

1 XAVIER BECERRA
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 ERIN M. SUNSERI
Deputy Attorney General
4 State Bar No. 207031
600 West Broadway, Suite 1800
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 738-9419
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11
12 In the Matter of the Accusation Against:

Case No. 6251

13 **SHELAT ENTERPRISES INC.,**
DBA PROCARE PHARMACY
14 **25405 Hancock Ave. #100**
Murrieta, CA 92562

FIRST AMENDED ACCUSATION

15 **Pharmacy Permit No. PHY 46937**

16 **VIJAY V. SHELAT**
17 **25405 Hancock Ave. #100**
18 **Murrieta, CA 92562**

19 **Pharmacist License No. RPH 45111**

20 Respondents.

21
22 Complainant alleges:

23 **PARTIES**

24 1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her
25 official capacity as the Interim Executive Officer of the Board of Pharmacy, Department of
26 Consumer Affairs.

27 ///

28 ///

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

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

5 The pharmacist-in-charge shall be responsible for a pharmacy's compliance
6 with all state and federal laws and regulations pertaining to the practice of pharmacy.

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

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

9 Acts or omissions that involve, in whole or in part, the inappropriate exercise of
10 his or her education, training, or experience as a pharmacist, whether or not the act or
11 omission arises in the course of the practice of pharmacy or the ownership,
management, administration, or operation of a pharmacy or other entity licensed by
the board.

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

14 ...

15
16 14. Section 4307(a) of the Code states that:

17 Any person who has been denied a license or whose license has been revoked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

23 (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
24 years.

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

26 ///

27 ///

28 ///

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

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

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

...

16. Health and Safety Code section 11162.1(a) states:

(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive 'void' pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1-24

25-49

50-74

75-100

101-150

151 and over.

1 (B) In conjunction with the quantity boxes, a space shall be provided to
designate the units referenced in the quantity boxes when the drug is not in tablet or
2 capsule form.

3 (8) Prescription blanks shall contain a statement printed on the bottom of the
prescription blank that the "Prescription is void if the number of drugs prescribed is
4 not noted."

5 (9) The preprinted name, category of licensure, license number, federal
controlled substance registration number, and address of the prescribing practitioner.

6 (10) Check boxes shall be printed on the form so that the prescriber may
indicate the number of refills ordered.

7 (11) The date of origin of the prescription.

8 (12) A check box indicating the prescriber's order not to substitute.

9 (13) An identifying number assigned to the approved security printer by the
10 Department of Justice.

11 (14) (A) A check box by the name of each prescriber when a prescription form
lists multiple prescribers.

12 (B) Each prescriber who signs the prescription form shall identify himself or
13 herself as the prescriber by checking the box by his or her name.

14 17. Health and Safety Code section 11164(a) states in pertinent part:

15 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
16 controlled substance, unless it complies with the requirements of this section.

17 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
18 prescription form as specified in Section 11162.1...

19 18. Health and Safety Code section 111250 states:

20 Any drug or device is adulterated if it consists, in whole or in part, of any filthy,
putrid, or decomposed substance.

21 19. Health and Safety Code section 111255 states:

22 Any drug or device is adulterated if it has been produced, prepared, packed, or
held under conditions whereby it may have been contaminated with filth, or whereby
23 it may have been rendered injurious to health.

24 20. Health and Safety Code section 111295 states:

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

27 ///

28

1 21. Health and Safety Code section 111300 states:

2 It is unlawful for any person to adulterate any drug or device.

3 22. Section 1714(b) of title 16, California Code of Regulations states:

4 Each pharmacy licensed by the board shall maintain its facilities, space,
5 fixtures, and equipment so that drugs are safely and properly prepared, maintained,
6 secured and distributed. The pharmacy shall be of sufficient size and unobstructed
area to accommodate the safe practice of pharmacy.

7 23. Section 1718 of title 16, California Code of Regulations states:

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

10 The controlled substances inventories required by Title 21, CFR, Section 1304
11 shall be available for inspection upon request for at least three years.

12 24. Section 1735(c) of title 16, California Code of Regulations states:

13 The parameters and requirements stated by Article 4.5 (Section 1735 et seq.)
14 apply to all compounding practices. Additional parameters and requirements
15 applicable solely to sterile compounding are stated by Article 7 (Section 1751 et
seq.).

16 25. Section 1735.2(d)(3) of title 16, California Code of Regulations states:

17 No pharmacy or pharmacist shall compound a drug preparation that:

18 ...

19 Is a copy or essentially a copy of one or more commercially available drug
20 products, unless that drug product appears on an ASHP (American Society of Health-
21 System Pharmacists) or FDA list of drugs that are in short supply at the time of
22 compounding and at the time of dispense, and the compounding of that drug
23 preparation is justified by a specific, documented medical need made known to the
pharmacist prior to compounding. The pharmacy shall retain a copy of the
documentation of the shortage and the specific medical need in the pharmacy records
for three years from the date of receipt of the documentation.

24 26. Sections 1735.3(a)(2)(D) and (F) of title 16, California Code of Regulations states:

25 (a) For each compounded drug preparation, pharmacy records shall include:

26 ...

27 (2) A compounding log consisting of a single document containing all of the
28 following:

1 ...

(D) The identity of the pharmacist reviewing the final drug preparation.

3 ...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (1) shall apply.

27. Sections 1735.7(a) and (c) of title 16, California Code of Regulations state:

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding practice.

13 ...

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

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

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

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

COST RECOVERY

29. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

27 ///

28 ///

1 **DRUGS**

2 30. Dilaudid is the brand name for hydromorphone, a Schedule II controlled substance
3 pursuant to Health and Safety Code section 11055, subdivision (b)(1)(J) and a dangerous drug
4 pursuant to Business and Professions Code section 4022.

5 31. Norco is the brand name for hydrocodone/acetaminophen, a Schedule II controlled
6 substance pursuant to Code of Federal Regulations, title 21, section 1308.12, subdivision
7 (b)(1)(vi) and a dangerous drug pursuant to Business and Professions Code section 4022.

8 32. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code
9 section 11055, subdivision (b)(1)(M) and a dangerous drug pursuant to Business and Professions
10 Code section 4022.

11 33. Phenergan with Codeine is the brand name for promethazine with codeine, a
12 Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision
13 (c)(1) and is a dangerous drug pursuant to Business and Professions Code section 4022.

14 34. Progesterone cream is a dangerous drug pursuant to Business and Professions Code
15 section 4022.

16 35. Tretinoin cream is a dangerous drug pursuant to Business and Professions Code
17 section 4022.

18 36. Thymol is a dangerous drug pursuant to Business and Professions Code section 4022.

19 37. Xanax is the brand name for alprazolam, a Schedule IV controlled substance pursuant
20 to Health and Safety Code section 11057, subdivision (d)(1) and a dangerous drug pursuant to
21 Business and Professions Code section 4022.

22 **FACTUAL ALLEGATIONS**

23 38. At all times relevant herein, Vijay Shelat was the Pharmacist-in-Charge of Procure
24 Pharmacy. Procure Pharmacy and Vijay Shelat (collectively Respondents) dispensed controlled
25 substances, including addictive drugs of high abuse and diversion potential. They also
26 compounded and dispensed nonsterile drug preparations.

1 39. On February 2, 2017, Vijay Shelat was the only pharmacist on duty, along with two
2 pharmacy technicians simultaneously filling prescriptions, removing medications from shelves,
3 counting medications, placing medications into prescription containers and affixing prescription
4 labels on the containers.

5 **Controlled Substances Inventory:**

6 40. From November 15, 2014 through August 9, 2016, there was a shortage of 461 tablets
7 of oxycodone 30mg in Respondents' inventory of drugs.

8 **Dispensing of Dr. V. S. Prescriptions:**

9 41. From July 2, 2013 through January 19, 2015, Respondents filled **198** prescriptions for
10 controlled substances which were written by Dr. V.S., whose address was listed on the
11 prescriptions as being 65 miles away from Procure Pharmacy. "Patients" travelled as far as 65
12 miles to allegedly receive medical treatment from Dr. V.S., and traveled up to 39 miles to have
13 their prescriptions dispensed at Procure Pharmacy. Dr. V.S. was an internist who primarily
14 prescribed controlled substances. Patients paid for the controlled substance prescriptions
15 primarily in cash (sometimes hundreds of dollars) and did not seek reimbursement from an
16 insurance company or government agency.

17 42. Respondents dispensed similar or identical prescriptions written by Dr. V.S. to
18 multiple patients. Dr. V.S. primarily wrote these prescriptions for controlled substances of high
19 abuse and diversion potential to multiple patients as follows: (1) alprazolam 2mg; (2) oxycodone
20 30mg; and (3) hydrocodone/APAP 10/325. There was no adjustments in the prescribing patterns
21 for sex, age, weight, renal or hepatic function, race, diagnosis, past medications used or any other
22 patient related factor.

23 43. None of the "patients" being treated by Dr. V.S. were receiving a long acting pain
24 medication to control their baseline pain. Dr. V.S. was not a pain specialist but he wrote
25 prescriptions primarily for pain medications. Dr. V.S. prescribed only the highest dosage of
26 oxycodone and alprazolam without prescribing a lower strength and increasing the strength as
27 needed. Many patients were prescribed both oxycodone and alprazolam which was
28 contraindicated. The majority of patients received the same diagnosis from Dr. V.S.

1 44. On or about June 8, 2016, in the case entitled *United States of America v. V. B. H. S.*,
2 *et al.*, United States District Court, Central District of California, Southern Division, Case No.
3 SACR16-00079, an indictment was filed against Dr. V.S., charging him with one count of
4 conspiracy to distribute controlled substances (21 U.S.C. § 846), thirty-two counts of distribution
5 of a controlled substance in Schedule II (21 U.S.C. § 841, subds. (a)(1), (b)(1)(C)), and twenty-
6 two counts of distribution of a controlled substance in Schedule IV (21 U.S.C. § 841, subds.
7 (a)(1), (b)(2)). On or about June 1, 2017, Dr. V.S. pled guilty to one count of distribution of a
8 controlled substance in Schedule II, namely, oxycodone (Count 3), and one count of distribution
9 of a controlled substance in Schedule IV, namely, alprazolam (Count 36).

10 45. Effective January 10, 2018, the Medical Board of California adopted a Stipulated
11 Surrender of License and Disciplinary Order as the Decision and Order of the Medical Board of
12 California in *In the Matter of the Accusation Against: V. B. H. S., M.D.*, Case No. 800-2014-
13 002943.

14 **Dispensing of Dr. K.T. Prescriptions:**

15 46. From July 5, 2013 through December 16, 2013, Respondents filled **87** prescriptions
16 for controlled substances which were written by Dr. K.T. whose addresses were listed on the
17 prescriptions as being 99 and 53 miles away from Procure Pharmacy. “Patients” traveled as far as
18 104 miles to allegedly receive medical treatment from Dr. K.T. and up to 106 miles to fill
19 prescriptions at Procure Pharmacy. Patients paid for the controlled substance prescriptions in
20 cash (sometimes hundreds of dollars) at Procure Pharmacy and did not seek reimbursement from
21 an insurance company or government agency.

22 47. Respondents dispensed similar or identical prescriptions written by Dr. K.T. to
23 multiple patients on the same day, including possibly groups of patients within minutes of each
24 other. Some of these patients had identical diagnoses from Dr. K.T. Prescriptions were written
25 on the same date, had identical batch numbers and were either sequential (or close to) in script
26 numbers, possibly indicating prescriptions dispensed to groups of patients or cappers. On
27 multiple occasions, Respondents dispensed drugs pursuant to prescriptions which had been
28 written days earlier.

1 48. Dr. K.T. wrote these prescriptions for controlled substances of high abuse and
2 diversion potential to multiple patients as follows: (1) promethazine with codeine in a quantity of
3 480ml (full pint size); and (2) oxycodone 30mg. There were no adjustment in the prescribing
4 pattern for sex, age, weight, renal or hepatic function, race, diagnosis, past medications used or
5 any other patient related factor.

6 49. None of the “patients” being treated by Dr. K.T. were receiving a long acting pain
7 medication to control their baseline pain. Dr. K.T. prescribed only the highest dosage of
8 oxycodone without prescribing a lower strength and increasing the strength as needed. Most
9 patients were only prescribed promethazine with codeine without an antibiotic. The majority of
10 the patients were given the same diagnosis by Dr. K.T.

11 50. Since in or around July 11, 2013, Dr. K.T. has been retired from the practice of
12 medicine due to his diagnosis of Parkinson’s disease and has resided in Minnesota.

13 **Dispensing of PA S.D. Prescriptions:**

14 51. From November 15, 2013 through February 29, 2016, Respondents filled **142**
15 prescriptions for controlled substances which were written by a physician assistant, S.D., for an
16 internist, Dr. S.K. whose addresses were listed on the prescriptions as being 96, 39, 93 and 55
17 miles away from Procure Pharmacy. Patients’ residences were as far away as 114 miles from
18 Procure Pharmacy and they travelled as far as 115 miles to have their prescriptions filled at
19 Procure Pharmacy. Patients paid for the controlled substance prescriptions in cash (sometimes
20 hundreds of dollars) and did not seek reimbursement from an insurance company or government
21 agency.

22 52. Respondents dispensed similar or identical prescriptions written by PA S.D. to
23 multiple patients on the same day, including possibly to groups of patients or cappers, within
24 minutes of each other. The patients were assigned consecutive or nearly consecutive prescription
25 numbers and identical batch numbers and either sequential (or close to) script numbers were on
26 prescriptions. On multiple occasions, Respondents dispensed drugs pursuant to prescriptions
27 which had been written days earlier.

28

1 53. PA S.D. wrote these prescriptions primarily for controlled substances of high abuse
2 and diversion potential for multiple patients including: (1) promethazine with codeine (full pint
3 size 473 ml); (2) oxycodone 30mg; and (3) alprazolam 2mg. Many patients received both
4 alprazolam 2mg with an opioid which is contraindicated. There were no adjustments in the
5 prescribing patterns for sex, age, weight, renal or hepatic function, race, diagnosis, past
6 medications used or any other patient related factor. Physician assistants who are supervised by
7 internists also typically do not prescribe primarily controlled substances. In addition, PA S.D.
8 prescribed only opioids, mainly oxycodone 30mg for the treatment of pain, rather than other pain
9 medications.

10 54. None of the “patients” being treated by PA S.D. were receiving a long acting pain
11 medication to control their baseline pain. PA S.D. prescribed only the highest dosage of
12 oxycodone and alprazolam without prescribing a lower strength and increasing the strength as
13 needed. Promethazine with codeine was prescribed without an antibiotic.

14 55. “Adult Progress Notes” and “Justification for Prescribed Medication (Controlled
15 Substanced [sic])” stapled to PA S.D.’s prescriptions. These documents contained misspellings
16 of common medical terms and drugs while drugs withdrawn from the market and only the highest
17 strengths of oxycodone and alprazolam were listed on the drug lists.

18 56. PA S.D.’s supervising physician, Dr. S.K. had a rule that PA S.D. was never to
19 prescribe more than 120 tablets of oxycodone per month and only with the appropriate medical
20 necessity.

21 **Dispensing of Dr. S.K. Prescriptions:**

22 57. From January 4, 2014 through November 2, 2015, Respondents filled **59** prescriptions
23 for controlled substances which were written by Dr. S.K. whose office addresses were listed on
24 the prescriptions as being 103, 93, 97 and 57 miles away from Procure Pharmacy. Patients
25 travelled as far as 148 miles to allegedly receive medical treatment from Dr. S.K. and as far as 86
26 miles to fill their prescriptions at Procure Pharmacy. Dr. S.K.’s areas of practice were internal
27 medicine, family medicine and complementary and alternative medicine; yet he primarily
28 dispensed controlled substances. Patients paid for the controlled substance prescriptions in cash

1 (sometimes hundreds of dollars) and did not seek reimbursement from an insurance company or
2 government agency.

3 58. Respondents dispensed similar or identical prescriptions written by S.K. to multiple
4 patients on the same day, including possibly groups of patients or cappers, within minutes of each
5 other. Prescriptions had identical batch numbers and were either sequential or close in script
6 number even some of those not written on the same date. On multiple occasions, Respondents
7 dispensed drugs pursuant to prescriptions which had been written days earlier.

8 59. Dr. S.K. wrote these prescriptions for controlled substances of high abuse and
9 diversion potential to multiple patients as follows: (1) promethazine with codeine in a quantity of
10 480ml (pint size); (2) oxycodone 30mg; and (3) hydrocodone/APAP 10/325. There were no
11 adjustments in the prescribing patterns for sex, age, weight, renal or hepatic function, race,
12 diagnosis, past medications used or any other patient related factor. The majority of prescriptions
13 written were for controlled substances even though Dr. S.K. was an internist.

14 60. None of the “patients” being treated by Dr. S.K. were receiving a long acting pain
15 medication to control their baseline pain. Dr. S.K. prescribed only the highest dosage of
16 oxycodone without prescribing a lower strength and increasing the strength as needed. No
17 antibiotics were prescribed with promethazine with codeine. Some patients were prescribed both
18 oxycodone and alprazolam which was contraindicated.

19 61. Dr. S.K. reported to law enforcement that his prescription forms had been stolen from
20 his practice during the relevant time frame. He also did not write prescriptions which were filled
21 by Respondents nor did he or his staff verify any prescriptions for Respondents.

22 **Dispensing of Dr. R.G. Prescriptions:**

23 62. From December 10, 2014 through November 18, 2015, Respondents filled **80**
24 prescriptions for controlled substances which were written by Dr. R.G. whose address was listed
25 on the prescriptions as being 55 miles away from Procure Pharmacy. Dr. R.G. was a family
26 medicine practitioner, but dispensed primarily controlled substances. Patients travelled between
27 25 and 75 miles to allegedly receive medical treatment from Dr. R.G. and traveled up to 100
28 miles to have their prescriptions dispensed at Procure Pharmacy. Patients paid for the controlled

1 substance prescriptions primarily in cash (sometimes for hundreds of dollars) and did not seek
2 reimbursement from an insurance company or government agency.

3 63. Respondents dispensed similar or identical prescriptions written by Dr. R.G. to
4 multiple patients on the same day, including possibly groups of patients or cappers, within
5 minutes of each other. On multiple occasions, Respondents dispensed drugs pursuant to
6 prescriptions which had been written days earlier.

7 64. Dr. R.G. primarily wrote these prescriptions for controlled substances of high abuse
8 and diversion potential to multiple patients as follows: (1) promethazine with codeine in a
9 quantity of 473ml (full pint size); (2) hydrocodone/APAP 10/325; and (3) oxycodone 30mg.
10 There were no adjustments in the prescribing patterns for sex, age, weight, renal or hepatic
11 function, race, diagnosis, past medications used or any other patient related factor. Phenergan
12 with codeine was misspelled on the prescriptions.

13 65. None of the “patients” being treated by Dr. R.G. were receiving a long acting pain
14 medication to control their baseline pain. Dr. R.G. was not a pain specialist but he almost always
15 prescribed pain medication. Dr. R.G. prescribed only the strongest dosage of oxycodone without
16 prescribing a lower strength and increasing the strength as needed. No antibiotics were prescribed
17 with promethazine with codeine.

18 66. Documents providing “justification” for the prescribing of the controlled substances
19 were stapled to the prescriptions but these contained misspellings of drugs and medical terms.

20 **Dispensing of Dr. R.I.’s Prescriptions:**

21 67. From August 18, 2014 through September 21, 2016, Respondents filled **101**
22 prescriptions for controlled substances which were written by Dr. R.I. Dr. R.I. was not a pain
23 management specialist but instead held board certifications in allergies and pediatrics.
24 Nonetheless, he wrote the majority of prescriptions for controlled substances used to treat pain.
25 Patients paid for the controlled substance prescriptions primarily in cash (sometimes hundreds of
26 dollars) and did not seek reimbursement from an insurance company or government agency.

27 68. Respondents dispensed similar or identical prescriptions written by Dr. R.I. to
28 multiple patients. Dr. R.I. primarily wrote these prescriptions for controlled substances of high

1 abuse and diversion potential to multiple patients as follows: (1) oxycodone 30mg; (2)
2 promethazine with codeine in a quantity of 473ml (full pint size); and (3) alprazolam 2mg. There
3 were no adjustments in the prescribing patterns for sex, age, weight, renal or hepatic function,
4 race, diagnosis, past medications used or any other patient related factor.

5 69. None of the “patients” being treated by Dr. R.I. were receiving a long acting pain
6 medication to control their baseline pain. Dr. R.I. prescribed only the highest dosage of
7 oxycodone and alprazolam without prescribing a lower dosage and increasing the strength as
8 needed. Only one patient was prescribed both an antibiotic and promethazine with codeine. Dr.
9 R.I. allegedly prescribed both oxycodone and alprazolam which is contraindicated.

10 70. Dr. R.I. had prescription pads stolen from his practice during the relevant time frame
11 by a former employee. Respondents filled controlled substance prescriptions for eight “patients”
12 of Dr. R.I. but they were not his patients. Yet, Respondents noted in the pharmacy records that
13 they had verified prescriptions with Dr. R.I.’s staff.

14 **Dispensing of Dr. E.S.’ Prescriptions:**

15 71. From April 18 through 26, 2016, Respondents filled **12** prescriptions for controlled
16 substances which were written by Dr. E.S. whose address was listed on the prescriptions as being
17 104 miles away from Procare Pharmacy. Patients travelled as far as 109 miles to allegedly
18 receive medical treatment from Dr. E.S. and traveled up to 85 miles to have their prescriptions
19 dispensed at Procare Pharmacy. Patients paid for the controlled substance prescriptions primarily
20 in cash (sometimes hundreds of dollars) and did not seek reimbursement from an insurance
21 company or government agency.

22 72. Respondents dispensed similar or identical prescriptions written by Dr. E.S. to
23 multiple patients on the same day. Dr. E.S. wrote prescriptions for Viagra, along with controlled
24 substances to two females, which were dispensed by Respondents. All of the prescriptions were
25 written on April 4, 2016 but dispensed weeks later. The patients received identical diagnoses
26 from Dr. E.S. A justification for dispensing one of the controlled substances indicated that the
27 patient had failed in his use of Percocet but then was prescribed oxycodone by Dr. E.S. However,
28 oxycodone is contained in Percocet.

1 **Dispensing from Non-Compliant Security Forms:**

2 73. In 2015, Respondents dispensed controlled substances pursuant to prescriptions
3 which were written by Dr. R.G., PA S.D. and Dr. E.S. on non-compliant prescription forms
4 missing such required security elements as a watermark printed on the backside of the
5 prescription blank entitled “California Security Prescription,” an identifying number assigned to
6 an approved security printer by the Department of Justice, a lot number printed on the forms and
7 proper check off boxes.

8 74. Respondents dispensed controlled substances to individuals who obtained
9 prescriptions for controlled substances from more than one of the same prescribers (in some
10 cases, five prescribers) identified in the preceding paragraphs.

11 75. Respondents marked up the price of controlled substances dispensed to patients who
12 paid cash for their prescriptions. For example, PA S.D.’s patients paid in cash as much as
13 \$500.00 for prescriptions of oxycodone 30 mg, \$699.98-\$1,529.42 for prescriptions of
14 hydromorphone 4mg and approximately \$800.00 for prescriptions of Tussionex Pennkinetic. Dr.
15 R.G.’s patients paid in cash as much as \$299.99-\$524.72 for oxycodone 30 mg and \$788.79-
16 \$849.99 for prescriptions of Dilaudid 4 mg. Dr. V.S.’s patients paid as much as \$347.72 in cash
17 for controlled substance prescriptions. Dr. K.T.’s patients paid as much as \$698.99 in cash for
18 prescriptions of Dilaudid 4mg and \$499.90 for prescriptions of oxycodone 30 mg. Dr. R.I.’s
19 patients paid as much as \$399.99 in cash for prescriptions of oxycodone 30mg. Dr. S.K.’s
20 patients paid as much as \$499.99 for prescriptions of oxycodone 30mg and \$1,599.99 for
21 prescriptions of Dilaudid 4mg. Dr. E.S.’s patients paid \$538.72 for prescriptions of oxycodone
22 30 mg.

23 76. The federal government during the execution of federal search and seizure warrants
24 seized \$645,348.05 in U.S. currency from three safe deposit boxes rented in the names of
25 Respondent Vijay Shelat and his wife at a branch of the Bank of America in Riverside and
26 \$22,062.50 in U.S. currency and ten \$1000.00 U.S. Postal money orders at Respondent Vijay
27 Shelat’s residence.

28

1 77. When interviewed by Board inspectors during an August 10, 2016 inspection,
2 Respondent Vijay Shelat stated that pharmacists at Respondent Procure Pharmacy followed the
3 following protocol to satisfy corresponding responsibility requirements to dispense only
4 medically legitimate controlled substance prescriptions: (1) check the prescription's issue date
5 and the prescriber's signature; (2) check CURES/PDMP on all new patients evaluating the drug
6 quantity and the last fill date. If the pharmacist determined that a patient saw multiple prescribers
7 and used multiple pharmacies to fill or a prescription was recently filled, the prescription would
8 be declined; (3) check where the patient resided and the location of the prescriber's practice.
9 Respondents would refuse to fill out of the area patients (i.e., more than 25 miles from the
10 pharmacy). If a local patient saw a prescriber farther than Riverside, the pharmacist would
11 contact the prescriber and ask for the diagnosis and additional medical information; (4) check the
12 profile of established patients and sometimes CURES/PDMP before filling; and (5) check the
13 prescriptions more carefully of patients who pay in cash.

14 78. Respondent Vijay Shelat further told the inspectors that the appropriate starting dose
15 for: (1) alprazolam was 0.25 or 0.5mg twice to three times per day; (2) for hydrocodone-
16 acetaminophen 5/325 mg twice to three times daily; and (3) for oxycodone 10mg twice to three
17 times daily.

18 79. Respondents did not follow their own procedures and/or the proper procedures for
19 verifying whether controlled substance prescriptions were written for a legitimate medical
20 purpose.

21 **Nonsterile Compounding Drug Operations:**

22 80. Respondents stored expired active pharmaceutical ingredients or excipients along
23 with other active pharmaceutical ingredients or excipients used to prepare compounded drug
24 preparations.

25 81. On July 26, 2016, Respondents compounded Thymol 4% in alcohol 30 ml lot number
26 07262016G using a pharmaceutical excipient, Thymol crystals which had expired on June 30,
27 2016. Respondents dispensed that compounded drug to a patient (Prescription Number 657815).
28

1 82. On January 17, 2017, Respondents compounded Progesterone 25 mg/gm cream lot
2 number 01172017M3 using an excipient, hormonal replacement therapy (HRT) cream base which
3 had expired on July 31, 2016. Respondents dispensed that compounded drug to a patient
4 (Prescription Number 670799).

5 83. The compounding log used to document the compounding of Thymol 4% in alcohol
6 30 ml lot number 07262016G did not contain the correct expiration date for the Thymol crystals
7 used in that preparation. Similarly, the compounding log used to document the compounding of
8 progesterone 25 mg/gm cream lot number 01172017M3 did not contain the correct expiration
9 date for the HRT cream base used in that preparation. The identity of the pharmacists reviewing
10 those final drug preparations was also not listed on the compounding logs, as well as in the logs
11 used to document the compounding of Tretinoin 0.1% cream from July 2016 through November
12 2016.

13 84. Respondents did not possess any records showing that a pharmacy technician who
14 compounded drug preparations was trained and possessed the skills necessary to properly and
15 accurately perform his assigned compounding tasks and the knowledge about processes and
16 procedures used in compounding drug preparations.

17 85. From January 1, 2016 through February 2, 2017, Respondents compounded Tretinoin
18 0.1% cream which they used to fill 273 prescriptions, although there was a commercially
19 available product to dispense. Respondents had no documentation to show that their compounded
20 Tretinoin 0.1% cream qualified for exemptions to the prohibition against the compounding of
21 commercially available drug products.

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

28 ///

1 **FIRST CAUSE FOR DISCIPLINE**

2 **(Failing to Comply with Corresponding Responsibility**

3 **for Legitimate Controlled Substance Prescriptions against Respondents)**

4 86. Respondents are subject to disciplinary action under Code section 4301(j), for
5 violating Health and Safety Code section 11153(a), in that they failed to comply with their
6 corresponding responsibility to ensure that controlled substances were dispensed for a legitimate
7 medical purpose when they furnished prescriptions for controlled substances even though “red
8 flags” were present, indicating those prescriptions were not issued for a legitimate medical
9 purpose, as set forth in paragraphs 38 through 85 above, which are incorporated herein by
10 reference.

11 **SECOND CAUSE FOR DISCIPLINE**

12 **(Clearly Excessive Furnishing of Controlled Substances against Respondents)**

13 87. Respondents are subject to disciplinary action under Code section 4301(d), for the
14 clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section
15 11153 of the Health and Safety Code, as set forth in paragraphs 38 through 85 above, which are
16 incorporated herein by reference.

17 **THIRD CAUSE FOR DISCIPLINE**

18 **(Dispensing Controlled Substance Prescriptions with Significant Errors, Omissions,**
19 **Irregularities, Uncertainties, Ambiguities or Alterations against Respondents)**

20 88. Respondents are subject to disciplinary action under Code section 4301(o), for
21 violating title 16, California Code of Regulations, sections 1761(a) and (b), in that they dispensed
22 prescriptions for controlled substances, which contained significant errors, omissions,
23 irregularities, uncertainties, ambiguities or alterations, as set forth in paragraphs 38 through 85
24 above, which are incorporated herein by reference.

25 ///

26 ///

27 ///

28 ///

1 **FOURTH CAUSE FOR DISCIPLINE**

2 **(Dispensing Controlled Substance Prescriptions Written on Unauthorized Forms)**

3 89. Respondents are subject to disciplinary action under Code section 4301(j), for
4 violating Health and Safety Code sections 11162.1(a) and 11164(a), in that they dispensed
5 prescriptions written on unauthorized forms, as set forth in paragraphs 38 through 85 above,
6 which are incorporated herein by reference.

7 **FIFTH CAUSE FOR DISCIPLINE**

8 **(Failure to Maintain Security of Drugs against Respondents)**

9 90. Respondents are subject to disciplinary action under Code section 4301(o), for
10 violating title 16, California Code of Regulations, section 1714(b), in that there was a shortage of
11 approximately 461 tablets of oxycodone 30 mg from November 15, 2014 through August 9, 2016,
12 as set forth in paragraphs 38 through 85 above, which are incorporated herein by reference.

13 **SIXTH CAUSE FOR DISCIPLINE**

14 **(Failure to Maintain Current Inventory of Controlled Substance against Respondents)**

15 91. Respondents are subject to disciplinary action under Code section 4301(o), for
16 violating Code section 4081(a) and title 16, California Code of Regulations, section 1718, in that
17 they did not maintain a current inventory of a controlled substance, oxycodone, as set forth in
18 paragraphs 38 through 85 above, which are incorporated herein by reference.

19 **SEVENTH CAUSE FOR DISCIPLINE**

20 **(Failure to Exercise or Implement Best Professional Judgment or Corresponding**
21 **Responsibility when Dispensing Controlled Substances against Vijay Shelat)**

22 92. Respondent Vijay Shelat is subject to disciplinary action under Code section 4301(o),
23 for violating Business and Professions Code section 4306.5(a) and (b), in that he failed to exercise
24 or implement his best professional judgment or corresponding responsibility when dispensing
25 controlled substances, as set forth in paragraphs 38 through 85 above, which are incorporated
26 herein by reference.

27 ///

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

EIGHTH CAUSE FOR DISCIPLINE

(Exceeding Lawful Pharmacy and Pharmacy Technician Ratio)

93. Respondents are subject to disciplinary action under Code section 4301(o), for violating Business and Professions Code section 4115(f)(1), in that on February 2, 2017, they had one pharmacist, Vijay Shelat, on duty when two pharmacy technicians were simultaneously filling prescriptions, removing medications from shelves, counting medications, placing medications into containers and affixing the prescription labels on containers, as set forth in paragraphs 38 through 85, which are incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Manufactured, Sold, Delivered, Held or Offered for Sale Adulterated Drugs)

94. Respondents are subject to disciplinary action under Code sections 4301(j) and 4301(o), for violating Health and Safety Code section 111295 and Business and Professions Code section 4169(a)(2), in that they manufactured, sold, delivered, held or offered for sale compounded drugs, Thymol 4% in alcohol and Progesterone 25 mg/gm cream that were adulterated within the meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 38 through 85, which are incorporated herein by reference.

TENTH CAUSE FOR DISCIPLINE

(Compounded Adulterated Drugs)

95. Respondents are subject to disciplinary action under Code sections 4301(j) and 4301(o), for violating Health and Safety Code section 111300, in that they compounded adulterated drugs, Thymol 4% in alcohol and Progesterone 25 mg/gm cream, within the meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 38 through 85, which are incorporated herein by reference.

///
///
///
///
///

1 **ELEVENTH CAUSE FOR DISCIPLINE**

2 **(Failure to Maintain Complete Records of Compounded Drug Products)**

3 96. Respondents are subject to disciplinary action under Code section 4301(o), for
4 violating title 16, California Code of Regulations, section 1735.3(a)(2)(F), in that they did not list
5 the correct expiration date for active pharmaceutical ingredients or the excipients used to prepare
6 compounded drug preparations and for violating section 1735.3(a)(2)(D), in that they did not list
7 the identity of the pharmacist reviewing the final drug preparations, as set forth in paragraphs 38
8 through 85, which are incorporated herein by reference.

9 **TWELFTH CAUSE FOR DISCIPLINE**

10 **(Failure to Train Compounding Drug Staff)**

11 97. Respondents are subject to disciplinary action under Code section 4301(o), for
12 violating title 16, California Code of Regulations, sections 1735.7(a) and (c), in that they did not
13 possess any documentation or make any showing which indicated that the pharmacy technician
14 assigned to compound drug preparations had: (a) the skills and training required to properly and
15 accurately perform his assigned responsibilities, (b) the training in all aspects of policies and
16 procedures, and (c) the knowledge about processes and procedures used in compounding prior to
17 compounding any drug preparation, as set forth in paragraphs 38 through 85, which are
18 incorporated herein by reference.

19 **THIRTEENTH CAUSE FOR DISCIPLINE**

20 **(Compounding Commercially Available Drug Products)**

21 98. Respondents are subject to disciplinary action under Code section 4301(o), for
22 violating title 16, California Code of Regulations, sections 1735(c) and 1735.2(d)(3), in that they
23 compounded a commercially available drug product, as set forth in paragraphs 38 through 85,
24 which are incorporated herein by reference.

25 ///

26 ///

27 ///

28 ///

1 **FOURTEENTH CAUSE FOR DISCIPLINE**

2 **(Unprofessional Conduct)**

3 99. Respondents are subject to disciplinary action under Code section 4301 for
4 unprofessional conduct in that they engaged in the activities described in paragraphs 38 through
5 85 above, which are incorporated herein by reference.

6 **OTHER MATTERS**

7 100. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY
8 46937 issued to Shelat Enterprises, Inc., doing business as Procure Pharmacy shall be prohibited
9 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
10 of a licensee for five years if Pharmacy Permit Number PHY 46937 is placed on probation or
11 until Pharmacy Permit Number PHY 46937 is reinstated if it is revoked.

12 101. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY
13 46937 issued to Shelat Enterprises, Inc., doing business as Procure Pharmacy while Vijay V.
14 Shelat has been an officer and owner and had knowledge of or knowingly participated in any
15 conduct for which the licensee was disciplined, Vijay V. Shelat shall be prohibited from serving
16 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
17 for five years if Pharmacy Permit Number PHY 46937 is placed on probation or until Pharmacy
18 Permit Number PHY 46937 is reinstated if it is revoked.

19 102. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No.
20 RPH 45111 issued to Vijay V. Shelat, Vijay V. Shelat shall be prohibited from serving as a
21 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
22 five years if Pharmacist License Number RPH 45111 is placed on probation or until Pharmacist
23 License Number RPH 45111 is reinstated if it is revoked.

24 ///

25 ///

26 ///

27 ///

28 ///

1 **DISCIPLINARY CONSIDERATIONS**

2 103. To determine the degree of discipline, if any, to be imposed on Respondents,
3 Complainant alleges that on May 31, 2016, the Board issued Citation number CI 2014 65926
4 against Procare Pharmacy and Citation number CI 2015 70554 against Vijay Shelat for violating
5 California Code of Regulations, sections 1735.4(c), 1735.7 (a), (b) and (c), 1735.5(a),
6 1735.3(a)(4), (6) and (8) for various drug compounding violations. The Board issued fines which
7 Respondents paid.

8 **PRAYER**

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

- 11 1. Revoking or suspending Pharmacy Permit Number PHY 46937, issued to Shelat
12 Enterprises, Inc., doing business as Procare Pharmacy;
- 13 2. Revoking or suspending Pharmacist License Number RPH 45111, issued to Vijay V.
14 Shelat;
- 15 3. Prohibiting Shelat Enterprises, Inc., doing business as Procare Pharmacy from serving
16 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
17 for five years if Pharmacy Permit Number PHY 46937 is placed on probation or until Pharmacy
18 Permit Number PHY 46937 is reinstated if Pharmacy Permit Number PHY 46937 issued to
19 Shelat Enterprises, Inc., doing business as Procare Pharmacy is revoked;
- 20 4. Prohibiting Vijay V. Shelat from serving as a manager, administrator, owner,
21 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
22 Number PHY 46937 is placed on probation or until Pharmacy Permit Number PHY 46937 is
23 reinstated if Pharmacy Permit Number PHY 46937 issued to Shelat Enterprises, Inc., doing
24 business as Procare Pharmacy is revoked;
- 25 5. Prohibiting Vijay V. Shelat from serving as a manager, administrator, owner,
26 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License
27 Number RPH 45111 is placed on probation or until Pharmacist License Number RPH 45111 is
28 reinstated if Pharmacist License Number RPH 45111 issued to Vijay V. Shelat is revoked;

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

6. Ordering Shelat Enterprises, Inc., doing business as Procare Pharmacy and Vijay V. Shelat to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: July 23, 2019



ANNE SODERGREN
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SD2017802002
82184325.docx

1 XAVIER BECERRA
Attorney General of California
2 HARINDER K. KAPUR
Supervising Deputy Attorney General
3 DESIREE I. KELLOGG
Deputy Attorney General
4 State Bar No. 126461
600 West Broadway, Suite 1800
5 San Diego, CA 92101
P.O. Box 85266
6 San Diego, CA 92186-5266
Telephone: (619) 738-9429
7 Facsimile: (619) 645-2061
Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 6251

12 **SHELAT ENTERPRISES INC.,**
13 **DBA PROCARE PHARMACY**
25405 Hancock Ave. #100
14 Murrieta, CA 92562

ACCUSATION

15 **Pharmacy Permit No. PHY 46937**

16 **VIJAY V. SHELAT**
25405 Hancock Ave. #100
17 Murrieta, CA 92562

18 **Pharmacist License No. RPH 45111**

19 Respondents.

20
21 Complainant alleges:

22 **PARTIES**

- 23 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
24 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 25 2. On or about January 3, 2005, the Board of Pharmacy issued Pharmacy Permit Number
26 PHY 46937 to Shelat Enterprises, Inc., doing business as Procare Pharmacy (Procare Pharmacy).
27 The Pharmacy Permit was in full force and effect at all times relevant to the charges and
28 allegations brought herein and will expire on January 1, 2019, unless renewed.

1 (b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary
2 food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge
3 or representative-in-charge, for maintaining the records and inventory described in
4 this section.

5 9. Section 4115(f)(1) of the Code states:

6 A pharmacy with only one pharmacist shall have no more than one pharmacy
7 technician performing the tasks specified in subdivision (a) the ratio of pharmacy
8 technicians performing the tasks specified in subdivision (a) to any additional
9 pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel
10 performing clerical functions pursuant to Section 4116 or 4117. This ratio is
11 applicable to all practice settings, except for an inpatient of a licensed health facility,
12 a patient of a licensed home health agency, as specified in paragraph (2), an inmate of
13 a correctional facility of the Department of Corrections and Rehabilitation, and for a
14 person receiving treatment in a facility operated by the State Department of State
15 Hospitals, the State Department of Developmental Services, or the Department of
16 Veterans Affairs.

17 10. Section 4169(a)(4) of the Code states:

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

19 ...

20 (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after
21 the beyond use date on the label.

22 11. Section 4301 of the Code states in pertinent part:

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

26 ...

27 (d) The clearly excessive furnishing of controlled substances in violation of
28 subdivision (a) of Section 11153 of the Health and Safety Code.

...

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

...

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

///

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

2 The pharmacist-in-charge shall be responsible for a pharmacy's compliance
3 with all state and federal laws and regulations pertaining to the practice of pharmacy.

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

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

6 Acts or omissions that involve, in whole or in part, the inappropriate exercise of
7 his or her education, training, or experience as a pharmacist, whether or not the act or
8 omission arises in the course of the practice of pharmacy or the ownership,
9 management, administration, or operation of a pharmacy or other entity licensed by
10 the board.

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

14 ...

15 14. Section 4307(a) of the Code states that:

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

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

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

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

30 A prescription for a controlled substance shall only be issued for a legitimate
31 medical purpose by an individual practitioner acting in the usual course of his or her
32 professional practice. The responsibility for the proper prescribing and dispensing of
33 controlled substances is upon the prescribing practitioner, but a corresponding
34 responsibility rests with the pharmacist who fills the prescription. Except as
35 authorized by this division, the following are not legal prescriptions: (1) an order
36 purporting to be a prescription which is issued not in the usual course of professional
37 treatment or in legitimate and authorized research; or (2) an order for an addict or
38 habitual user of controlled substances, which is issued not in the course of
professional treatment or as part of an authorized narcotic treatment program, for the
purpose of providing the user with controlled substances, sufficient to keep him or her

comfortable by maintaining customary use.

...

16. Health and Safety Code section 11162.1(a) states:

(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive 'void' pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1-24

25-49

50-74

75-100

101-150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

1 (11) The date of origin of the prescription.

2 (12) A check box indicating the prescriber's order not to substitute.

3 (13) An identifying number assigned to the approved security printer by the
4 Department of Justice.

5 (14) (A) A check box by the name of each prescriber when a prescription form
6 lists multiple prescribers.

7 (B) Each prescriber who signs the prescription form shall identify himself or
8 herself as the prescriber by checking the box by his or her name.

9 17. Health and Safety Code section 11164(a) states in pertinent part:

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

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

16 18. Health and Safety Code section 111250 states:

17 Any drug or device is adulterated if it consists, in whole or in part, of any filthy,
18 putrid, or decomposed substance.

19 19. Health and Safety Code section 111255 states:

20 Any drug or device is adulterated if it has been produced, prepared, packed, or
21 held under conditions whereby it may have been contaminated with filth, or whereby
22 it may have been rendered injurious to health.

23 20. Health and Safety Code section 111295 states:

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

26 21. Health and Safety Code section 111300 states:

27 It is unlawful for any person to adulterate any drug or device.

28 22. Section 1714(b) of title 16, California Code of Regulations states:

Each pharmacy licensed by the board shall maintain its facilities, space,
fixtures, and equipment so that drugs are safely and properly prepared, maintained,
secured and distributed. The pharmacy shall be of sufficient size and unobstructed
area to accommodate the safe practice of pharmacy.

///

///

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

23. Section 1718 of title 16, California Code of Regulations states:

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

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least three years.

24. Section 1735(c) of title 16, California Code of Regulations states:

The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).

25. Section 1735.2(d)(3) of title 16, California Code of Regulations states:

No pharmacy or pharmacist shall compound a drug preparation that:

...

Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

26. Sections 1735.3(a)(2)(D) and (F) of title 16, California Code of Regulations states:

(a) For each compounded drug preparation, pharmacy records shall include:

...

(2) A compounding log consisting of a single document containing all of the following:

...

(D) The identity of the pharmacist reviewing the final drug preparation.

...

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (1) shall apply.

///

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

27. Sections 1735.7(a) and (c) of title 16, California Code of Regulations state:

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding practice.

...

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

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

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

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

COST RECOVERY

29. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUGS

30. Dilaudid is the brand name for hydromorphone, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(J) and a dangerous drug pursuant to Business and Professions Code section 4022.

31. Norco is the brand name for hydrocodone/acetaminophen, a Schedule II controlled substance pursuant to Code of Federal Regulations, title 21, section 1308.12, subdivision (b)(1)(vi) and a dangerous drug pursuant to Business and Professions Code section 4022.

1 **Dispensing of Dr. V. S. Prescriptions:**

2 41. From July 2, 2013 through January 19, 2015, Respondents filled prescriptions for
3 controlled substances which were written by Dr. V.S. whose address was listed on the
4 prescriptions as being 65 miles away from Procure Pharmacy. Patients travelled as far as 65 miles
5 to receive medical treatment from Dr. V.S. and traveled up to 39 miles to have their prescriptions
6 dispensed at Procure Pharmacy. Dr. V.S. was an internist who primarily prescribed controlled
7 substances. Patients paid for the controlled substance prescriptions primarily in cash (sometimes
8 hundreds of dollars) and did not seek reimbursement from an insurance company or government
9 agency.

10 42. Respondents dispensed similar or identical prescriptions written by Dr. V.S. to
11 multiple patients. Dr. V.S. primarily wrote these prescriptions for controlled substances of high
12 abuse and diversion potential to multiple patients as follows: (1) alprazolam 2mg; (2) oxycodone
13 30mg; and (3) hydrocodone/APAP 10/325. There was no adjustment in the prescribing pattern
14 for sex, age, weight, renal or hepatic function, race, diagnosis, past medications used or any other
15 patient related factor.

16 43. None of the "patients" being treated by Dr. V.S. were receiving a long acting pain
17 medication to control their baseline pain. Dr. V.S. was not a pain specialist but he wrote
18 prescriptions primarily for pain medications. Dr. V.S. prescribed only the highest dosage of
19 oxycodone and alprazolam without prescribing a lower strength and increasing the strength as
20 needed. Many patients were prescribed both oxycodone and alprazolam which was
21 contraindicated. The majority of patients received the same diagnosis from Dr. V.S.

22 **Dispensing of Dr. K.T. Prescriptions:**

23 44. From July 5, 2013 through December 16, 2013, Respondents filled prescriptions for
24 controlled substances which were written by Dr. K.T. whose addresses were listed on the
25 prescriptions as being 99 and 53 miles away from Procure Pharmacy. Patients traveled as far as
26 104 miles to receive medical treatment from Dr. K.T. and up to 106 miles to fill prescriptions at
27 Procure Pharmacy. Patients paid for the controlled substance prescriptions in cash (sometimes
28

1 hundreds of dollars) at Procure Pharmacy and did not seek reimbursement from an insurance
2 company or government agency.

3 45. Respondents dispensed similar or identical prescriptions written by Dr. K.T. to
4 multiple patients on the same day, including groups of patients within minutes of each other.
5 Some of these patients had identical diagnoses from Dr. K.T. Prescriptions were written on the
6 same date, had identical batch numbers and were either sequential or close in script number. On
7 multiple occasions, Respondents dispensed drugs pursuant to prescriptions which had been
8 written days earlier.

9 46. Dr. K.T. wrote these prescriptions for controlled substances of high abuse and
10 diversion potential to multiple patients as follows: (1) promethazine with codeine in a quantity of
11 480ml (full pint size); and (2) oxycodone 30mg. There was no adjustment in the prescribing
12 pattern for sex, age, weight, renal or hepatic function, race, diagnosis, past medications used or
13 any other patient related factor.

14 47. None of the "patients" being treated by Dr. K.T. were receiving a long acting pain
15 medication to control their baseline pain. Dr. K.T. prescribed only the highest dosage of
16 oxycodone without prescribing a lower strength and increasing the strength as needed. Most
17 patients were only prescribed promethazine with codeine without an antibiotic. The majority of
18 the patients were given the same diagnosis by Dr. K.T.

19 **Dispensing of PA S.D. Prescriptions:**

20 48. From November 15, 2013 through February 29, 2016, Respondents filled
21 prescriptions for controlled substances which were written by a physician assistant, S.D., for an
22 internist whose addresses were listed on the prescriptions as being 96, 39, 93 and 55 miles away
23 from Procure Pharmacy. Patients' residences were as far away as 114 miles from Procure
24 Pharmacy and they travelled as far as 115 miles to have their prescriptions filled at Procure
25 Pharmacy. Patients paid for the controlled substance prescriptions in cash (sometimes hundreds
26 of dollars) and did not seek reimbursement from an insurance company or government agency.

27 49. Respondents dispensed similar or identical prescriptions written by PA S.D. to
28 multiple patients on the same day, including groups of patients, within minutes of each other. The

1 patients were assigned consecutive or nearly consecutive prescription numbers and identical batch
2 numbers and either sequential or close script numbers were on prescriptions. On multiple
3 occasions, Respondents dispensed drugs pursuant to prescriptions which had been written days
4 earlier.

5 50. PA S.D. wrote these prescriptions primarily for controlled substances of high abuse
6 and diversion potential for multiple patients including: (1) promethazine with codeine (full pint
7 size 473 ml); (2) oxycodone 30mg; and (3) alprazolam 2mg. Many patients received both
8 alprazolam 2mg with an opioid. PA S.D. prescribed both an opioid and alprazolam which is
9 contraindicated. There was no adjustment in the prescribing pattern for sex, age, weight, renal or
10 hepatic function, race, diagnosis, past medications used or any other patient related factor.
11 Physician assistants who are supervised by internists also typically do not prescribe primarily
12 controlled substances. In addition, PA S.D. prescribed only opioids, mainly oxycodone 30mg for
13 the treatment of pain, rather than other pain medications.

14 51. None of the "patients" being treated by PA S.D. were receiving a long acting pain
15 medication to control their baseline pain. PA S.D. prescribed only the highest dosage of
16 oxycodone and alprazolam without prescribing a lower strength and increasing the strength as
17 needed. Promethazine with codeine was prescribed without an antibiotic.

18 52. "Adult Progress Notes" and "Justification for Prescribed Medication (Controlled
19 Substanced [sic])" stapled to PA S.D.'s prescriptions. These documents contained misspellings
20 of common medical terms and drugs while drugs withdrawn from the market and only the highest
21 strengths of oxycodone and alprazolam were listed on the drug lists.

22 **Dispensing of Dr. S.K. Prescriptions:**

23 53. From January 4, 2014 through November 2, 2015, Respondents filled prescriptions
24 for controlled substances which were written by Dr. S.K. whose office addresses were listed on
25 the prescriptions as being 103, 93, 97 and 57 miles away from Procure Pharmacy. Patients
26 travelled as far as 148 miles to receive medical treatment from Dr. S.K. and as far as 86 miles to
27 fill their prescriptions at Procure Pharmacy. Dr. S.K.'s areas of practice were internal medicine,
28 family medicine and complementary and alternative medicine; yet he primarily dispensed

1 controlled substances. Patients paid for the controlled substance prescriptions in cash (sometimes
2 hundreds of dollars) and did not seek reimbursement from an insurance company or government
3 agency.

4 54. Respondents dispensed similar or identical prescriptions written by S.K. to multiple
5 patients on the same day, including groups of patients, within minutes of each other. Although
6 some of the prescriptions were not written on the same date, they had identical batch numbers and
7 consecutive script numbers. Prescriptions had identical batch numbers and were either sequential
8 or close in script number. On multiple occasions, Respondents dispensed drugs pursuant to
9 prescriptions which had been written days earlier.

10 55. Dr. S.K. wrote these prescriptions for controlled substances of high abuse and
11 diversion potential to multiple patients as follows: (1) promethazine with codeine in a quantity of
12 480ml (pint size); (2) oxycodone 30mg; and (3) hydrocodone/APAP 10/325. There was no
13 adjustment in the prescribing pattern for sex, age, weight, renal or hepatic function, race,
14 diagnosis, past medications used or any other patient related factor. The majority of prescriptions
15 written were for controlled substances even though Dr. S.K. was an internist.

16 56. None of the "patients" being treated by Dr. S.K. were receiving a long acting pain
17 medication to control their baseline pain. Dr. S.K. prescribed only the highest dosage of
18 oxycodone without prescribing a lower strength and increasing the strength as needed. No
19 antibiotics were prescribed with promethazine with codeine. Some patients were prescribed both
20 oxycodone and alprazolam which was contraindicated.

21 **Dispensing of Dr. R.G. Prescriptions:**

22 57. From December 10, 2014 through November 18, 2015, Respondents filled
23 prescriptions for controlled substances which were written by Dr. R.G. whose address was listed
24 on the prescriptions as being 55 miles away from Procure Pharmacy. Dr. R.G. was a family
25 medicine practitioner but dispensed primarily controlled substances. Patients travelled between
26 25 and 75 miles to receive medical treatment from Dr. R.G. and traveled up to 100 miles to have
27 their prescriptions dispensed at Procure Pharmacy. Patients paid for the controlled substance
28

1 prescriptions primarily in cash (sometimes for hundreds of dollars) and did not seek
2 reimbursement from an insurance company or government agency.

3 58. Respondents dispensed similar or identical prescriptions written by Dr. R.G. to
4 multiple patients on the same day, including groups of patients, within minutes of each other. On
5 multiple occasions, Respondents dispensed drugs pursuant to prescriptions which had been
6 written days earlier.

7 59. Dr. R.G. primarily wrote these prescriptions for controlled substances of high abuse
8 and diversion potential to multiple patients as follows: (1) promethazine with codeine in a
9 quantity of 473ml (full pint size); (2) hydrocodone/APAP 10/325; and (3) oxycodone 30mg.
10 There was no adjustment in the prescribing pattern for sex, age, weight, renal or hepatic function,
11 race, diagnosis, past medications used or any other patient related factor. Phenergan with codeine
12 was misspelled on the prescriptions.

13 60. None of the "patients" being treated by Dr. R.G. were receiving a long acting pain
14 medication to control their baseline pain. Dr. R.G. was not a pain specialist but he almost always
15 prescribed pain medication. Dr. R.G. prescribed only the strongest dosage of oxycodone without
16 prescribing a lower strength and increasing the strength as needed. No antibiotics were prescribed
17 with promethazine with codeine.

18 61. Documents providing "justification" for the prescribing of the controlled substances
19 were stapled to the prescriptions but these contained misspellings of drugs and medical terms.

20 **Dispensing of Dr. R.I.'s Prescriptions:**

21 62. From August 18, 2014 through September 21, 2016, Respondents filled prescriptions
22 for controlled substances which were written by Dr. R.I. Dr. R.I. was not a pain management
23 specialist but instead held board certifications in allergies and pediatrics. Nonetheless, he wrote
24 the majority of prescriptions for controlled substances used to treat pain. Patients paid for the
25 controlled substance prescriptions primarily in cash (sometimes hundreds of dollars) and did not
26 seek reimbursement from an insurance company or government agency.

27 63. Respondents dispensed similar or identical prescriptions written by Dr. R.I. to
28 multiple patients. Dr. R.I. primarily wrote these prescriptions for controlled substances of high

1 abuse and diversion potential to multiple patients as follows: (1) oxycodone 30mg; (2)
2 promethazine with codeine in a quantity of 473ml (full pint size); and (3) alprazolam 2mg. There
3 was no adjustment in the prescribing pattern for sex, age, weight, renal or hepatic function, race,
4 diagnosis, past medications used or any other patient related factor.

5 64. None of the "patients" being treated by Dr. R.I. were receiving a long acting pain
6 medication to control their baseline pain. Dr. R.I. prescribed only the highest dosage of
7 oxycodone and alprazolam without prescribing a lower dosage and increasing the strength as
8 needed. Only one patient was prescribed both an antibiotic and promethazine with codeine. Dr.
9 R.I. prescribed both oxycodone and alprazolam which is contraindicated.

10 **Dispensing of Dr. E.S.' Prescriptions:**

11 65. From April 18 through 26, 2016, Respondents filled prescriptions for controlled
12 substances which were written by Dr. E.S. whose address was listed on the prescriptions as being
13 104 miles away from Procure Pharmacy. Patients travelled as far as 109 miles to receive medical
14 treatment from Dr. E.S. and traveled up to 85 miles to have their prescriptions dispensed at
15 Procure Pharmacy. Patients paid for the controlled substance prescriptions primarily in cash
16 (sometimes hundreds of dollars) and did not seek reimbursement from an insurance company or
17 government agency.

18 66. Respondents dispensed similar or identical prescriptions written by Dr. E.S. to
19 multiple patients on the same day. Dr. E.S. wrote prescriptions for Viagra, along with controlled
20 substances to two females which were dispensed by Respondents. All of the prescriptions were
21 written on April 4, 2016 but dispensed weeks later. The patients received identical diagnoses
22 from Dr. E.S. A justification for dispensing one of the controlled substances indicated that the
23 patient had failed in his use of Percocet but then was prescribed oxycodone by Dr. E.S. However,
24 oxycodone is contained in Percocet.

25 **Dispensing from Non-Compliant Security Forms:**

26 67. In 2015, Respondents dispensed controlled substances pursuant to prescriptions which
27 were written by Dr. R.G., PA S.D. and Dr. E.S. on non-compliant prescription forms missing such
28

1 required security elements as a watermark printed on the backside of the prescription blank
2 entitled "California Security Prescription," an identifying number assigned to an approved
3 security printer by the Department of Justice, a lot number printed on the forms and proper check
4 off boxes.

5 68. Respondents dispensed controlled substances to individuals who obtained
6 prescriptions for controlled substances from more than one of the same prescribers (in some
7 cases, five prescribers) identified in the preceding paragraphs.

8 69. Respondents did not follow proper procedures for verifying if controlled substance
9 prescriptions were written for a legitimate medical purpose.

10 **Non-Sterile Compounding Drug Operations:**

11 70. Respondents stored expired active pharmaceutical ingredients or excipients along
12 with other active pharmaceutical ingredients or excipients used to prepare compounded drug
13 preparations.

14 71. On July 26, 2016, Respondents compounded Thymol 4% in alcohol 30 ml lot number
15 07262016G using a pharmaceutical excipient, Thymol crystals which had expired on June 30,
16 2016. Respondents dispensed that compounded drug to a patient (Prescription Number 657815).

17 72. On January 17, 2017, Respondents compounded Progesterone 25 mg/gm cream lot
18 number 01172017M3 using an excipient, hormonal replacement therapy (HRT) cream base which
19 had expired on July 31, 2016. Respondents dispensed that compounded drug to a patient
20 (Prescription Number 670799).

21 73. The compounding log used to document the compounding of Thymol 4% in alcohol
22 30 ml lot number 07262016G did not contain the correct expiration date for the Thymol crystals
23 used in that preparation. Similarly, the compounding log used to document the compounding of
24 progesterone 25 mg/gm cream lot number 01172017M3 did not contain the correct expiration
25 date for the HRT cream base used in that preparation. The identity of the pharmacists reviewing
26 those final drug preparations was also not listed on the compounding logs, as well as in the logs
27 used to document the compounding of Tretinoin 0.1% cream from July 2016 through November
28 2016.

1 74. Respondents did not possess any records showing that a pharmacy technician who
2 compounded drug preparations was trained and possessed the skills necessary to properly and
3 accurately perform his assigned compounding tasks and the knowledge about processes and
4 procedures used in compounding drug preparations.

5 75. From January 1, 2016 through February 2, 2017, Respondents compounded Tretinoin
6 0.1% cream which they used to fill 273 prescriptions, although there was a commercially
7 available product to dispense. Respondents had no documentation to show that their compounded
8 Tretinoin 0.1% cream qualified for exemptions to the prohibition against the compounding of
9 commercially available drug products.

10 **FIRST CAUSE FOR DISCIPLINE**

11 **(Failing to Comply with Corresponding Responsibility**

12 **for Legitimate Controlled Substance Prescriptions against Respondents)**

13 76. Respondents are subject to disciplinary action under Code section 4301(j), for
14 violating Health and Safety Code section 11153(a), in that they failed to comply with their
15 corresponding responsibility to ensure that controlled substances were dispensed for a legitimate
16 medical purpose when they furnished prescriptions for controlled substances even though “red
17 flags” were present, indicating those prescriptions were not issued for a legitimate medical
18 purpose, as set forth in paragraphs 38 through 75 above, which are incorporated herein by
19 reference.

20 **SECOND CAUSE FOR DISCIPLINE**

21 **(Clearly Excessive Furnishing of Controlled Substances against Respondents)**

22 77. Respondents are subject to disciplinary action under Code section 4301(d), for the
23 clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section
24 11153 of the Health and Safety Code, as set forth in paragraphs 38 through 75 above, which are
25 incorporated herein by reference.

26 //

27 ///

28 ///

1 **SEVENTH CAUSE FOR DISCIPLINE**

2 **(Failure to Exercise or Implement Best Professional Judgment or Corresponding**
3 **Responsibility when Dispensing Controlled Substances against Vijay Shelat)**

4 82. Respondent Vijay Shelat is subject to disciplinary action under Code section 4301(o),
5 for violating Business and Professions Code section 4306.5(a) and (b), in that he failed to exercise
6 or implement his best professional judgment or corresponding responsibility when dispensing
7 controlled substances, as set forth in paragraphs 38 through 75 above, which are incorporated
8 herein by reference.

9 **EIGHTH CAUSE FOR DISCIPLINE**

10 **(Exceeding Lawful Pharmacy and Pharmacy Technician Ratio)**

11 83. Respondents are subject to disciplinary action under Code section 4301(o), for
12 violating Business and Professions Code section 4115(f)(1), in that on February 2, 2017, they had
13 one pharmacist, Vijay Shelat, on duty when two pharmacy technicians were simultaneously filling
14 prescriptions, removing medications from shelves, counting medications, placing medications
15 into containers and affixing the prescription labels on containers, as set forth in paragraphs 38
16 through 75, which are incorporated herein by reference.

17 **NINTH CAUSE FOR DISCIPLINE**

18 **(Manufactured, Sold, Delivered, Held or Offered for Sale Adulterated Drugs)**

19 84. Respondents are subject to disciplinary action under Code sections 4301(j) and
20 4301(o), for violating Health and Safety Code section 111295 and Business and Professions Code
21 section 4169(a)(2), in that they manufactured, sold, delivered, held or offered for sale
22 compounded drugs, Thymol 4% in alcohol and Progesterone 25 mg/gm cream that were
23 adulterated within the meaning of Health and Safety Code sections 111250 and 111255, as set
24 forth in paragraphs 38 through 75, which are incorporated herein by reference.

25 **TENTH CAUSE FOR DISCIPLINE**

26 **(Compounded Adulterated Drugs)**

27 85. Respondents are subject to disciplinary action under Code sections 4301(j) and
28 4301(o), for violating Health and Safety Code section 111300, in that they compounded

1 adulterated drugs, Thymol 4% in alcohol and Progesterone 25 mg/gm cream, within the meaning
2 of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 38 through 75,
3 which are incorporated herein by reference.

4 **ELEVENTH CAUSE FOR DISCIPLINE**

5 **(Failure to Maintain Complete Records of Compounded Drug Products)**

6 86. Respondents are subject to disciplinary action under Code section 4301(o), for
7 violating title 16, California Code of Regulations, section 1735.3(a)(2)(F), in that they did not list
8 the correct expiration date for active pharmaceutical ingredients or the excipients used to prepare
9 compounded drug preparations and for violating section 1735.3(a)(2)(D), in that they did not list
10 the identity of the pharmacist reviewing the final drug preparations, as set forth in paragraphs 38
11 through 75, which are incorporated herein by reference.

12 **TWELFTH CAUSE FOR DISCIPLINE**

13 **(Failure to Train Compounding Drug Staff)**

14 87. Respondents are subject to disciplinary action under Code section 4301(o), for
15 violating title 16, California Code of Regulations, sections 1735.7(a) and (c), in that they did not
16 possess any documentation or make any showing which indicated that the pharmacy technician
17 assigned to compound drug preparations had: (a) the skills and training required to properly and
18 accurately perform his assigned responsibilities, (b) the training in all aspects of policies and
19 procedures, and (c) the knowledge about processes and procedures used in compounding prior to
20 compounding any drug preparation, as set forth in paragraphs 38 through 75, which are
21 incorporated herein by reference.

22 **THIRTEENTH CAUSE FOR DISCIPLINE**

23 **(Compounding Commercially Available Drug Products)**

24 88. Respondents are subject to disciplinary action under Code section 4301(o), for
25 violating title 16, California Code of Regulations, sections 1735(c) and 1735.2(d)(3), in that they
26 compounded a commercially available drug product, as set forth in paragraphs 38 through 75,
27 which are incorporated herein by reference.

28 ///

1 **FOURTEENTH CAUSE FOR DISCIPLINE**

2 **(Unprofessional Conduct)**

3 89. Respondents are subject to disciplinary action under Code section 4301 for
4 unprofessional conduct in that they engaged in the activities described in paragraphs 38 through
5 75 above, which are incorporated herein by reference.

6 **OTHER MATTERS**

7 90. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY
8 46937 issued to Shelat Enterprises, Inc., doing business as Procure Pharmacy shall be prohibited
9 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
10 of a licensee for five years if Pharmacy Permit Number PHY 46937 is placed on probation or until
11 Pharmacy Permit Number PHY 46937 is reinstated if it is revoked.

12 91. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY
13 46937 issued to Shelat Enterprises, Inc., doing business as Procure Pharmacy while Vijay V.
14 Shelat has been an officer and owner and had knowledge of or knowingly participated in any
15 conduct for which the licensee was disciplined, Vijay V. Shelat shall be prohibited from serving
16 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
17 for five years if Pharmacy Permit Number PHY 46937 is placed on probation or until Pharmacy
18 Permit Number PHY 46937 is reinstated if it is revoked.

19 92. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No.
20 RPH 45111 issued to Vijay V. Shelat, Vijay V. Shelat shall be prohibited from serving as a
21 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
22 five years if Pharmacist License Number RPH 45111 is placed on probation or until Pharmacist
23 License Number RPH 45111 is reinstated if it is revoked.

24 **DISCIPLINARY CONSIDERATIONS**

25 93. To determine the degree of discipline, if any, to be imposed on Respondents,
26 Complainant alleges that on May 31, 2016, the Board issued Citation number CI 2014 65926
27 against Procure Pharmacy and Citation number CI 2015 70554 against Vijay Shelat for violating
28 California Code of Regulations, sections 1735.4(c), 1735.7 (a), (b) and (c), 1735.5(a),

1 1735.3(a)(4), (6) and (8) for various drug compounding violations. The Board issued fines which
2 Respondents paid.

3 **PRAYER**

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

6 1. Revoking or suspending Pharmacy Permit Number PHY 46937, issued to Shelat
7 Enterprises, Inc., doing business as Procure Pharmacy;

8 2. Revoking or suspending Pharmacist License Number RPH 45111, issued to Vijay V.
9 Shelat;

10 3. Prohibiting Shelat Enterprises, Inc., doing business as Procure Pharmacy from serving
11 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
12 for five years if Pharmacy Permit Number PHY 46937 is placed on probation or until Pharmacy
13 Permit Number PHY 46937 is reinstated if Pharmacy Permit Number PHY 46937 issued to Shelat
14 Enterprises, Inc., doing business as Procure Pharmacy is revoked;

15 4. Prohibiting Vijay V. Shelat from serving as a manager, administrator, owner,
16 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
17 Number PHY 46937 is placed on probation or until Pharmacy Permit Number PHY 46937 is
18 reinstated if Pharmacy Permit Number PHY 46937 issued to Shelat Enterprises, Inc., doing
19 business as Procure Pharmacy is revoked;

20 5. Prohibiting Vijay V. Shelat from serving as a manager, administrator, owner,
21 member, officer, director, associate, or partner of a licensee for five years if Pharmacist License
22 Number RPH 45111 is placed on probation or until Pharmacist License Number RPH 45111 is
23 reinstated if Pharmacist License Number RPH 45111 issued to Vijay V. Shelat is revoked;

24 6. Ordering Shelat Enterprises, Inc., doing business as Procure Pharmacy and Vijay V.
25 Shelat to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of
26 this case, pursuant to Business and Professions Code section 125.3; and,

27 //

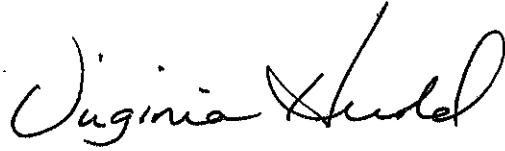
28 ///

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

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

DATED: _____

5/9/18



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

SD2017802002
81883205.doc