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

In the Matter of the Accusation Against: **SUTTER PHARMACY, INC., dba SUTTER PHARMACY;** **BIJU G. GEORGE, OWNER, CHIEF EXECUTIVE OFFICER, SECRETARY, AND TREASURER/CHIEF FINANCIAL OFFICER;** **RANJIT SINGH, FORMER CHIEF EXECUTIVE OFFICER;** **ANU GOYAL, FORMER CHIEF EXECUTIVE OFFICER;** **ANSU GEORGE, FORMER SECRETARY;** **470 Plumas Blvd., Ste. 103** **Yuba City, CA 95991** **Retail Pharmacy Permit No. PHY 47489;** **And** **BIJU G. GEORGE** **470 Plumas Blvd., Ste. 103** **Yuba City, CA 95991** **Pharmacist License No. RPH 49255** Respondents.	Case No. 6177 **SECOND AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity

as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.

2. On or about March 30, 2006, the Board issued Retail Pharmacy License Number PHY 47489 to Sutter Pharmacy Inc. dba Sutter Pharmacy ("Respondent Sutter"). At all times relevant to the charges brought herein, Respondent Sutter's corporate officers were Biju G. George, Chief Executive Officer and Secretary (from September 7, 2017, to present), and Treasurer/Chief Financial Officer (from March 30, 2006, to present); Ranjit Singh, Chief Executive Officer (from March 30, 2006, to December 1, 2016); Anu Goyal, Chief Executive Officer (from December 1, 2016, to September 7, 2017); and Ansu George, Secretary (from March 30, 2006, to September 7, 2017). On or about March 30, 2016, Biju G. George ("Respondent George") became the pharmacist-in-charge. The Retail Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2019, unless renewed.

3. On or about March 18, 1997, the Board issued Registered Pharmacist License Number RPH 49255 to Respondent George. The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2020, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Code section 4300 states, in pertinent part:

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

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

(1) Suspending judgment.
(2) Placing him or her upon probation.
(3) Suspending his or her right to practice for a period not exceeding one year.
(4) Revoking his or her license.
(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

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6. Code section 4300.1 states:

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

7. Code section 4307 states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of 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 manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

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

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

STATUTORY AND REGULATORY PROVISIONS

A. Business & Professions Code

8. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of

unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(d) The clearly excessive furnishing of controlled substances in violation of 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 by any other state or federal regulatory agency . . . .

9. Code section 4306.5 states, in pertinent part:

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

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

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

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

10. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

11. Section 4105 of the Code states:

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e)

(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

12. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

B. Health & Safety Code

13. Health and Safety Code section 11153, subdivision (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.

14. Health and Safety Code section 11159.2, states, in pertinent part:

(a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

. . .

15. Health and Safety Code section 11162.1 states, in pertinent part:

(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."

. . . .

(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 . . .

. . . .

(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.

. . . .

(c)

. . . .

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

. . . .

16. Health and Safety Code section 11164 states, in pertinent part:

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

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

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

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the

address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b)

(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

C. Federal Regulation

17. Title 21, Code of Federal Regulations ("CFR"), section 1306.05, subsection (a) states, "[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner."

D. California Regulations

18. Title 16, California Code of Regulations ("CCR"), section 1707.1 states:

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following

information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

3. The date on which a drug was dispensed or refilled;

4. The prescription number for each prescription; and

5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

19. Title 16, CCR, section 1761, subdivision (a), states:

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.

COST RECOVERY

20. Code section 125.3 provides, in pertinent part, that a 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.

DRUG CLASSIFICATIONS

21. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M), and a dangerous drug pursuant to Code section 4022. Oxycodone is used to treat pain. "Roxicodone" is a brand of oxycodone.

22. Alprazolam is a Schedule IV controlled substance pursuant to Health and Safety Code

section 11057, subdivision (d)(1), and a dangerous drug pursuant to Code section 4022. Alprazolam is used to treat anxiety. "Xanax" is a brand of alprazolam.

23. Promethazine with codeine is a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c)(1), and a dangerous drug pursuant to Code section 4022. Promethazine with codeine is used to treat cough. "Phenergan with codeine" is a brand of promethazine with codeine.

24. Hydrocodone/acetaminophen is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (e), and a Schedule II controlled substance pursuant to Title 21, CFR, section 1308.12, subdivision (b)(1)(vi).[1] Hydrocodone/acetaminophen is also a dangerous drug pursuant to Code section 4022. Hydrocodone/acetaminophen is used to treat pain. "Norco" is a brand of hydrocodone/acetaminophen.

25. Carisoprodol is a Schedule IV Controlled Substance pursuant to Title 21, CFR, section 1308.14, subdivision (c)(6), and a dangerous drug pursuant to Code section 4022. Carisoprodol is used as a muscle relaxant. "Soma" is a brand of carisoprodol.

CURES PROGRAM

26. The Controlled Substance Utilization Review and Evaluation System ("CURES") program was initiated in 1998 and required mandatory monthly pharmacy reporting of dispensed Schedule II controlled substances. The program was amended in January 2005 to include mandatory weekly reporting of Schedule II to IV medications. The data is collected statewide and can be used by healthcare professionals, such as pharmacists and prescribers, to evaluate and determine whether their patients are utilizing their controlled substances safely and appropriately.

27. The component of CURES which is accessible to pharmacists and prescribers is called the Prescription Drug Monitoring Program ("PDMP"). Registration for access to the PDMP has been available since February 2009. The data may be used to aid in determining whether a patient sees multiple prescribers, frequents multiple pharmacies to fill controlled substance prescriptions, and/or obtains early refills of controlled substance prescriptions.

[1] Hydrocodone/acetaminophen was rescheduled to a Schedule II controlled substance effective October 6, 2014.

FACTUAL ALLEGATIONS

28. On or about February 7, 2017, Board Inspector P.P. analyzed CURES data for Respondent Sutter and found certain "red flags" or irregularities indicating that various doctors were potentially issuing prescriptions for controlled substances for other than a legitimate medical purpose and that Respondent Sutter was dispensing the drugs indiscriminately; i.e., without exercising its corresponding responsibility with regard to the dispensing or furnishing of the drugs. Those "red flags" included CURES data showing that Respondent Sutter dispensed larger quantities of controlled substances than other nearby pharmacies, and that Respondent Sutter's top patients (i.e. patients who received 111 or more controlled substances) received more, on average, controlled substances than other nearby pharmacies. Inspector P.P. also obtained the names of patients who appeared to receive many controlled substances, patients who lived out of state, and the top prescribers at Respondent Sutter.

29. On or about February 8, 2017, Board Inspectors P.P. and J.H. conducted an inspection at Respondent Sutter, and were assisted by Respondent George and pharmacist A.G. Inspector P.P. instructed Respondent George to conduct an on-hand count of all hydrocodone drugs in stock because the CURES report showed that Respondent Sutter had dispensed over one million doses of hydrocodone from February 1, 2014 through February 7, 2017, and Inspector P.P. planned to conduct an audit. Inspector P.P. also obtained a dispensing report from Respondent George for February 8, 2017, as well as the Biennial inventory Respondent George had conducted on October 5, 2014, and included that information in the audit. During the inspection, Inspector P.P. received and reviewed approximately forty-nine (49) patient profiles with Respondent George. During the review of those patient profiles, Respondent George told Inspector P.P. that "[t]here are no notes on the profiles but they could be on the prescription blanks." Also during the inspection, Respondent George informed Inspector P.P. that he had no recollection of ever looking up any ICD 10 codes to verify them, and that he had no recollection of calling prescribers to discuss pain management. During the inspection, Inspector P.P. also reviewed Respondent Sutter's controlled substance prescriptions for hospice patients, and found that those prescriptions were initially received by either fax transmission or verbally. Respondent

Sutter did not reduce those hospice prescriptions to writing on a form developed by the pharmacy, and did not receive the prescribers' signed orders or chart orders prior to dispensing the prescriptions.

30. At the February 8, 2017, inspection, Inspector P.P. also requested the following from Respondent George: (a) dispensing report for hydrocodone 5/325, 7.5/325, 10/325, and Zohydro ER from October 5, 2014, through February 7, 2017; (b) acquisition records for the foregoing hydrocodone products from October 5, 2014, through February 8, 2017; and (c) the outcome of Respondent George's discussion with a doctor whose prescription forms did not contain a physical address.

31. On or about February 9, 2017, Respondent George informed Inspector P.P. that "my last Controlled substance inventory date was 05/26/15 at 8:35AM (I will be glad to scan a copy and email you) if you are looking to tally the purchase vs dispensing 10/05/14 may not work." Also, on or about February 14, 2017, Respondent George informed Inspector P.P. that Respondent George's dispensing records only went back twenty-four months.

32. Over the course of approximately February 22, 2017, through approximately May 3, 2017, Respondent George provided Inspector P.P. with the following information:

a. A dispensing report for hydrocodone/apap 5/325, 7/325, 10/325 mg and Zohydro ER products from October 5, 2014 to February 7, 2017;

b. Physician dispensing reports;

c. The CURES profile for seventeen patients who received controlled substances at Respondent Sutter, and the pharmacist identification on the profiles;

d. The profile for patient B.B., because the one provided to Inspector P.P. at the time of the inspection contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016;

e. Hospice prescriptions from February 8, 2014, through February 8, 2017, and

f. Notes on patient files, which had not been on the patient files at the time of the February 8, 2017, inspection.

33. Inspector P.P. reviewed the CURES report for Respondent Sutter, the top prescribers for Respondent Sutter (none of whom were certified in pain management), and the information and patient profiles provided by Respondent George. Inspector P.P. also interviewed Respondent

George about Respondent Sutter's service area, his knowledge concerning the patient profiles, the patients who received controlled substances, and about Respondent Sutter's pharmacy practices. Following her inspection of Respondent Sutter, interview of Respondent George, review of CURES data, and review of documents provided by Respondent George, Inspector P.P. found the following:

a. Between 2014 and 2017, Respondents dispensed numerous prescriptions for oxycodone, hydrocodone/apap, alprazolam, diazepam, carisoprodol, tramadol, methadone, promethazine with codeine, and oxycontin without regard to the following irregularities or factors:

   i. Prescribers were not certified in pain management, and were family physicians;

   ii. Prescribers' medical offices were located long distances from Respondent Sutter Pharmacy;

   iii. Patients traveled long distances (including from out of state) to have controlled substance prescriptions filled at Respondent Sutter;

   iv. Patients did not provide their address to Respondent Sutter;

   v. Respondents did not have any diagnosis or treatment on file for patients who had controlled substance prescriptions filled at Respondent Sutter;

   vi. Patients had high dosages of controlled substance prescriptions;

b. That Respondent George and Respondent Sutter dispensed numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose;

c. That the pharmacist did not contact the prescribers for uncertain prescriptions, specifically regarding their quantities, directions, and purpose;

d. That Respondent George and Respondent Sutter dispensed prescriptions which contained errors therein, such as a prescription dispensed with too many refills, a prescription dispensed without prescribed refills, and prescriber not listed on a secure prescription blank;

e. That Respondent George and Respondent Sutter failed to maintain records of acquisition and disposition for at least three years from the date of making;

f. That Respondent George and Respondent Sutter dispensed controlled substances to patients when the patient's address was not known to the pharmacy;

g. That Respondent George and Respondent Sutter dispensed Schedule II Controlled Substances without a hard-copy of the prescription; and

h. That Respondent George and Respondent Sutter failed to properly maintain a patient profile.

CAUSES FOR DISCIPLINE

A. Respondent Sutter Pharmacy

FIRST CAUSE FOR DISCIPLINE

(Dispensing Using Erroneous Prescriptions – Respondent Sutter)

34. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (d), (j), and (o), in that Respondent violated Code section 4113, Health and Safety Code section 11153, and Title 16, California Code of Regulations, section 1761, by dispensing numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose, by failing to contact the prescribers for uncertain prescriptions (e.g. regarding their quantities, directions, and purpose), and by dispensing prescriptions which contained errors therein (e.g. prescription dispensed with too many refills, dispensed without prescribed refills, and prescriber not listed on a secure prescription blank), as set forth in paragraphs 28 through 32, and their subparagraphs, above.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records – Respondent Sutter)

35. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301, subdivisions (j) and (o), in that Respondent violated Code sections 4081 subdivisions (a) and (b), 4105, and 4113, by failing to maintain records of the acquisition and disposition of dangerous drugs, for at least three years from the date of making, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

THIRD CAUSE FOR DISCIPLINE

(Improperly Issuing Prescriptions – Respondent Sutter)

36. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Title 24, Code of Federal Regulations, section 1306.5 subdivision (a), by dispensing controlled substances to patients when the patient's address was not known to Respondents, and when the security blank lacked an address for the prescriber, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

FOURTH CAUSE FOR DISCIPLINE

(No Hard-Copy of Controlled Substance Prescriptions – Respondent Sutter)

37. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Health and Safety Code sections 11159.2 and 11164 by dispensing controlled substances using prescriptions that were initially received by either fax transmission or verbally, which Respondents did not reduce to writing on a form developed by the pharmacy, and which Respondents did not receive the prescribers' signed orders or chart orders for prior to dispensing the prescriptions, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

FIFTH CAUSE FOR DISCIPLINE

(Dispensed Without Required Prescription Form – Respondent Sutter)

38. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Health and Safety Code section 11162.1 subdivision (a)(9), by dispensing Schedule II controlled substance prescriptions pursuant to a secure form which did not contain the address of the prescriber, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Patient Profile – Respondent Sutter)

39. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Title 16 California Code of Regulations, section 1707.1 subdivision (a) when the patient report that Respondents provided for patient B.B. contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

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B. Respondent Biju G. George

40. Respondent George has been the designated Pharmacist-In-Charge for Respondent Sutter Pharmacy under Code section 4113(a) since March 30, 2016. As Pharmacist-In-Charge for Respondent Sutter, Respondent George was responsible for Respondent Sutter's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy under Code section 4113(c).

SEVENTH CAUSE FOR DISCIPLINE

(Dispensing Using Erroneous Prescriptions – Respondent George)

41. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (d), (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, Health and Safety Code section 11153, and Title 16, California Code of Regulations, section 1761, by dispensing numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose, by failing to contact the prescribers for uncertain prescriptions (e.g. regarding their quantities, directions, and purpose), and by dispensing prescriptions which contained errors therein (e.g. prescription dispensed with too many refills, dispensed without prescribed refills, and prescriber not listed on a secure prescription blank), as set forth in paragraphs 28 through 32, and their subparagraphs, above.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records – Respondent George)

42. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code sections 4081, subdivisions (a) and (b), 4105, and 4113, by failing to maintain records of the acquisition and disposition of dangerous drugs, for at least three years from the date of making, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

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NINTH CAUSE FOR DISCIPLINE

(Improperly Issuing Prescriptions – Respondent George)

43. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Title 24, Code of Federal Regulations, section 1306.05 subdivision (a), by dispensing controlled substances to patients when the patient's address was not known to Respondents, and when the security blank lacked an address for the prescriber, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

TENTH CAUSE FOR DISCIPLINE

(No Hard-Copy of Controlled Substance Prescriptions – Respondent George)

44. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Health and Safety Code sections 11159.2 and 11164 by dispensing controlled substances using prescriptions that were initially received by either fax transmission or verbally, which Respondents did not reduce to writing on a form developed by the pharmacy, and which Respondents did not receive the prescribers' signed orders or chart orders for prior to dispensing the prescriptions, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Dispensed Without Required Prescription Form – Respondent George)

45. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Health and Safety Code section 11162.1 subdivision (a)(9), by dispensing Schedule II controlled substance prescriptions pursuant to a secure form which did not contain the address of the prescriber, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

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TWELFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Patient Profile – Respondent George)

46. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Title 16 California Code of Regulations, section 1707.1 subdivision (a) when the patient report that Respondents provided for patient B.B. contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Respondent's Education, Training, or Experience as a Pharmacist – Respondent George)

47. Respondent George is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (a), for inappropriately exercising his education, training or experience as a pharmacist, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility – Respondent George)

48. Respondent George is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (b), for failing to exercise or implement his best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, as set forth in paragraphs 28 through 32, and their subparagraphs, above.

OTHER MATTERS

49. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy, then Sutter Pharmacy Inc. dba Sutter Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number

PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy, while Biju G. George has been an owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, then Biju G. George shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

51. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy, while Ranjit Singh has been a manager, administrator, owner, member, officer, director, associate, or partner, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, then Ranjit Singh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

52. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy, while Anu Goyal has been a manager, administrator, owner, member, officer, director, associate, or partner, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, then Anu Goyal shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

53. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy, while Ansu George has been a manager, administrator, owner, member, officer, director, associate, or partner, and had

knowledge of or knowingly participated in any conduct for which the licensee was disciplined, then Ansu George shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Retail Pharmacy License Number PHY 47489, issued to Sutter Pharmacy Inc. dba Sutter Pharmacy,

2. Revoking or suspending Registered Pharmacist License Number RPH 49255, issued to Biju G. George;

3. Prohibiting Sutter Pharmacy Inc. dba Sutter Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

4. Prohibiting Biju G. George from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

5. Prohibiting Ranjit Singh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

6. Prohibiting Anu Goyal from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number

PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

7. Prohibiting Ansu George, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

8. Ordering Sutter Pharmacy Inc. dba Sutter Pharmacy and Biju G. George, 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;

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

DATED: 10/27/18

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

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

In the Matter of the Accusation Against: **SUTTER PHARMACY, dba SUTTER PHARMACY;** **BIJU G. GEORGE, OWNER, CHIEF EXECUTIVE OFFICER, SECRETARY, AND TREASURER/CHIEF FINANCIAL OFFICER;** **RANJIT SINGH, FORMER CHIEF EXECUTIVE OFFICER;** **ANU GOYLE, FORMER CHIEF EXECUTIVE OFFICER;** **ANSU GEORGE, FORMER SECRETARY;** **470 Plumas Blvd., Ste. 103** **Yuba City, CA 95991** **Retail Pharmacy Permit No. PHY 47489;** **And** **BIJU G. GEORGE** **470 Plumas Blvd., Ste. 103** **Yuba City, CA 95991** **Pharmacist License No. RPH 49255** Respondents.	Case No. 6177 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity

as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.

2. On or about March 30, 2006, the Board issued Retail Pharmacy License Number PHY 47489 to Sutter Pharmacy Inc. dba Sutter Pharmacy ("Respondent Sutter"). At all times relevant to the charges brought herein, Respondent Sutter's corporate officers were Biju G. George, Chief Executive Officer and Secretary (from September 7, 2017, to present), and Treasurer/Chief Financial Officer (from March 30, 2006, to present); Ranjit Singh, Chief Executive Officer (from March 30, 2006, to December 1, 2016); Anu Goyle, Chief Executive Officer (from December 1, 2016, to September 7, 2017); and Ansu George, Secretary (from March 30, 2006, to September 7, 2017). On or about March 30, 2016, Biju G. George ("Respondent George") became the pharmacist-in-charge. The Retail Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2018, unless renewed.

3. On or about March 18, 1997, the Board issued Registered Pharmacist License Number RPH 49255 to Respondent George. The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2018, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Code section 4300 states, in pertinent part:

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

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

(1) Suspending judgment.
(2) Placing him or her upon probation.
(3) Suspending his or her right to practice for a period not exceeding one year.
(4) Revoking his or her license.
(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

/ / /

6. Code section 4300.1 states:

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

7. Code section 4307 states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of 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 manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

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

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

STATUTORY AND REGULATORY PROVISIONS

A. Business & Professions Code

8. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of

unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(d) The clearly excessive furnishing of controlled substances in violation of 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 by any other state or federal regulatory agency . . . .

9. Code section 4306.5 states, in pertinent part:

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

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

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

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

10. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

11. Section 4105 of the Code states:

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e)

(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

12. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

B. Health & Safety Code

13. Health and Safety Code section 11153, subdivision (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.

14. Health and Safety Code section 11159.2, states, in pertinent part:

(a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

. . .

15. Health and Safety Code section 11162.1 states, in pertinent part:

(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."

. . . .

(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 . . .

. . . .

(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.

. . . .

(c)

. . . .

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

. . . .

16. Health and Safety Code section 11164 states, in pertinent part:

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

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

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

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the

address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b)

(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

C. Federal Regulation

17. Title 21, Code of Federal Regulations ("CFR"), section 1306.05, subsection (a) states, "[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner."

D. California Regulations

18. Title 16, California Code of Regulations ("CCR"), section 1707.1 states:

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following

information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

3. The date on which a drug was dispensed or refilled;

4. The prescription number for each prescription; and

5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

19. Title 16, CCR, section 1761, subdivision (a), states:

> 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.

COST RECOVERY

20. Code section 125.3 provides, in pertinent part, that a 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.

DRUG CLASSIFICATIONS

21. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M), and a dangerous drug pursuant to Code section 4022. Oxycodone is used to treat pain. "Roxicodone" is a brand of oxycodone.

22. Alprazolam is a Schedule IV controlled substance pursuant to Health and Safety Code

section 11057, subdivision (d)(1), and a dangerous drug pursuant to Code section 4022. Alprazolam is used to treat anxiety. "Xanax" is a brand of alprazolam.

23. Promethazine with codeine is a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c)(1), and a dangerous drug pursuant to Code section 4022. Promethazine with codeine is used to treat cough. "Phenergan with codeine" is a brand of promethazine with codeine.

24. Hydrocodone/acetaminophen is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (e), and a Schedule II controlled substance pursuant to Title 21, CFR, section 1308.12, subdivision (b)(1)(vi).[1] Hydrocodone/acetaminophen is also a dangerous drug pursuant to Code section 4022. Hydrocodone/acetaminophen is used to treat pain. "Norco" is a brand of hydrocodone/acetaminophen.

25. Carisoprodol is a Schedule IV Controlled Substance pursuant to Title 21, CFR, section 1308.14, subdivision (c)(6), and a dangerous drug pursuant to Code section 4022. Carisoprodol is used as a muscle relaxant. "Soma" is a brand of carisoprodol.

CURES PROGRAM

26. The Controlled Substance Utilization Review and Evaluation System ("CURES") program was initiated in 1998 and required mandatory monthly pharmacy reporting of dispensed Schedule II controlled substances. The program was amended in January 2005 to include mandatory weekly reporting of Schedule II to IV medications. The data is collected statewide and can be used by healthcare professionals, such as pharmacists and prescribers, to evaluate and determine whether their patients are utilizing their controlled substances safely and appropriately.

27. The component of CURES which is accessible to pharmacists and prescribers is called the Prescription Drug Monitoring Program ("PDMP"). Registration for access to the PDMP has been available since February 2009. The data may be used to aid in determining whether a patient sees multiple prescribers, frequents multiple pharmacies to fill controlled substance prescriptions, and/or obtains early refills of controlled substance prescriptions.

[1] Hydrocodone/acetaminophen was rescheduled to a Schedule II controlled substance effective October 6, 2014.

FACTUAL ALLEGATIONS

28. On or about February 7, 2017, Board Inspector P.P. analyzed CURES data for Respondent Sutter and found certain "red flags" or irregularities indicating that various doctors were potentially issuing prescriptions for controlled substances for other than a legitimate medical purpose and that Respondent Sutter was dispensing the drugs indiscriminately; i.e., without exercising its corresponding responsibility with regard to the dispensing or furnishing of the drugs. Those "red flags" included CURES data showing that Respondent Sutter dispensed larger quantities of controlled substances than other nearby pharmacies, and that Respondent Sutter's top patients (i.e. patients who received 111 or more controlled substances) received more, on average, controlled substances than other nearby pharmacies. Inspector P.P. also obtained the names of patients who appeared to receive many controlled substances, patients who lived out of state, and the top prescribers at Respondent Sutter.

29. On or about February 8, 2017, Board Inspectors P.P. and J.H. conducted an inspection at Respondent Sutter, and were assisted by Respondent George and pharmacist A.G. Inspector P.P. instructed Respondent George to conduct an on-hand count of all hydrocodone drugs in stock because the CURES report showed that Respondent Sutter had dispensed over one million doses of hydrocodone from February 1, 2014 through February 7, 2017, and Inspector P.P. planned to conduct an audit. Inspector P.P. also obtained a dispensing report from Respondent George for February 8, 2017, as well as the Biennial inventory Respondent George had conducted on October 5, 2014, and included that information in the audit. During the inspection, Inspector P.P. received and reviewed approximately forty-nine (49) patient profiles with Respondent George. During the review of those patient profiles, Respondent George told Inspector P.P. that "[t]here are no notes on the profiles but they could be on the prescription blanks." Also during the inspection, Respondent George informed Inspector P.P. that he had no recollection of ever looking up any ICD 10 codes to verify them, and that he had no recollection of calling prescribers to discuss pain management. During the inspection, Inspector P.P. also reviewed Respondent Sutter's controlled substance prescriptions for hospice patients, and found that those prescriptions were initially received by either fax transmission or verbally. Respondent

Sutter did not reduce those hospice prescriptions to writing on a form developed by the pharmacy, and did not receive the prescribers' signed orders or chart orders prior to dispensing the prescriptions.

30. At the February 8, 2017, inspection, Inspector P.P. also requested the following from Respondent George: (a) dispensing report for hydrocodone 5/325, 7.5/325, 10/325, and Zohydro ER from October 5, 2014, through February 7, 2017; (b) acquisition records for the foregoing hydrocodone products from October 5, 2014, through February 8, 2017; and (c) the outcome of Respondent George's discussion with a doctor whose prescription forms did not contain a physical address.

31. On or about February 9, 2017, Respondent George informed Inspector P.P. that "my last Controlled substance inventory date was 05/26/15 at 8:35AM (I will be glad to scan a copy and email you) if you are looking to tally the purchase vs dispensing 10/05/14 may not work." Also, on or about February 14, 2017, Respondent George informed Inspector P.P. that Respondent George's dispensing records only went back twenty-four months.

32. Over the course of approximately February 22, 2017, through approximately May 3, 2017, Respondent George provided Inspector P.P. with the following information:

a. A dispensing report for hydrocodone/apap 5/325, 7/325, 10/325 mg and Zohydro ER products from October 5, 2014 to February 7, 2017;

b. Physician dispensing reports;

c. The CURES profile for seventeen patients who received controlled substances at Respondent Sutter, and the pharmacist identification on the profiles;

d. The profile for patient B.B., because the one provided to Inspector P.P. at the time of the inspection contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016;

e. Hospice prescriptions from February 8, 2014, through February 8, 2017, and

f. Notes on patient files, which had not been on the patient files at the time of the February 8, 2017, inspection.

33. Inspector P.P. reviewed the CURES report for Respondent Sutter, the top prescribers for Respondent Sutter (none of whom were certified in pain management), and the information and patient profiles provided by Respondent George. Inspector P.P. also interviewed Respondent

George about Respondent Sutter's service area, his knowledge concerning the patient profiles, the patients who received controlled substances, and about Respondent Sutter's pharmacy practices. Following her inspection of Respondent Sutter, interview of Respondent George, review of CURES data, and review of documents provided by Respondent George, Inspector P.P. found the following:

a. Between 2014 and 2017, Respondents dispensed numerous prescriptions for oxycodone, hydrocodone/apap, alprazolam, diazepam, carisoprodol, tramadol, methadone, promethazine with codeine, and oxycontin without regard to the following irregularities or factors:

   i. Prescribers were not certified in pain management, and were family physicians;

   ii. Prescribers' medical offices were located long distances from Respondent Sutter Pharmacy;

   iii. Patients traveled long distances (including from out of state) to have controlled substance prescriptions filled at Respondent Sutter;

   iv. Patients did not provide their address to Respondent Sutter;

   v. Respondents did not have any diagnosis or treatment on file for patients who had controlled substance prescriptions filled at Respondent Sutter;

   vi. Patients had high dosages of controlled substance prescriptions;

b. That Respondent George and Respondent Sutter dispensed numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose;

c. That the pharmacist did not contact the prescribers for uncertain prescriptions, specifically regarding their quantities, directions, and purpose;

d. That Respondent George and Respondent Sutter dispensed prescriptions which contained errors therein, such as a prescription dispensed with too many refills, a prescription dispensed without prescribed refills, and prescriber not listed on a secure prescription blank;

e. That Respondent George and Respondent Sutter failed to maintain records of acquisition and disposition for at least three years from the date of making;

f. That Respondent George and Respondent Sutter dispensed controlled substances to patients when the patient's address was not known to the pharmacy;

g. That Respondent George and Respondent Sutter dispensed Schedule II Controlled Substances without a hard-copy of the prescription; and

h. That Respondent George and Respondent Sutter failed to properly maintain a patient profile.

CAUSES FOR DISCIPLINE

A. Respondent Sutter Pharmacy

FIRST CAUSE FOR DISCIPLINE

(Dispensing Using Erroneous Prescriptions – Respondent Sutter)

34. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (d), (j), and (o), in that Respondent violated Code section 4113, Health and Safety Code section 11153, and Title 16, California Code of Regulations, section 1761, by dispensing numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose, by failing to contact the prescribers for uncertain prescriptions (e.g. regarding their quantities, directions, and purpose), and by dispensing prescriptions which contained errors therein (e.g. prescription dispensed with too many refills, dispensed without prescribed refills, and prescriber not listed on a secure prescription blank), as set forth in paragraphs 27 through 32, and their subparagraphs, above.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records – Respondent Sutter)

35. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301, subdivisions (j) and (o), in that Respondent violated Code sections 4081 subdivisions (a) and (b), 4105, and 4113, by failing to maintain records of the acquisition and disposition of dangerous drugs, for at least three years from the date of making, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

THIRD CAUSE FOR DISCIPLINE

(Improperly Issuing Prescriptions – Respondent Sutter)

36. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Title 24, Code of Federal Regulations, section 1306.5 subdivision (a), by dispensing controlled substances to patients when the patient's address was not known to Respondents, and when the security blank lacked an address for the prescriber, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

FOURTH CAUSE FOR DISCIPLINE

(No Hard-Copy of Controlled Substance Prescriptions – Respondent Sutter)

37. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Health and Safety Code sections 11159.2 and 11164 by dispensing controlled substances using prescriptions that were initially received by either fax transmission or verbally, which Respondents did not reduce to writing on a form developed by the pharmacy, and which Respondents did not receive the prescribers' signed orders or chart orders for prior to dispensing the prescriptions, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

FIFTH CAUSE FOR DISCIPLINE

(Dispensed Without Required Prescription Form – Respondent Sutter)

38. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Health and Safety Code section 11162.1 subdivision (a)(9), by dispensing Schedule II controlled substance prescriptions pursuant to a secure form which did not contain the address of the prescriber, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Patient Profile – Respondent Sutter)

39. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Title 16 California Code of Regulations, section 1707.1 subdivision (a) when the patient report that Respondents provided for patient B.B. contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

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B. Respondent Biju G. George

40. Respondent George has been the designated Pharmacist-In-Charge for Respondent Sutter Pharmacy under Code section 4113(a) since March 30, 2016. As Pharmacist-In-Charge for Respondent Sutter, Respondent George was responsible for Respondent Sutter's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy under Code section 4113(c).

SEVENTH CAUSE FOR DISCIPLINE

(Dispensing Using Erroneous Prescriptions – Respondent George)

41. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (d), (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, Health and Safety Code section 11153, and Title 16, California Code of Regulations, section 1761, by dispensing numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose, by failing to contact the prescribers for uncertain prescriptions (e.g. regarding their quantities, directions, and purpose), and by dispensing prescriptions which contained errors therein (e.g. prescription dispensed with too many refills, dispensed without prescribed refills, and prescriber not listed on a secure prescription blank), as set forth in paragraphs 27 through 32, and their subparagraphs, above.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records – Respondent George)

42. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code sections 4081, subdivisions (a) and (b), 4105, and 4113, by failing to maintain records of the acquisition and disposition of dangerous drugs, for at least three years from the date of making, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

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NINTH CAUSE FOR DISCIPLINE

(Improperly Issuing Prescriptions – Respondent George)

43. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Title 24, Code of Federal Regulations, section 1306.05 subdivision (a), by dispensing controlled substances to patients when the patient's address was not known to Respondents, and when the security blank lacked an address for the prescriber, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

TENTH CAUSE FOR DISCIPLINE

(No Hard-Copy of Controlled Substance Prescriptions – Respondent George)

44. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Health and Safety Code sections 11159.2 and 11164 by dispensing controlled substances using prescriptions that were initially received by either fax transmission or verbally, which Respondents did not reduce to writing on a form developed by the pharmacy, and which Respondents did not receive the prescribers' signed orders or chart orders for prior to dispensing the prescriptions, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Dispensed Without Required Prescription Form – Respondent George)

45. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Health and Safety Code section 11162.1 subdivision (a)(9), by dispensing Schedule II controlled substance prescriptions pursuant to a secure form which did not contain the address of the prescriber, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

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TWELFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Patient Profile – Respondent George)

46. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Title 16 California Code of Regulations, section 1707.1 subdivision (a) when the patient report that Respondents provided for patient B.B. contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Respondent's Education, Training, or Experience as a Pharmacist – Respondent George)

47. Respondent George is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (a), for inappropriately exercising his education, training or experience as a pharmacist, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility – Respondent George)

48. Respondent George is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (b), for failing to exercise or implement his best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

OTHER MATTERS

49. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy, then Sutter Pharmacy Inc. dba Sutter Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number

PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy, while Biju G. George has been an owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, then Biju G. George shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Retail Pharmacy License Number PHY 47489, issued to Sutter Pharmacy Inc. dba Sutter Pharmacy,

2. Revoking or suspending Registered Pharmacist License Number RPH 49255, issued to Biju G. George;

3. Prohibiting Sutter Pharmacy Inc. dba Sutter Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

4. Prohibiting Biju G. George from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

5. Prohibiting Ranjit Singh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number

PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

6. Prohibiting Anu Goyle from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

7. Prohibiting Ansu George, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy Inc. dba Sutter Pharmacy is revoked;

8. Ordering Sutter Pharmacy Inc. dba Sutter Pharmacy and Biju G. George, 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;

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

DATED: 4/5/18

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

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

In the Matter of the Accusation Against: **SUTTER PHARMACY; BIJU G. GEORGE, OWNER AND PHARMACIST-IN-CHARGE** **470 Plumas Blvd., Ste. 103** **Yuba City, CA 95991** **Retail Pharmacy Permit No. PHY 47489** **And** **BIJU G. GEORGE** **470 Plumas Blvd., Ste. 103** **Yuba City, CA 95991** **Pharmacist License No. RPH 49255** Respondents.	Case No. 6177 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about March 30, 2006, the Board issued Retail Pharmacy License Number PHY 47489 to Sutter Pharmacy ("Respondent Sutter"). On or about March 30, 2016, Biju G. George ("Respondent George") became the pharmacist-in-charge. The Retail Pharmacy License was in full force and effect at all times relevant to the charges brought herein and will expire on

March 1, 2018, unless renewed.

3. On or about March 18, 1997, the Board issued Registered Pharmacist License Number RPH 49255 to Respondent George. The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2018, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Code section 4300 states, in pertinent part:

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

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

(1) Suspending judgment.
(2) Placing him or her upon probation.
(3) Suspending his or her right to practice for a period not exceeding one year.
(4) Revoking his or her license.
(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

6. Code section 4300.1 states:

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

7. Code section 4307 states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of 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 manager, administrator, owner,

member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

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

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

STATUTORY AND REGULATORY PROVISIONS

A. Business & Professions Code

8. Code section 4301 states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(d) The clearly excessive furnishing of controlled substances in violation of 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 by any other state or federal regulatory agency . . . .

9. Code section 4306.5 states, in pertinent part:

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

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

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

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

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

10. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

11. Section 4105 of the Code states:

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed

premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e)

(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

12. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

B. Health & Safety Code

13. Health and Safety Code section 11153, subdivision (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.

14. Health and Safety Code section 11159.2, states, in pertinent part:

(a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

. . .

15. Health and Safety Code section 11162.1 states, in pertinent part:

(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."

. . . .

(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 . . .

. . . .

(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.

. . . .

(c)

. . . .

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

. . . .

16. Health and Safety Code section 11164 states, in pertinent part:

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

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

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

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b)

(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision

specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

C. Federal Regulation

17. Title 21, Code of Federal Regulations ("CFR"), section 1306.05, subsection (a) states, "[a]ll prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner."

D. California Regulations

18. Title 16, California Code of Regulations ("CCR"), section 1707.1 states:

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:
1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;
2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;
3. The date on which a drug was dispensed or refilled;
4. The prescription number for each prescription; and
5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

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(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

19. Title 16, CCR, section 1761, subdivision (a), states:

> 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.

COST RECOVERY

20. Code section 125.3 provides, in pertinent part, that a 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.

DRUG CLASSIFICATIONS

21. Oxycodone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M), and a dangerous drug pursuant to Code section 4022. Oxycodone is used to treat pain. "Roxicodone" is a brand of oxycodone.

22. Alprazolam is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(1), and a dangerous drug pursuant to Code section 4022. Alprazolam is used to treat anxiety. "Xanax" is a brand of alprazolam.

23. Promethazine with codeine is a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c)(1), and a dangerous drug pursuant to Code section 4022. Promethazine with codeine is used to treat cough. "Phenergan with codeine" is a brand of promethazine with codeine.

24. Hydrocodone/acetaminophen is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (e), and a Schedule II controlled substance pursuant to Title 21, CFR, section 1308.12, subdivision (b)(1)(vi).[1] Hydrocodone/acetaminophen

[1] Hydrocodone/acetaminophen was rescheduled to a Schedule II controlled substance effective October 6, 2014.

is also a dangerous drug pursuant to Code section 4022. Hydrocodone/acetaminophen is used to treat pain. "Norco" is a brand of hydrocodone/acetaminophen.

25. Carisoprodol is a Schedule IV Controlled Substance pursuant to Title 21, CFR, section 1308.14, subdivision (c)(6), and a dangerous drug pursuant to Code section 4022. Carisoprodol is used as a muscle relaxant. "Soma" is a brand of carisoprodol.

CURES PROGRAM

26. The Controlled Substance Utilization Review and Evaluation System ("CURES") program was initiated in 1998 and required mandatory monthly pharmacy reporting of dispensed Schedule II controlled substances. The program was amended in January 2005 to include mandatory weekly reporting of Schedule II to IV medications. The data is collected statewide and can be used by healthcare professionals, such as pharmacists and prescribers, to evaluate and determine whether their patients are utilizing their controlled substances safely and appropriately.

27. The component of CURES which is accessible to pharmacists and prescribers is called the Prescription Drug Monitoring Program ("PDMP"). Registration for access to the PDMP has been available since February 2009. The data may be used to aid in determining whether a patient sees multiple prescribers, frequents multiple pharmacies to fill controlled substance prescriptions, and/or obtains early refills of controlled substance prescriptions.

FACTUAL ALLEGATIONS

28. On or about February 7, 2017, Board Inspector P.P. analyzed CURES data for Respondent Sutter and found certain "red flags" or irregularities indicating that various doctors were potentially issuing prescriptions for controlled substances for other than a legitimate medical purpose and that Respondent Sutter was dispensing the drugs indiscriminately; i.e., without exercising its corresponding responsibility with regard to the dispensing or furnishing of the drugs. Those "red flags" included CURES data showing that Respondent Sutter dispensed larger quantities of controlled substances than other nearby pharmacies, and that Respondent Sutter's top patients (i.e. patients who received 111 or more controlled substances) received more, on average, controlled substances than other nearby pharmacies. Inspector P.P. also obtained the names of patients who appeared to receive many controlled substances, patients who lived out of

state, and the top prescribers at Respondent Sutter.

29. On or about February 8, 2017, Board Inspectors P.P. and J.H. conducted an inspection at Respondent Sutter, and were assisted by Respondent George and pharmacist A.G. Inspector P.P. instructed Respondent George to conduct an on-hand count of all hydrocodone drugs in stock because the CURES report showed that Respondent Sutter had dispensed over one million doses of hydrocodone from February 1, 2014 through February 7, 2017, and Inspector P.P. planned to conduct an audit. Inspector P.P. also obtained a dispensing report from Respondent George for February 8, 2017, as well as the Biennial inventory Respondent George had conducted on October 5, 2014, and included that information in the audit. During the inspection, Inspector P.P. received and reviewed approximately forty-nine (49) patient profiles with Respondent George. During the review of those patient profiles, Respondent George told Inspector P.P. that "[t]here are no notes on the profiles but they could be on the prescription blanks." Also during the inspection, Respondent George informed Inspector P.P. that he had no recollection of ever looking up any ICD 10 codes to verify them, and that he had no recollection of calling prescribers to discuss pain management. During the inspection, Inspector P.P. also reviewed Respondent Sutter's controlled substance prescriptions for hospice patients, and found that those prescriptions were initially received by either fax transmission or verbally. Respondent Sutter did not reduce those hospice prescriptions to writing on a form developed by the pharmacy, and did not receive the prescribers' signed orders or chart orders prior to dispensing the prescriptions.

30. At the February 8, 2017, inspection, Inspector P.P. also requested the following from Respondent George: (a) dispensing report for hydrocodone 5/325, 7.5/325, 10/325, and Zohydro ER from October 5, 2014, through February 7, 2017; (b) acquisition records for the foregoing hydrocodone products from October 5, 2014, through February 8, 2017; and (c) the outcome of Respondent George's discussion with a doctor whose prescription forms did not contain a physical address.

31. On or about February 9, 2017, Respondent George informed Inspector P.P. that "my last Controlled substance inventory date was 05/26/15 at 8:35AM (I will be glad to scan a copy

and email you) if you are looking to tally the purchase vs dispensing 10/05/14 may not work." Also, on or about February 14, 2017, Respondent George informed Inspector P.P. that Respondent George's dispensing records only went back twenty-four months.

32. Over the course of approximately February 22, 2017, through approximately May 3, 2017, Respondent George provided Inspector P.P. with the following information:

a. A dispensing report for hydrocodone/apap 5/325, 7/325, 10/325 mg and Zohydro ER products from October 5, 2014 to February 7, 2017;

b. Physician dispensing reports;

c. The CURES profile for seventeen patients who received controlled substances at Respondent Sutter, and the pharmacist identification on the profiles;

d. The profile for patient B.B., because the one provided to Inspector P.P. at the time of the inspection contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016;

e. Hospice prescriptions from February 8, 2014, through February 8, 2017, and

f. Notes on patient files, which had not been on the patient files at the time of the February 8, 2017, inspection.

33. Inspector P.P. reviewed the CURES report for Respondent Sutter, the top prescribers for Respondent Sutter (none of whom were certified in pain management), and the information and patient profiles provided by Respondent George. Inspector P.P. also interviewed Respondent George about Respondent Sutter's service area, his knowledge concerning the patient profiles, the patients who received controlled substances, and about Respondent Sutter's pharmacy practices. Following her inspection of Respondent Sutter, interview of Respondent George, review of CURES data, and review of documents provided by Respondent George, Inspector P.P. found the following:

a. Between 2014 and 2017, Respondents dispensed numerous prescriptions for oxycodone, hydrocodone/apap, alprazolam, diazepam, carisoprodol, tramadol, methadone, promethazine with codeine, and oxycontin without regard to the following irregularities or factors:

i. Prescribers were not certified in pain management, and were family physicians;

ii. Prescribers' medical offices were located long distances from Respondent Sutter Pharmacy;

iii. Patients traveled long distances (including from out of state) to have controlled substance prescriptions filled at Respondent Sutter;

iv. Patients did not provide their address to Respondent Sutter;

v. Respondents did not have any diagnosis or treatment on file for patients who had controlled substance prescriptions filled at Respondent Sutter;

vi. Patients had high dosages of controlled substance prescriptions;

b. That Respondent George and Respondent Sutter dispensed numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose;

c. That the pharmacist did not contact the prescribers for uncertain prescriptions, specifically regarding their quantities, directions, and purpose;

d. That Respondent George and Respondent Sutter dispensed prescriptions which contained errors therein, such as a prescription dispensed with too many refills, a prescription dispensed without prescribed refills, and prescriber not listed on a secure prescription blank;

e. That Respondent George and Respondent Sutter failed to maintain records of acquisition and disposition for at least three years from the date of making;

f. That Respondent George and Respondent Sutter dispensed controlled substances to patients when the patient's address was not known to the pharmacy;

g. That Respondent George and Respondent Sutter dispensed Schedule II Controlled Substances without a hard-copy of the prescription; and

h. That Respondent George and Respondent Sutter failed to properly maintain a patient profile.

CAUSES FOR DISCIPLINE

A. Respondent Sutter Pharmacy

FIRST CAUSE FOR DISCIPLINE

(Dispensing Using Erroneous Prescriptions – Respondent Sutter)

34. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (d), (j), and (o), in that Respondent violated Code section 4113, Health and Safety Code section 11153, and Title 16, California Code of Regulations, section 1761, by dispensing numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose, by failing to contact the prescribers for uncertain prescriptions (e.g. regarding their quantities, directions, and purpose), and by dispensing prescriptions which contained errors therein (e.g. prescription dispensed with too

many refills, dispensed without prescribed refills, and prescriber not listed on a secure prescription blank), as set forth in paragraphs 27 through 32, and their subparagraphs, above.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records – Respondent Sutter)

35. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301, subdivisions (j) and (o), in that Respondent violated Code sections 4081 subdivisions (a) and (b), 4105, and 4113, by failing to maintain records of the acquisition and disposition of dangerous drugs, for at least three years from the date of making, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

THIRD CAUSE FOR DISCIPLINE

(Improperly Issuing Prescriptions – Respondent Sutter)

36. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Title 24, Code of Federal Regulations, section 1306.5 subdivision (a), by dispensing controlled substances to patients when the patient's address was not known to Respondents, and when the security blank lacked an address for the prescriber, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

FOURTH CAUSE FOR DISCIPLINE

(No Hard-Copy of Controlled Substance Prescriptions – Respondent Sutter)

37. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Health and Safety Code sections 11159.2 and 11164 by dispensing controlled substances using prescriptions that were initially received by either fax transmission or verbally, which Respondents did not reduce to writing on a form developed by the pharmacy, and which Respondents did not receive the prescribers' signed orders or chart orders for prior to dispensing the prescriptions, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

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FIFTH CAUSE FOR DISCIPLINE

(Dispensed Without Required Prescription Form – Respondent Sutter)

38. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Health and Safety Code section 11162.1 subdivision (a)(9), by dispensing Schedule II controlled substance prescriptions pursuant to a secure form which did not contain the address of the prescriber, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Patient Profile – Respondent Sutter)

39. Respondent Sutter Pharmacy is subject to disciplinary action for unprofessional conduct under Code sections 4301 subdivisions (j) and (o), in that Respondent violated Code section 4113, and Title 16 California Code of Regulations, section 1707.1 subdivision (a) when the patient report that Respondents provided for patient B.B. contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

B. Respondent Biju G. George

40. Respondent George has been the designated Pharmacist-In-Charge for Respondent Sutter Pharmacy under Code section 4113(a) since March 30, 2016. As Pharmacist-In-Charge for Respondent Sutter, Respondent George was responsible for Respondent Sutter's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy under Code section 4113(c).

SEVENTH CAUSE FOR DISCIPLINE

(Dispensing Using Erroneous Prescriptions – Respondent George)

41. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (d), (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, Health and Safety Code

section 11153, and Title 16, California Code of Regulations, section 1761, by dispensing numerous prescriptions for controlled substances when the prescriptions had no known legitimate medical purpose, by failing to contact the prescribers for uncertain prescriptions (e.g. regarding their quantities, directions, and purpose), and by dispensing prescriptions which contained errors therein (e.g. prescription dispensed with too many refills, dispensed without prescribed refills, and prescriber not listed on a secure prescription blank), as set forth in paragraphs 27 through 32, and their subparagraphs, above.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records – Respondent George)

42. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code sections 4081, subdivisions (a) and (b), 4105, and 4113, by failing to maintain records of the acquisition and disposition of dangerous drugs, for at least three years from the date of making, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

NINTH CAUSE FOR DISCIPLINE

(Improperly Issuing Prescriptions – Respondent George)

43. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Title 24, Code of Federal Regulations, section 1306.05 subdivision (a), by dispensing controlled substances to patients when the patient's address was not known to Respondents, and when the security blank lacked an address for the prescriber, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

TENTH CAUSE FOR DISCIPLINE

(No Hard-Copy of Controlled Substance Prescriptions – Respondent George)

44. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-

in-charge of Respondent Sutter, violated Code section 4113, and Health and Safety Code sections 11159.2 and 11164 by dispensing controlled substances using prescriptions that were initially received by either fax transmission or verbally, which Respondents did not reduce to writing on a form developed by the pharmacy, and which Respondents did not receive the prescribers' signed orders or chart orders for prior to dispensing the prescriptions, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Dispensed Without Required Prescription Form – Respondent George)

45. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Health and Safety Code section 11162.1 subdivision (a)(9), by dispensing Schedule II controlled substance prescriptions pursuant to a secure form which did not contain the address of the prescriber, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Patient Profile – Respondent George)

46. Respondent George is subject to disciplinary action for unprofessional conduct under Code section 4301 subdivisions (j) and (o), and section 4306, in that Respondent, as pharmacist-in-charge of Respondent Sutter, violated Code section 4113, and Title 16 California Code of Regulations, section 1707.1 subdivision (a) when the patient report that Respondents provided for patient B.B. contained two dangerous drugs and no controlled substances while the CURES report showed that Respondent Sutter had filled at least 70 controlled substances for B.B. between February 12, 2014, and June 9, 2016, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

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THIRTEENTH CAUSE FOR DISCIPLINE
(Inappropriate Exercise of Respondent's Education, Training, or Experience as a Pharmacist – Respondent George)

47. Respondent George is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (a), for inappropriately exercising his education, training or experience as a pharmacist, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

FOURTEENTH CAUSE FOR DISCIPLINE
(Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility – Respondent George)

48. Respondent George is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5, subdivision (b), for failing to exercise or implement his best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, as set forth in paragraphs 27 through 32, and their subparagraphs, above.

OTHER MATTERS

49. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy, then Sutter Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 47489 issued to Sutter Pharmacy, while Biju G. George has been an owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, then Biju G. George shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number PHY 47489 is reinstated if it is revoked.

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PRAYER

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

1. Revoking or suspending Retail Pharmacy License Number PHY 47489, issued to Sutter Pharmacy,

2. Revoking or suspending Registered Pharmacist License Number RPH 49255, issued to Biju G. George;

3. Prohibiting Sutter Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy is revoked;

4. Prohibiting Biju G. George from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 47489 is placed on probation or until Pharmacy Permit Number 47489 is reinstated if Pharmacy Permit Number 47489 issued to Sutter Pharmacy is revoked;

5. Ordering Sutter Pharmacy and Biju G. George, 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;

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

DATED: 11/6/17

Virginia Herold

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

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