENTIETH CAUSE OF ACTION
26	(Failure to Properly Maintain Records) (Health & Saf. Code, §§ 11200, subd. (b), 11164; 21 C.F.R. § 1304.04, subd. (f)(2))
27	(1,2)
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	19
	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

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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) (Cal. Code Regs., tit. 16, § 1735.2, subd. (f))
14	66. Respondent Patel has subjected her Pharmacist License to disciplinary action by
15	failing to meet compounding requirements for potency. (Cal. Code Regs., tit. 16, § 1735.2, subd.
16	(f).) A qualitative analysis report revealed that a prescription compounded by Respondent Patel
17	had a component that was sub-potent. The circumstances are further explained in paragraph 44,
18	above.
19	DISCIPLINARY CONSIDERATIONS
20	67. To determine the degree of discipline, if any, to be imposed on Respondent San
21	Dimas, Complainant alleges that on or about July 3, 2013, in a prior action, the Board of
22	Pharmacy issued Citation Number CI-2011-52726 and ordered Respondent San Dimas to pay a
23	\$250.00 fine for deviating from prescriptions (Cal. Code Regs., tit. 16, § 1716); a \$250.00 fine for
24	not following proper requirements for off-site storage of records (Cal. Code Reg., tit. 16, § 1707,
25	subds. (e), (f)); a \$500.00 fine for engaging in compounding and failing to maintain proper
26	written documentation of its personnel having the necessary skills and training, to maintain an
27	evaluation process for personnel involved in compounding, to ensure that personnel involved in
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	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

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

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

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

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	<u>PRAYER</u>
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 &
	22
	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

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	1.1-1.1
8	DATED: 10/7/16 Urginia Aud
9	VIRGINIA HEROLD Executive Officer
10	Board of Pharmacy
11	Department of Consumer Affairs State of California Complainant
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	23
	(SAN DIMAS PHARMACY & COMPOUNDING CENTER) FIRST AMENDED ACCUSATION

1	KAMALA D. HARRIS Attorney General of California		
2	DIANN SOKOLOFF	<u> </u>	
3	Supervising Deputy Attorney General SHEILA J. VASANTHARAM		
4	Deputy Attorney General State Bar No. 289217		
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	Oakland, CA 94612-0550		
6	Telephone: (510) 622-2141 Facsimile: (510) 622-2270		
7	E-mail: Sheila.Vasantharam@doj.ca.gov Attorneys for Complainant		
8	BEFO	RE THE	
9	BOARD OF	PHARMACY CONSUMER AFFAIRS	
10		CALIFORNIA	
11]	
12	In the Matter of the Accusation Against: SAN DIMAS PHARMACY &	Case No. 5192	
13	COMPOUNDING CENTER;		
14	KALPANA PATEL AKA KALPANA KALPESHKUMAR PATEL,	ACCUSATION	
15	President		
	3805 San Dimas Street, Suite A Bakersfield, CA 93301		
16	Pharmacy Permit No. PHY 48922		
17			
18	and		
19	KALPANA PATEL AKA KALPANA KALPESHKUMAR		
20	PATEL		
21	5111 Vista Rica Court Bakersfield, CA 93311		
22	Pharmacist License No. RPH 49676		
23	Respondents.		
24			
25	Complainant alleges:		
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1	PARTIES
2	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
3	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
4	32. On or about January 7, 2008, the Board of Pharmacy issued Pharmacy Permit
5	Number PHY 48922 to San Dimas Pharmacy & Compounding Center (Respondent San Dimas).
6	The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in
7	this Accusation and will expire on January 1, 2016, unless renewed.
8	3. On or about August 22, 1997, the Board of Pharmacy issued Pharmacist License
9	Number RPH 49676 to Kalpana Patel, also known as Kalpana Kalpeshkumar Patel (Respondent
10	Patel). The Pharmacist License was in full force and effect at all times relevant to the charges
11	brought in this Accusation and will expire on November 30, 2016, unless renewed.
12	JURISDICTION
13	4. This Accusation is brought before the Board of Pharmacy (Board), Department of
14	Consumer Affairs, under the authority of the following laws. All section references are to the
15	Business and Professions Code unless otherwise indicated.
16	5. Section 4011 of the Code provides that the Board shall administer and enforce both
17	the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
18	Act [Health & Safety Code, § 11000 et seq.].
19	6. Section 4300 of the Code states, in pertinent part:
20	"(a) Every license issued may be suspended or revoked.
21	"(b) The board shall discipline the holder of any license issued by the board, whose default
22	has been entered or whose case has been heard by the board and found guilty, by any of the
23	following methods:
24	"(1) Suspending judgment.
25	"(2) Placing him or her upon probation.
26	"(3) Suspending his or her right to practice for a period not exceeding one year.
27	"(4) Revoking his or her license.
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	2
	Accusation

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

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

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Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by
operation of law or by order or decision of the board or a court of law, 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."

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STATUTORY/REGULATORY PROVISIONS

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

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

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

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

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

"(C) The date of issue.

"(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and
 telephone number of the prescriber, his or her license classification, and his or her federal registry
 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	11. Section 4307 of the Code states:
23	"(a) Any person who has been denied a license or whose license has been revoked or is
24	under suspension, or who has failed to renew his or her license while it was under suspension, or
25	who has been a manager, administrator, owner, member, officer, director, associate, or partner of
26	any partnership, corporation, firm, or association whose application for a license has been denied
27	or revoked, is under suspension or has been placed on probation, and while acting as the manager,
28	administrator, owner, member, officer, director, associate, or partner had knowledge of or
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l	Accusation

knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

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

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

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

"(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to 11 12 Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, 13 as to whom the pleading alleges the applicability of this section, and where the person has been 14 given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of 15 Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this 16 subdivision shall be in addition to the board's authority to proceed under Section 4339 or any 17 other provision of law." 18

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

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

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

"(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the
prescriber's address and telephone number; the name of the ultimate user or research subject, or
contact information as determined by the Secretary of the United States Department of Health and

Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed."

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

"Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue 5 a prescription may result in loss of life or intense suffering, an order for a controlled substance 6 may be dispensed on an oral order, an electronic data transmission order, or a written order not 7 made on a controlled substance form as specified in Section 11162.1, subject to all of the 8 following requirements: 9

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"(a) The order contains all information required by subdivision (a) of Section 11164. (b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.

"(c) The prescriber provides a written prescription on a controlled substance prescription 14 form that meets the requirements of Section 11162.1, by the seventh day following the 15 transmission of the initial order; a postmark by the seventh day following transmission of the 16 initial order shall constitute compliance. 17

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"(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Department of Justice in writing within 144 hours of the prescriber's failure to do so and shall 19 make and retain a hard copy, readily retrievable record of the prescription, including the date and 20 method of notification of the Department of Justice. 21

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

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 24 and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply." 25

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

"Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it 27 to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is 28

then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription 1 to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by 2 a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in 3 section 4019 of the Business and Professions Code are not subject to the provisions of this 4 subsection." 5 16. California Code of Regulations, title 16, section 1735.2 states, in pertinent part: 6 "(f) The pharmacist performing or supervising compounding is responsible for the integrity, 7 potency, quality, and labeled strength of a compounded drug product until it is dispensed. 8 9 . . . "(h) Every compounded drug product shall be given an expiration date representing the date 10 beyond which, in the professional judgment of the pharmacist performing or supervising the 11 compounding, it should not be used. This "beyond use date" of the compounded drug product 12 shall not exceed 180 days from preparation or the shortest expiration date of any component in 13 the compounded drug product, unless a longer date is supported by stability studies of finished 14 drugs or compounded drug products using the same components and packaging. Shorter dating 15 than set forth in this subsection may be used if it is deemed appropriate in the professional 16 judgment of the responsible pharmacist." 17 17. California Code of Regulations, title 16, section 1735.3 states, in pertinent part: 18 "(a) For each compounded drug product, the pharmacy records shall include: 19 "(1) The master formula record. 20 "(2) The date the drug product was compounded. 21 "(3) The identity of the pharmacy personnel who compounded the drug product. 22 "(4) The identity of the pharmacist reviewing the final drug product. 23 "(5) The quantity of each component used in compounding the drug product. 24 "(6) The manufacturer, expiration date and lot number of each component. If the 25 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. 26 Exempt from the requirements in this paragraph are sterile products compounded on a one-time 27 basis for administration within seventy-two (72) hours and stored in accordance with standards 28 7

l	for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National
2	Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference,
	to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code
	"(7) A pharmacy assigned reference or lot number for the compounded drug product.
	"(8) The expiration date of the final compounded drug product.
	"(9) The quantity or amount of drug product compounded."
	18. Code of Federal Regulations, title 21, section 1304.04 states, in pertinent part:
	"(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment
	program and compounder for narcotic treatment program shall maintain inventories and records
	of controlled substances as follows:
	"(2) Inventories and records of controlled substances listed in Schedules III, IV, and V sha
9	be maintained either separately from all other records of the registrant or in such form that the
	information required is readily retrievable from the ordinary business records of the registrant."
	CONTROLLED SUBSTANCES
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	19. Section 4021 of the Code states:
r	"Controlled substance' means any substance listed in Chapter 2 (commencing with Section
	11053) of Division 10 of the Health and Safety Code."
,	20. Oxycodone is a Schedule II controlled substance as designated by Health and Safety
	Code section 11055, subdivision (b)(1)(M).
	21. Morphine is a Schedule II controlled substance as designated by Health and Safety
	Code section 11055, subdivision (b)(1)(L). 22. Vyvanase is a Schedule II controlled substance as designated by Health and Safety
	Code section 11055, subdivision (d)(2).
	23. Methadone is a Schedule II controlled substance as designated by Health and Safety
	Code section 11055, subdivision (c)(14).
	24. Methadone is a Schedule II controlled substance as designated by Health and Safety
,	Code section 11055, subdivision (c)(14).
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25. Ketamine is a Schedule III controlled substance as designated by Health and Safety 1 Code section 11056, subdivision (g). 2 COST RECOVERY 26. Code section 125.3 states, in part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act

to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FACTUAL STATEMENT

8 27. From about January 1, 2008, to the present, Respondent San Dimas Pharmacy & 9 Compounding Center (Respondent San Dimas) has been operating as a pharmacy in Bakersfield, 10 California. From about January 7, 2008, to the present, Kalpana Patel (Respondent Patel) has 11 been the pharmacist-in-charge (PIC) at Respondent San Dimas. 12

13 **2012** Complaint and Investigation

14 28. On or about May 9, 2012, a private individual submitted an online complaint to the 15 Board, alleging that Respondent San Dimas was committing various license violations, including 16 filling faxed copies of prescriptions in non-emergency situations and failing to obtain the original 17 hard copies of the prescriptions until much later; and sometimes submitting invoices to insurance 18 companies for larger quantities of medication than the pharmacy actually dispensed to the 19 insurance companies' customers and never giving the customers their remaining balance of 20 21 medication.

22 29. On or about August 29, 2012, in response to the complaint, a Board inspector 23 (inspector) conducted an inspection at Respondent San Dimas. 24

30. While at the pharmacy, the inspector found five prescriptions for Schedule II 25 26 controlled substances that the pharmacy had filled even though the prescriptions were not signed and dated in ink by the original prescriber. The specifics of the five prescriptions are as follows: 27

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A prescription dated August 24, 2012, for oxycodone. The prescription was a 1 a. photocopy of the original prescription. The prescription was not signed and dated in ink by the 2 prescriber. 3 b. A prescription dated March 15, 2012, for methadone. The prescription was on a 4 faxed refill authorization request form. The prescription was not signed and dated in ink by the 5 prescriber. 6 A prescription dated March 17, 2012, for morphine. The prescription was on a faxed c. 7 refill authorization request form. The prescription was not signed and dated in ink by the 8 prescriber. 9 d. A prescription dated April 6, 2012, for oxycodone. The prescription was on a faxed 10 refill authorization request form. The prescription was not signed and dated in ink by the 11 prescriber. 12 e. A prescription dated May 16, 2012, for Vyvanse. The prescription was on a faxed 13 refill authorization request form. The prescription was not signed and dated in ink by the 14 prescriber. 15 31. Respondent Patel told the inspector that she filled these five prescriptions for 16 Schedule II controlled substances without the required signatures because there was a possibility 17 the patients would run out of their medications while their doctors' offices were closed. The 18 inspector informed Respondent Patel that she could not provide Schedule II controlled substances 19 without a properly signed prescription unless there was a true emergency situation, meaning that 20not providing the medication would result in harm to the patient. The inspector did not believe 21 that the patients with the five prescriptions in question had been in true emergency situations. 22 Respondents San Dimas and Patel did not obtain the original prescriptions, signed 32. 23 and dated in ink by the prescriber, within seven days of filling the prescriptions. The investigator 24 asked Respondents San Dimas and Patel to show her the original prescriptions, but they could not 25 produce these documents. 26 The inspector found a folder in the pharmacy containing many labels bearing the 33. 27 words "balance owed". The inspector determined that these labels showed the quantity of 28 10

medications still owed to patients on prescriptions that they had purchased from Respondent San Dimas.

34. Respondent Patel did not reverse the insurance claims she submitted for the prescriptions where there was a balanced owed. She also did not resubmit the claims for the actual quantity of medication the pharmacy had provided to the patient. Respondent Patel instead waited for the patients who were owed additional medication to return to the pharmacy to request the balance owed.

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

13 **2013 Investigation**

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

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

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

39. The inspectors noticed that Respondents had a number of containers labeled "sample
cream" on the premises. Respondents said that occasionally, when their customers had to wait
for approval from their insurance companies for payment for a compound drug, Respondents'

staff members would ask the patients' physicians for permission to provide "sample creams" during the interim period.

One of Respondents' pharmacy technicians would speak with patients' physicians' 40. 3 offices to ask for approval to give patients "sample cream". The technicians would write down 4 the order for the "sample cream" on the original prescription copy. The sample creams contained 5 dangerous drugs. The orders were not valid prescriptions because a pharmacist did not orally 6 receive them and a physician did not handwrite or transmit them. The approved prescriptions 7 were incomplete because they did not include the name of the physician's office's staff member 8 who authorized the prescription, the list of ingredients, the quantity or length of time, directions, Q or the initials of Respondents' staff member who received the oral prescription. 10

41. Many of the compound prescriptions were on pre-printed prescription forms provided 11 by Respondents to the patients' physicians' offices. Respondents' preprinted prescription forms, 12 which included controlled substance prescriptions, were multiple, check-off prescription blank 13 forms. Three of the prescription "formulas" on the preprinted prescription forms contained 14 ketamine, a controlled substance. Prescriptions for controlled substance are required to be 15 written on a secure blank prescription form, faxed with a physician's signature and date, or orally 16 prescribed by the patient's physician to the pharmacist. Respondents' controlled substance pre-17 printed prescriptions were not on secure blank prescription forms or orally received by 18 Respondents' pharmacists. 19

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

43. Respondents failed to identify ketamine as a Schedule III controlled substance in their
compounding software program. Due to this oversight, Respondents did not record prescriptions
using or incorporating ketamine as controlled substance prescriptions. Respondents did not
ensure that prescriptions using or incorporating ketamine were written on secure blank
prescription forms or that oral prescriptions using or incorporating ketamine were only received

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1	by the pharmacist. Respondents did not report prescriptions using or incorporating ketamine to
2	the Controlled Substance Utilization Review and Evaluation System (CURES).
3	44. On or about December 17, 2013, Respondents dispensed a prescription for T3/T4
4	Mixture C 20/80 mg capsules. A qualitative analysis report taken on or about February 21, 2014,
5	revealed that the T4 (Levothyroxine Sodium) component of the compounded drug was sub-potent
6	because the T4 was 73.5% of the expected potency.
7	FIRST CAUSE OF ACTION (Failure to Follow Filling Requirements for Prescriptions for Controlled Substances)
9	(Health & Saf. Code, § 11164, subd. (a)(1))
10	45. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action for
11	filling prescriptions for Schedule II controlled substances that were not signed and dated in ink by $(1) = (1) =$
12	the prescribers. (Health & Saf. Code, § 11164, subd. (a)(1).) The circumstances are further
13	explained in paragraphs 30 to 32, above.
14 15	SECOND CAUSE OF ACTION (Failure to Follow Requirements for Dispensing Controlled Substances in Emergency Situations) (Health & Saf. Code, § 11167)
16	46. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action
17	because it filled prescriptions not signed and dated in ink by the prescribers in non-emergency
18	situations. (Health & Saf. Code, § 11167.) Respondent San Dimas also failed to obtain the
10	original prescriptions, signed and dated in ink by the prescribers, within seven days of filling the
20	improperly formatted prescriptions. The circumstances are further explained in paragraphs 30 to
21	33, above.
22	THIRD CAUSE OF ACTION (Unprofessional Conduct: Fraud)
23	(Bus. & Prof. Code, § 4301, subd. (f))
24	47. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
25	engaging in unprofessional conduct because it committed acts involving fraud. (Bus. & Prof.
26	Code, § 4301, subd. (f).) Respondent San Dimas left a balance of medications owing on 178 of
27	the prescriptions it sold. The circumstances are further explained in paragraphs 34 to 35, above.
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	13 Accusation
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1	FOURTH CAUSE OF ACTION (Unprofessional Conduct: False Representation)
2	(Bus. & Prof. Code, § 4301, subd. (g))
3	48. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
4	engaging in unprofessional conduct by knowingly making or signing certificates or documents
5	that falsely represented the existence or nonexistence of a state of facts. (Bus. & Prof. Code, §
6	4301, subd. (g).) Respondent San Dimas left a balance of medications owing on 178 of the
7	prescriptions it sold. The patients for these 178 prescriptions did not receive their owed
8	quantities of medications and the pharmacy failed to reverse these claims to the patients'
9	insurance companies to reflect the actual quantity dispensed to the patients. The circumstances
10	are further explained in paragraphs 34 to 35, above.
11	FIFTH CAUSE OF ACTION
12	(Failure to Follow Compounding Limitations and Requirements) (Cal. Code Regs., tit. 16, § 1735.3, subd. (a))
13	49. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
14	maintaining incomplete pharmacy compounding records. (Cal. Code Regs., tit. 16, § 1735.3,
15	subd. (a).) A number of records were missing required information, including the identity of the
16	manufacturer, the lot number for each ingredient used in the compound, and the expiration date
17	for each ingredient used in the compound. The circumstances are further explained in paragraph
18	38, above.
19	SIXTH CAUSE OF ACTION
20	(Failure to Follow Compounding Limitations and Requirements) (Cal. Code Regs., tit. 16, § 1735.2, subd. (h))
21	50. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
22	allowing pharmacy staff to assign beyond use dates to compounded products which exceeded the
23	expiration date of at least one ingredient of the compounded drug. (Cal. Code Regs., tit. 16, §
24	1735.2, subd. (h).) The circumstances are further explained in paragraphs 37, above.
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I	Accusation

1	SEVENTH CAUSE OF ACTION (Failure to Follow Content Requirements for Prescriptions) (Bus. & Prof. Code, § 4040, subd. (a)(1))
3	51. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
4	accepting prescriptions for compounded medications that did not contain all of the statutorily
5	required information. (Bus. & Prof. Code, § 4040, subd. (a)(1).) Respondent San Dimas filled
6	prescriptions that did not contain the following required elements: the name, strength, and
7	quantity of the drug prescribed and directions on how to use the medication. The circumstances
8	are further explained in paragraphs 39 to 40, above.
9 10	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))
11	52. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
12	allowing non-pharmacists to orally receive prescriptions and not requiring the pharmacist to
13	receive, transcribe, and complete the prescription. (Bus. & Prof. Code, §§ 4040, 4051, subd. (a);
14	Cal. Code Regs., tit. 16, § 1717, subd. (c).) The circumstances are further explained in
15	paragraphs 39 to 41, above.
16 17	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))
8	53. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
19	failing to properly maintain records for ketamine powder, a Schedule III controlled substance.
20	(Health & Saf. Code, §§ 11200, subd. (b), 11164; 21 C.F.R. § 1304.04, subd. (f)(2).) Respondent
21	San Dimas did not identify ketamine powder as a Schedule III controlled substance, separate
22	invoices involving ketamine powder from invoices not involving controlled substances, and
23	identify prescriptions for medications containing ketamine as controlled substance prescriptions.
24 25	In addition, Respondent San Dimas did not require prescriptions involving ketamine powder to be
26	written on secure blank prescription forms or orally received by Respondent San Dimas's
27	pharmacist. Respondent San Dimas did not report prescriptions involving ketamine to CURES
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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) (Cal. Code Regs., tit. 16, § 1735.2, subd. (f))
5	54. Respondent San Dimas has subjected its Pharmacy Permit to disciplinary action by
6	failing to meet compounding requirements for potency. (Cal. Code Regs., tit. 16, § 1735.2, subd.
7	(f).) A qualitative analysis report revealed that a prescription compounded by Respondent San
8	Dimas and dispensed to a pateint was sub-potent. The circumstances are further explained in
9	paragraph 44, above.
10	ELEVENTH CAUSE OF ACTION
11 12	(Failure to Follow Filling Requirements for Prescriptions for Controlled Substances) (Health & Saf. Code, § 11164, subd. (a)(1))
13	55. Respondent Patel has subjected her Pharmacist License to disciplinary action for
14	filling prescriptions for Schedule II controlled substances that were not signed and dated in by the
15	prescribers. (Health & Saf. Code, § 11164, subd. (a)(1).) The circumstances are further
16	explained in paragraphs 30 to 32, above.
17 18	TWELFTH CAUSE OF ACTION (Failure to Follow Requirements for Dispensing Controlled Substances in Emergency Situations) (Health & Saf. Code, § 11167)
19	56. Respondent Patel has subjected her Pharmacy Permit to disciplinary action because
20	she filled prescriptions not signed and dated in ink by the prescribers in non-emergency
21	situations. (Health & Saf. Code, § 11167.) Respondent Patel also failed to obtain the original
22	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.
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	Accusation

1 2	<u>THIRTEENTH CAUSE OF ACTION</u> (Unprofessional Conduct: Fraud) (Bus. & Prof. Code, § 4301, subd. (f))
3	57. Respondent Patel has subjected her Pharmacist License to disciplinary action by
4	engaging in unprofessional conduct because she committed acts involving fraud. (Bus. & Prof.
5	Code, § 4301, subd. (g).) Respondent Patel left a balance of medications owing on 178 of the
6	prescriptions she sold. The circumstances are further explained in paragraphs 34 to 35, above.
7 8 9	FOURTEENTH CAUSE OF ACTION (Unprofessional Conduct: False Representation) (Bus. & Prof. Code, § 4301, subd. (g))
10	58. Respondent Patel has subjected her Pharmacist License to disciplinary action by
11	engaging in unprofessional conduct by knowingly making or signing certificates or documents
12	that falsely represented the existence or nonexistence of a state of facts. (Bus. & Prof. Code, §
13	4301, subd. (h).) Respondent Patel left a balance of medications owing on 178 of the
14	prescriptions she sold. The patients for these 178 prescriptions did not receive their owed
15	quantities of medications and she failed to reverse these claims to the patients' insurance
16	companies to reflect the actual quantity dispensed to the patients. The circumstances are further
17	explained in paragraphs 34 to 35, above.
18 19	FIFTEENTH CAUSE OF ACTION (Failure to Follow Compounding Limitations and Requirements) (Cal. Code Regs., tit. 16, § 1735.3, subd. (a))
20	59. Respondent Patel has subjected her Pharmacist License to disciplinary action by
21	maintaining incomplete pharmacy compounding records. (Cal. Code Regs., tit. 16, § 1735.3,
22	subd. (a).) A number of records at the pharmacy were missing required information, including
23	the identity of the manufacturer, the lot number for each ingredient used in the compound, and the
24	expiration date for each ingredient used in the compound. The circumstances are further
25	explained in paragraph 38, above.
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	Accusation

1 2	SIXTEENTH CAUSE OF ACTION (Failure to Follow Compounding Limitations and Requirements)
3	60. Respondent Patel has subjected her Pharmacist License to disciplinary action by
4	allowing pharmacy staff to assign beyond use dates to compounded products which exceeded the
5	expiration date of at least one ingredient of the compounded product. (Cal. Code Regs., tit. 16, §
6	1735.2, subd. (h).) The circumstances are further explained in paragraph 37, above.
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8 9	SEVENTEENTH CAUSE OF ACTION (Failure to Follow Content Requirements for Prescriptions) (Bus. & Prof. Code, § 4040, subd. (a)(1))
9 10	61. Respondent Patel has subjected her Pharmacist License to disciplinary action by
11	accepting prescriptions for compounded medications that did not contain all of the statutorily
12	required information. (Bus. & Prof. Code, § 4040, subd. (a)(1).) Respondent Patel filled
13	prescriptions that did not contain the following required elements: the name, strength, and
14	quantity of the drug prescribed and directions on how to use the medication. The circumstances
15	are further explained in paragraphs 39 to 40, above.
16 17	EIGHTEENTH 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))
18	62. Respondent Patel has subjected her Pharmacist License to disciplinary action by
19	allowing non-pharmacists to orally receive prescriptions and not receiving, transcribing, and
20	completing the prescription herself as the pharmacist-in-charge. (Bus. & Prof. Code, §§ 4040,
21	4051, subd. (a); Cal. Code Regs., tit. 16, § 1717, subd. (c).) The circumstances are further
22	explained in paragraphs 39 to 41, above.
23	NINETEENTH CAUSE OF ACTION
24	(Failure to Properly Maintain Records) (Health & Saf. Code, §§ 11200, subd. (b), 11164; 21 C.F.R. § 1304.04, subd. (f)(2))
25	63. Respondent Patel has subjected her Pharmacist License to disciplinary action by
26	failing to properly maintain records for ketamine powder, a Schedule III controlled substance.
27	(Health & Saf. Code, §§ 11200, subd. (b), 11164; 21 C.F.R. § 1304.04, subd. (f)(2).) Respondent
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	18 Accusation

1	Patel did not identify ketamine powder as a Schedule III controlled substance, separate invoices
2	involving ketamine powder from invoices not involving controlled substances, and identify
3	prescriptions for medications containing ketamine as controlled substance prescriptions. In
4	addition, Respondent Patel as did not require prescriptions involving ketamine powder to be
5	written on secure blank prescription forms or orally received by herself as Respondent San
6	Dimas's sole pharmacist. Respondent San Patel did not report prescriptions involving ketamine
7	to CURES and filled one that authorized for more than five refills. The circumstances are further
8	explained in paragraphs 41 to 43, above.
9 10	TWENTIETH CAUSE OF ACTION (Failure to Follow Compounding Requirements for Potency) (Cal. Code Regs., tit. 16, § 1735.2, subd. (f))
11	64. Respondent Patel has subjected her Pharmacist License to disciplinary action by
12	failing to meet compounding requirements for potency. (Cal. Code Regs., tit. 16, § 1735.2, subd.
13	(f).) A qualitative analysis report revealed that a prescription compounded by Respondent Patel
14	had a component that was sub-potent. The circumstances are further explained in paragraph 44,
15	above.
16	DISCIPLINARY CONSIDERATIONS
17	65. On or about May 23, 2014, in the matter entitled People v. Kalpana Kalpeshkumar Patel,
18	in Sacramento County Court, Case No. 14F03262, the Department of Justice on behalf of the People
19	of the State of California charged Respondent Patel with submitting a false and fraudulent Medi-Cal
20	claim (Welfare & Institutions Code, § 14107, subd. (b)(1)), grand theft of personal property (Pen.
21	Code, § 487, subd. (a)), presentation of a fraudulent claim (Pen. Code, § 72), and insurance fraud
22	(Pen. Code, §550, subd. (a)(6)). This matter is still pending.
23	66. To determine the degree of discipline, if any, to be imposed on Respondent San
24	Dimas, Complainant alleges that on or about July 3, 2013, in a prior action, the Board of
25	Pharmacy issued Citation Number CI-2011-52726 and ordered Respondent San Dimas to pay a
26	\$250.00 fine for deviating from prescriptions (Cal. Code Regs., tit. 16, § 1716); a \$250.00 fine for
27 28	not following proper requirements for off-site storage of records (Cal. Code Reg., tit. 16, § 1707,
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subds. (e), (f)); a \$500.00 fine for engaging in compounding and failing to maintain proper 1 2 written documentation of its personnel having the necessary skills and training, to maintain an evaluation process for personnel involved in compounding, to ensure that personnel involved in 3 compounding could demonstrate knowledge about processes and procedures used in 4 compounding (Cal. Code Regs., tit. 16, § 1735.7, subds. (a), (b), (c)); a \$250.00 fine for failing to 5 prevent the sale of preparations or drugs that lacked quality or strength (Bus. & Prof. Code, § 6 4342); a \$1,000.00 fine for failing to follow the requirement that a pharmacy with only one 7 pharmacist should have no more than one pharmacy technician performing tasks (Bus, & Prof. 8 Code, § 4115, subd. (f)(1)); a \$500.00 fine for engaging in unprofessional conduct (Bus. & Prof. 9 Code, § 4301, subd. (j); 21 U.S.C §§ 802, 822; 21 C.F.R. § 1307.21 (2013)), and a \$500.00 fine 10 for failing to maintaining proper records for compounded drug products (Cal. Code Regs., tit. 16, 11 12 § 1735.3, subd. (a)).

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

68. To determine the degree of discipline, if any, to be imposed on Respondent Patel, 19 Complainant alleges that on or about July 3, 2013, in a prior action, the Board of Pharmacy 20 21 issued Citation Number CI-2012-57375 and ordered Respondent Patel to pay a \$500.00 fine for deviating from prescriptions (Cal. Code Reg., tit. 16, § 1716); a \$250.00 fine for not following 22 proper requirements for off-site storage of records (Cal. Code Reg., tit. 16, § 1707, subds. (e), 23 (f)); a \$500.00 fine for engaging in compounding and failing to maintain proper written 24 documentation of its personnel having the necessary skills and training, to maintain an evaluation 25 26 process for personnel involved in compounding, to ensure that personnel involved in 27 compounding could demonstrate knowledge about processes and procedures used in compounding (Cal. Code Regs., tit. 16, § 1735.7, subds. (a), (b), (c)); a \$250.00 fine for failing to 28

prevent the sale of pharmaceutical preparations or drugs that lacked quality or strength (Bus. & 1 Prof. Code, § 4342); a \$1,000.00 fine for failing to follow the requirement that a pharmacy with 2 only one pharmacist should have no more than one pharmacy technician performing tasks (Bus. 3 & Prof. Code, § 4115, subd. (f)(1)); a \$500.00 fine for engaging in unprofessional conduct (Bus. 4 & Prof. Code, § 4301, subd. (j); 21 U.S.C §§ 802, 822; 21 C.F.R. § 1307.21 (2013)), and a 5 \$500.00 fine for failing to maintaining proper records for compounded drug products (Cal. Code 6 Reg., tit. 16, § 1735.3, subd. (a)). 7 69. To determine the degree of discipline, if any, to be imposed on Respondent Patel, 8 Complainant alleges that on or about December 15, 2010, in a prior action, the Board of 9 Pharmacy issued Citation Number CI-2010-46672 and ordered Respondent Patel to pay a 10 \$500.00 fine for failing to ensure that there was proper pharmacy security (Cal. Code Regs., tit. 11 16, § 1714, subd. (b)) and a \$500.00 fine for allowing an unlicensed individual to act as a 12 pharmacy technician (Bus. & Prof. Code, § 4115, subd. (e)). 13 PRAYER 14 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this 15 Accusation, and that following the hearing, the Board of Pharmacy issue a decision: 16 17 1.1. Revoking or suspending Pharmacy Permit Number PHY 48922, issued to San Dimas Pharmacy & Compounding Center; 18 19 1.2. Revoking or suspending Pharmacist License Number RPH 49676, issued to Kalpana Patel, also known as Kalpana Kalpeshkumar Patel: 20 1.3. Ordering San Dimas Pharmacy & Compounding Center and Kalpana Patel, also 2.1known as Kalpana Kalpeshkumar Patel, to pay the Board of Pharmacy the reasonable costs of the 22 investigation and enforcement of this case, pursuant to Business and Professions Code section 23 125.3; 24 1.4. Pursuant to Business and Professions Code section 4307, if discipline is imposed on 25 Pharmacy Permit Number PHY 48922, issued to San Dimas Pharmacy & Compounding Center, 26 and Kalpana Patel, also known as Kalpana Kalpeshkumar Patel, (Patel) while acting as the 27 manager, administrator, owner, member, officer, director, associate, or partner of San Dimas 28 21

Pharmacy & Compounding Center, had knowledge of or knowingly participated in any conduct 1 for which Pharmacy Permit Number PHY 48922, issued to San Dimas Pharmacy & 2 Compounding Center, was revoked, suspended, or placed on probation, Patel shall be prohibited 3 from serving as a manager, administrator, owner, member, officer, director, associate, or partner 4 of a licensee for five years if Pharmacy Permit Number PHY 48922, issued to San Dimas 5 Pharmacy & Compounding Center, is placed on probation or until PHY 48922, issued to San 6 Dimas Pharmacy & Compounding Center, is reinstated, if it is revoked; and 7 1.5. Taking such other and further action as deemed necessary and proper. 8 9 10 12/29/15 DATED: 11 VIRGINIA) HEROLD Executive Officer 12 Board of Pharmacy Department of Consumer Affairs 13 State of California Complainant 14 15 SF2014902425 90440380.doc 16 17 18 19 2021 22 23 24 25 26 27 28 22 Accusation