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

In the Matter of the Accusation Against: **SAMBAR CORPORATION DBA MEDICAL SQUARE PHARMACY, SAMUEL J. MILLER, PRES, BARBARA MILLER, SEC** 2100 West Third Street Los Angeles, CA 90057 **Permit No. PHY 36470,** **ALBERT GREEN** 11500 San Vincente Boulevard Los Angeles, CA 90049 **Pharmacist License No. RPH 17770,** **ELIANE HANNAH ESHAGHIAN** 542 Dalehurst Avenue Los Angeles, CA 90024 **Pharmacist License No. RPH 76111,** **ROSALINDA S. LEANO** 1003 West Glendale Street West Covina, CA 91790 **Pharmacy Technician Registration No. TCH 10968,** **and**	Case No. 6351 **DEFAULT DECISION AND ORDER AS TO SAMBAR CORPORATION DBA MEDICAL SQUARE PHARMACY AND EDWARD FOX** [Gov. Code, §11520]

EDWARD FOX
11500 San Vicente, #422
Los Angeles, CA 90049

Pharmacist License No. RPH 28768

Respondents.

FINDINGS OF FACT

1. On or about October 28, 2019, Complainant Anne Sodergren, in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs, filed Accusation No. 6351 against Respondents Sambar Corporation dba Medical Square Pharmacy, Samuel J. Miller, PRES, Barbara Miller, SEC, Albert Green, Eliane Hannah Eshaghian, Edward Fox, and Rosalinda S. Leano before the Board. (Accusation attached as Exhibit A.)

2. On or about July 11, 1990, the Board issued Permit No. PHY 36470 to Sambar Corporation dba Medical Square Pharmacy, Samuel J. Miller, PRES., Barbara Miller, SEC. (Respondent MSP). The Permit expired on February 10, 2017, and has not been renewed.

3. On or about April 24, 1974, the Board issued Pharmacist License Number RPH 28768 to Edward Fox (Respondent Fox). The Pharmacist License expired on July 31, 2019, and has not been renewed.

4. On or about October 29, 2019, Respondents were served by Certified and First Class Mail copies of the Accusation No. 6351, Statement to Respondent, Notice of Defense, Request for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6, and 11507.7) at Respondents' address of record which, pursuant to Business and Professions Code section 4100, is required to be reported and maintained with the Board. Respondents' addresses of record were and are: Respondent MSP 2100 West Third Street, Los Angeles, CA 90057 and Respondent Fox 11500 San Vicente, #422, Los Angeles, CA 90049.

5. Service of the Accusation was effective as a matter of law under the provisions of Government Code section 11505(c) and/or Business and Professions Code section 124.

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6. Government Code section 11506(c) states, in pertinent part:

> (c) The respondent shall be entitled to a hearing on the merits if the respondent files a notice of defense . . . and the notice shall be deemed a specific denial of all parts of the accusation . . . not expressly admitted. Failure to file a notice of defense . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its discretion may nevertheless grant a hearing.

7. The Board takes official notice of its records and the fact that Respondent MSP and Respondent Fox failed to file a Notice of Defense within 15 days after service upon them of the Accusation, and therefore waived their right to a hearing on the merits of Accusation No. 6351.

8. California Government Code section 11520(a) states, in pertinent part:

> (a) If the respondent either fails to file a notice of defense . . . or to appear at the hearing, the agency may take action based upon the respondent's express admissions or upon other evidence and affidavits may be used as evidence without any notice to respondent . . . .

9. Pursuant to its authority under Government Code section 11520, the Board finds Respondent is in default. The Board will take action without further hearing and, based on the relevant evidence contained in the Default Decision Investigatory Evidence Packet in this matter, as well as taking official notice of all the investigatory reports, exhibits and statements contained therein on file at the Board's offices regarding the allegations contained in Accusation No. 6351, finds that the charges and allegations in Accusation No. 6351, are separately and severally, found to be true and correct by clear and convincing evidence.

10. The Board finds that the actual costs for Investigation and Enforcement are $38,180.00 as of October 6, 2020.

DETERMINATION OF ISSUES

1. Based on the foregoing findings of fact, Respondent MSP has subjected its Permit No. PHY 36470 and Respondent Fox has subjected his Pharmacist License Number RPH 28768 to discipline.

2. The agency has jurisdiction to adjudicate this case by default.

3. The Board of Pharmacy is authorized to revoke Respondent MSP's Permit and Respondent Fox's Pharmacist License based upon the following violations alleged in the

Accusation which are supported by the evidence contained in the Default Decision Investigatory Evidence Packet in this case:

Respondent MSP

a. Code section 4301(o) - Operational Standards and Security;

b. Code sections 4301(o) and 4110(a) - Operating a Pharmacy Without a Valid License or Permit;

c. Code sections 4301(j) and 4301(o), C.C.R., title 16, sections 1714(b), 1735.5(c)(9), 1735.6(a), and 1735.3(b) - Compounding Facilities and Equipment;

d. Code sections 4301(o) and 4076(a)(11)(A) - Code section 4301(o) and 4076(a)(11)(A);

e. Code section 4301(o) and C.C.R., title 16, 1735.4(a)(2) - Labeling of Compounded Prescriptions;

f. Code sections 4342(a) and 4169(a)(2), C.C.R., title 16, 1735.2 (I)(1), and Health and Saf. Code section 111295 - Expired Medications;

g. Code section 4301(j) and C.C.R., title 16, 1735.2 (g) and (i)(1)(A-F) - Compounding Limitations and Requirements;

h. Code sections 4301(o) and 4169(a)(1), and Health and Saf. Code section 111440(a), and C.C.R., title 16, 1735.3(c) - Prohibited Act / Misbranded;

i. Code section 4301(j) and Health and Saf. Code sections 111295 and 111305 - Adulterated Drugs and Devices;

j. Code section 4301(o) by and through Code section 4081(a) and C.C.R., title 16, 1718 - Records of Acquisitions and Disposition;

k. Code section 4059 (a) and 4063 - Furnishing Dangerous Drugs Without a Prescription;

Respondent Fox

l. Code section 4301(j) and CCR 1735.2 (i)(1)(a-f) - Incorrect Beyond Use Date to a Non-Sterile Compound;

m. Code section 4301(j) and CCR 1735.4(a)(2) - Labeling of Compounded Prescriptions;

n. Code section 4301(j) and Health and Saf. Code section 111397(a) - Misbranded;

o. Code section 4301(o) and Health and Saf. Code sections 111295 and 111305 - Adulterated Drugs and Devises;

ORDER

IT IS SO ORDERED that Permit No. PHY 36470, issued to Respondent Sambar Corporation dba Medical Square Pharmacy, Samuel J. Miller, PRES, Barbara Miller, SEC, is revoked.

IT IS FURTHER ORDERED that Pharmacist License Number RPH 28768, issued to Respondent Edward Fox, is revoked.

Pursuant to Government Code section 11520, subdivision (c), Respondents may serve a written motion requesting that the Decision be vacated and stating the grounds relied on within seven (7) days after service of the Decision on Respondents. The agency in its discretion may vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

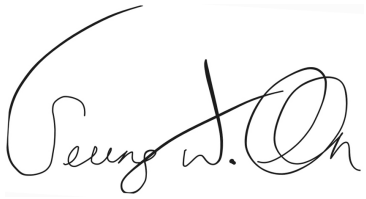
This Decision shall become effective at 5:00 p.m. on May 11, 2022.

It is so ORDERED on April 11, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

63647300.DOCX
DOJ Matter ID:LA2018500261

Attachment:
Exhibit A: Accusation

By 

Seung W. Oh, Pharm. D.
Board President

Exhibit A

Accusation

(SAMBAR CORPORATION DBA MEDICAL SQUARE PHARMACY, ET AL.)

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BEFORE THE
BOARD OF PHARMACY
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In the Matter of the Accusation Against**:** **SAMBAR CORPORATION DBA MEDICAL SQUARE PHARMACY,** **SAMUEL J. MILLER, PRES,** **BARBARA MILLER, SEC** **ALBERT GREEN, PHARMACIST-IN-CHARGE** 2100 West Third Street Los Angeles, CA 90057 **Pharmacy Permit No. PHY 36470,** **ALBERT GREEN** 11500 San Vincente Boulevard Los Angeles, CA 90049 **Pharmacist License No. RPH 17770,** **ELIANE HANNAH ESHAGHIAN** 542 Dalehurst Avenue Los Angeles, CA 90024 **Pharmacist License No. RPH 76111,** **EDWARD FOX** 11500 San Vicente, #422 Los Angeles, CA 90049 **Pharmacist License No. RPH 28768,**	Case No. 6351 **A C C U S A T I O N**

and

ROSALINDA S. LEANO
1003 West Glendale Street
West Covina, CA 91790

Pharmacy Technician Registration No. TCH 10968

Respondents.

PARTIES

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

2. On or about July 11, 1990, the Board issued Permit Number PHY 36470 to Sambar Corporation dba Medical Square Pharmacy, Samuel J. Miller, PRES., Barbara Miller, SEC. (Respondent MSP) with, Albert Green as Pharmacist-in-Charge (PIC)[1]. The Permit expired on February 10, 2017, and has not been renewed.

3. On or about February 15, 1950, the Board issued Pharmacist License Number RPH 17770 to Albert Green (Respondent Green). The Pharmacist License expired on August 31, 2017, and has not been renewed.

4. On or about December 21, 2016, the Board issued Pharmacist License Number RPH 76111 to Eliane Hannah Eshaghian (Respondent Eshaghian). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2020, unless renewed.

5. On or about April 24, 1974, the Board issued Pharmacist License Number RPH 28768 to Edward Fox (Respondent Fox). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2019, unless renewed.

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[1] Albert Green was the PIC for Medical Square Pharmacy from October 1, 2010 through January 31, 2017, after which time, no PIC was assigned to MSP

6. On or about December 14, 1993, the Board issued Pharmacy Technician Registration Number TCH 10968 to Rosalinda S. Leano (Respondent Leano). The Pharmacy Technician Registration expired on January 31, 2019, and has not been renewed.

JURISDICTION

7. 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.

8. Code section 4300, subdivision (a) states, in pertinent part:

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

. . .

9. 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.

STATUTORY PROVISIONS

10. Code section 4110 states, in pertinent part:

> (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

11. Code Section 4301 states, in pertinent part:

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

. . .

(b) Incompetence.

(c) Gross negligence.

. . .

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

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

. . .

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

. . .

(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.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

12. 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.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

13. Code section 4022 states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

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

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

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

14. Code section 4059, states in pertinent part:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7…

15. Code section 4063, states:

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

16. Code section 4081, states, in pertinent part:

(a) All records of manufacture and of sale, acquisition, receipt, shipment, 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, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

17. Code section 4169 states, in pertinent part:

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

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code .

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code .

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

18. Code section 4307 states, in pertinent part:

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, 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 manger, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, partner, or any other person 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.

19. Code section 4342 states, in pertinent part:

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

20. Health and Safety Code (Health and Saf. Code) section 111330 states:

Any drug or device is misbranded if its labeling is false or misleading in any particular.

21. Health and Saf. Code section 111430 states:

A drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States.

22. Health and Saf. Code section 111440 states:

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

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23. Health and Saf. 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.

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24. Health and Saf. Code section 111295 states:

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

25. Health and Saf. Code section 111397 states, in pertinent part:

(a) Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded.

REGULATORY PROVISIONS

26. California Code of Regulations (C.C.R.), title 16, section 1714, states, in pertinent part:

…

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

. . .

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

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

27. C.C.R., title 16, section 1718, states:

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

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

28. C.C.R., title 16, section 1735.2, states, in pertinent part:

. . .

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation,

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision; and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

(iv) the container in which it is packaged,

(v) the expected storage conditions, and

(vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

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29. C.C.R., title 16, section 1735.4, states, in pertinent part:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

. . .

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

30. C.C.R., title 16, section 1735, states, in pertinent part:

. . .

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

31. C.C.R., title 16, section 1735.3, states, in pertinent part:

. . .

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA- registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

32. C.C.R., title 16, section 1735.5, states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation

and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

. . .

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

33. C.C.R., title 16, section 1735.6, states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

34. C.C.R., title 16, section 1761, states:

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

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

35. C.C.R., title 16, section 1770, states:

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare

COST RECOVERY

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

enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DANGEROUS DRUGS

37. *Betahistine*, is the generic name of Vergo 16mg / Serc 16mg, a product unapproved by the Food and Drug Administration.

38. *Sulfanilamide*, 99+%, is a product unapproved by the Food and Drug Administration.

39. *Bystolic* is a beta-blocker used in the treatment of high blood pressure and is categorized as a dangerous drug pursuant to Code section 4022

40. *Nexium* DR 40mg is a proton pump inhibitor (PPI) and is used to treat the symptoms of acid reflux disease and is categorized as a dangerous drug pursuant to Code section 4022

41. *Zetia* is in a class of lipid-lowering compounds that is used to help lower cholesterol in the blood by reducing the amount of cholesterol the body absorbs and is categorized as a dangerous drug pursuant to Code section 4022

FACTS COMMON TO ALL CAUSES FOR DISCIPLINE

42. On or about January 19, 2016, an anonymous compliant was received by the Board regarding MSP. MSP is a small retail pharmacy located inside the "House of Ear Clinic" Medical Building. The complaint alleged numerous violations of pharmacy law including, but not limited to the following:

a. That a pharmacy technician had keys to the pharmacy and opened the pharmacy without a pharmacist;

b. That MSP purchased "outdated" samples;

c. That MSP sold Betahistine, which is not Food and Drug Administration (FDA) approved and which was purchased from Canada;

d. That a compounded drug which did not pass the accuracy test was used;

e. That compounded drugs were not labeled or labeled improperly;

f. That all prescriptions for Viagra, Cialis, and Levitra were forged;

g. That MSP compounded prescriptions using Sulfanilamide which is not authorized to be dispensed by the FDA;

g. That MSP dispensed LBC Complex without expiration dates or a certificate of accuracy; that the ascorbic acid in LBC was no longer time released although it was prescribed in time release form; that LBC was dispensed to patients without prescriptions; that LBC bottles were not labeled with an expiration date or control number; that MSP did not accurately pre-count LBC and only estimates the amount dispensed to patients;

h. That MSP dispensed NAC 600mg with Selenium and Molibdium instead of the prescribed NAC 600mg N-Acetyl Cystein plain with no added ingredients;

i. That medications were mislabeled and the dates on the bottles were not accurate;

j. That refrigerator temperatures were not monitored;

k. That MSP did not have a perpetual inventory for their controlled substances.

43. Additional complaints about MSP were received by the Board on February 28, 2017, and June 5, 2017.

February 8, 2017, Inspection

44. On or about February 8, 2017, Board inspector E.D. and M.K. went to MSP to conduct an inspection and investigation. E.D. and M.K. arrived at 8 a.m., prior to the opening of MSP.

45. At approximately 9:10 a.m., Respondent Leano, a pharmacy technician, was observed opening the pharmacy with the pharmacy keys. Respondent Eshaghian arrived approximately 3 minutes later.

46. During the investigation and inspection, E.D. and M.K. observed the following:

47. The back of the pharmacy, where Respondent Leano stated she performed the compounding, was observed to be cluttered and dirty.

48. Prescription labels did not have the description of the medication printed on the label, including its color, shape, and any identification code that appears on the tablets or capsules.

49. The Refrigerator temperature was not monitored daily and there was no thermometer inside the refrigerator. The refrigerator log showed the temperature was recorded once on

February 20, 2015. Respondent Leano was unable to locate a policy and procedure for monitoring of the refrigerator temperature. There were no records for freezer temperatures.

50. While reviewing the pharmacy stock, 12 expired medications and 10 expired compound ingredients or prescriptions were found in the active stock area.

51. E.D. and M.K. requested and received the following items from Respondent Leano:

a. An invoice from West Coast Laboratories for Niacin

b. A certificate of Analysis for Histamine Sublingual Solution 1:10,000 dated November 18, 2016;

c. MSP's compounding policy and procedures stating all compounded products at MSP were to be given a 6-month expiration date;

d. MSP's compounding training policy and procedure;

e. MSP's controlled substance Scheduled CII perpetual inventory log;

52. In the refrigerator, a compound prescription (Rx439853) for CIPRO/CLOTR/DEX/BA was observed for patient MO, initialed by Respondent Fox. Documentation was collected for compounding the CIPRO/CLOTR/DEX/BA including the stock bottle labeled Cirpofloxacin, Clotrimazole, Dexamethasone, Boric Acid NF and Lactose lot number 111-193. The compounding record showed that Lot No. 111-193 was compounded on February 2, 2017, with an expiration date of August 2, 2017, and was signed by Respondent Fox. Respondent Leano explained that prescription Rx439853 was filled from the 111-193 stock but was given an expiration date of February 7, 2018, one year from when it was compounded. When asked why the expiration date on the prescription was one year, instead of the six months as indicated on compound Lot No. 111-193 and MSP's compound policies, Respondent Leano stated it was a mistake.

53. E.D. and M.K. observed 54 dropper bottles containing 30 milliliters of pre-compounded histamine Subl Sol 1:10,000, Lot 111-188, with a compounded date of November 18, 2016 and an expiration date of May 18, 2017. All of the prescriptions droppers were labeled "histamine Subl Sol 1:10,000."

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54. After a review of records and explanations from Respondent Leano, E.D. and M.K. determined the histamine drops were a compound medication that MSP compounded for House of Ear Clinic's patients. A copy of histamine drops prescription (Rx439819) for patient KM, verified with Respondent Eshaghian's initials was provided by Respondent Leano. Compounding records for lots 111-187, dated November 16, 2016, and Lot 111-188, dated November 18, 2016, both had records showing the use of "Histamine Phosphate USP-Lot:69, with an expiration date marked N/A. Both lots were verified by Respondent Green. The invoice for histamine powder, lot #69, could not be located.

55. E.D. and M.K. located compounded products containing sulfanilamide in the refrigerator, including a prescription (Rx438047) vial for patient RM, labeled CF 50/5MG and initialed by Respondent Fox. Respondent Leano provided documents and explanations regarding the compound preparation containing Sulfanilamide as follows:

a. Sulfanilamide is a compound medication that MSP compounded for House of Ear Clinic's patient's;

b. The prescriptions were processed under the names CSF or CSF HC.

c. Two compounding lots, 111-191 and 111-184, had documented Chemsavers[2]' sulfanilamide, lot number CAS-63-74-1.

d. An invoice from Chemsavers, with an order date of February 10, 2015, documented MSP purchasing 200 grams of sulfanilamide 99+% powder from Chemsavers. Respondent Leano advised that this was the only invoice for sulfanilamide purchased by MSP between January 1, 2015, and February 8, 2017, and that to her knowledge, Chemsavers' sulfanilamide was used to compound the compounded preparations containing sulfanilamide.

e. The bottles of the Chemsavers' sulfanilamide stated "For Research and Development Not for drug, human, animal or food use."

f. Nine sulfanilamide original prescriptions were collected during the inspection.

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[2] Chemsavers offers products for research & development purposes only and products purchased from Chemsavers are not for drug, human, animal, or food use.

56. E.D. and M.K. observed 1,911 tablets of Vergo 16mg or Serc 16 mg and a prescription for Vergo 16mg in a drawer of the pharmacy counter. Respondent Leano provided the following information about the Vergo and Serc:

a. It was a medication that MSP dispensed to House of Ear Clinic's patients.

b. Respondent Leano was not aware where the Vergo or Serc was purchased and was unable to locate any invoices.

c. Vergo 16mg and Serc 16mg were both processed and dispensed under the generic name Betahistine.

d. 23 Betahistine prescriptions were collected during the inspection.

e. As E.D. and M.K. were unable to determine whether Vergo and/or Serc were FDA approved, the Vergo and Serc tablets were embargoed.

57. Inside of the pharmacy drawers labeled LBC Complex capsules, E.D. and M.K. observed several prefilled bottles labeled LBC Complex and several prefilled LBC Complex bottles as well as two LBC prescriptions in the waiting bin.

58. Respondent Leano explained that LBC Complex was a supplement that MSP received from Cosmo Pharm Inc. in bulk and which was pre-counted in 100 or 200 counts and placed them in a shrink-wrapped white bottle.

59. E.D. and M.K. requested that Respondent Eshaghian count the two LBC prescriptions located in the waiting bin which revealed the following:

a. Prescription No. 436832 for 200 LBC Complex capsules contained 199 capsules;

b. Prescription No. 439748 for 100 LBC Complex capsules contained 107 capsules.

60. Respondent Leano advised that she was the one who counted the LBC Prescriptions and was not sure why the counts were inaccurate.

61. E.D. and M.K. requested the inventory on hand report from Respondent Eshaghian on the following medications: Nexium 40mg; Zetia 10mg; Bystolic 10mg; LBC Capsules; Vergo

16mg, Vergo 16mg (Rx 439807); and Serc 16mg. E.D. requested a Drug Utilization Report[3] (DUR) for each of these medications.

62. E.D. asked Respondent Leano to print DURs for Viagra, Cialis and Levitra. From the printed DUR's, a random sample of original prescriptions was requested from Respondent Leano.

63. During the course of the investigation, it was learned that Ms. Miller's change of ownership application was pending with the board and was not completed properly. On July 21, 2016, the Board had noticed and requested Ms. Miller's representative to provide an issue date for the new pharmacy license but did not receive a response. As a result, the issuance of the license was still pending with the Board and MSP's license was not issued.

February 10, 2017, Inspection

64. On or about February 10, 2017, E.D. and M.K. revisited and re-inspected MSP.

65. E.D. and M.K. explained to Respondents Fox and Leano that the previous owner's license (Samuel Miller-deceased) cannot be transferred to the new owner (Barbara Miller). A new pharmacy license needed to have been obtained before the ownership of the pharmacy was transferred and the new pharmacy license must be issued before a new owner can legally operate a pharmacy. MSP was ordered to cease operation until a valid temporary permit or a permanent license was obtained.

66. E.D. and M.K. requested and received an estimated inventory on hand for LBC from Respondent Fox. The LBC was embargoed and the pharmacy was noticed to not remove, sell or dispense of the capsules without the permission of the Board.

67. During the inspection, Barbara Miller contacted the pharmacy and requested that E.D. and M.K. leave, stating the "pharmacy was closed".

68. At the conclusion of the inspection, E.D. went over the inspection report with Respondents Fox and Leano, and a written notice of non-compliance with Code section 4110(a) was issued. MSP was ordered to do the following:

[3] A Drug Utilization Report (DUR) is a computer generated report of the pharmacy's dispensing records. It contains the following data elements: date prescription was dispensed, prescription number, drug name, drug strength, quantity dispensed and national drug code (NDC) and some additional information.

a. Quarantine and recall any raw materials or active pharmaceutical ingredient that was prepared either with expired product(s) or with product lacking an expiration date that did not comply with CCR 1732.2(i), including but not limited to, histamine powder lot #69 and Chemsavers sulfanilamide.

b. Quarantine and recall any raw materials or active pharmaceutical ingredient purchased from any entity not licensed to ship to the pharmacy, including but not limited to, Chemsavers and betahistine.

c. Quarantine procedure: place the product in a tamper resistant box, provide an itemized list of what is inside the box and take pictures of the box. Send the box in for destruction or credit to a board certified reverse distributor.

d. Contact all patients who received the quarantine product(s) and recall the product.

February 23, 2017, Inspection

69. On or about February 23, 2017, E.D. returned to MSP after learning that LBC did not need to be embargoed, MSP was filing a DOB with the Board, and the embargoed Vergo 16mg and Serc 16mg needed to be taken as evidence.

70. Documents previously requested were provided to E.D. from Respondent Leano and Ms. Miller including, but not limited to the following:

a. An invoice from Chemsavers with an order date of February 10, 2015. Per Ms. Miller, this was the only invoice MSP had for the sulfanilamide which was used to compound medications between January 1, 2015, and February 8, 2017;

b. Confirmation emails representing all of the invoices for Vergo 16mg and Serc 16mg from January 1, 2015 and February 8, 2017.

71. Per Respondent Leano and Ms. Miller, MSP did not have an invoice for histamine powder lot #69 and the date of receipt was unknown. A certificate of Analysis was located which showed an expiration date of February 2007.

72. Respondent Leano and Ms. Miller advised that the sulfanilamide used to compound CSF and CSF-HC was purchased from Chemsavers.

73. By using the DUR provided by MSP, E.D. was able to determine that MSP dispensed 690 prescriptions which contained Chemsavers' sulfanilamide between January 1, 2015, and February 8, 2017.

74. A search of the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) and the FDA's approved drug products website failed to locate any approved products for Vergo 16mg, Serc 16mg, or betahistine. E.D. contacted FDA compliance officer L.D.S. who researched the FDA's drug databases and confirmed that Vergo and Serc were not approved in the United States.

75. By using the DUR provided by MSP, E.D. was able to determine that MSP in dispensing prescriptions for Vergo and/or Serc, dispensed 150,752 tablets of betahistine between January 1, 2015, and February 8, 2017.

76. An audit conducted by E.D. showed drug variances for Bystolic 10mg, Nexium DR 40mg, and Zetia 10mg.

77. A random sampling of physicians was conducted to determine the validity of prescriptions for Cialis and Viagra which were dispensed from MSP. The investigation revealed that prescriptions 434280 and 430321 were never authorized by the prescribing physician.

a. Prescription No. 430321 was prescribed twice, on April 30, 2014, and December 10, 2014 by Dr. M.S. MSP dispensed prescription No. 430321 on seven occasions between January 30, 2015, and August 3, 2015. Dr. M.S. advised that these prescriptions were never authorized. This was also confirmed with Dr. M.S.'s office manager. The prescriptions dispensed by MSP were initialed and dispensed by Respondent Green.

b. Prescription No. 434280 was never authorized by Dr. M.S. but was filled my MSP on nine occasions between September 2, 2015, and June 30, 2016. The prescriptions dispensed by MSP were initialed and dispensed by Respondent Green.

78. E.D. concluded that MSP authorized and processed unauthorized prescriptions 430321 and 434280 multiple times, without the prescribing physician's approvals.

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Respondent MSP

FIRST CAUSE FOR DISCIPLINE

(Operational Standards and Security)

79. Respondent MSP is subject to disciplinary action for unprofessional conduct under Code section 4301(o) in that Respondent MSP violated C.C.R. title 16, section 1714(e) by allowing a non-authorized person to possess and use the pharmacy key to access the pharmacy, as set forth in paragraph 45 above, and incorporated by reference herein as though fully set forth.

SECOND CAUSE FOR DISCIPLINE

(Operating a Pharmacy Without a Valid License or Permit)

80. Respondent MSP is subject to disciplinary action for unprofessional conduct under Code section 4301(o) and 4110, subdivision (a) in that Respondent MSP was operating a pharmacy when the owner of the pharmacy was deceased and without a temporary permit or new license being issued to the new owner, Barbara Miller, as set forth in paragraphs 63 and 65 above, and incorporated by reference herein as though fully set forth.

THIRD CAUSE FOR DISCIPLINE

(Compounding Facilities and Equipment)

81. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code section 4301(j); 4301(o), C.C.R., title 16, sections 1714(b), 1735.5(c)(9), 1735.6(a), and 1735.3(b) in that Respondent MSP failed to monitor, maintain and document daily the refrigerator and freezer temperatures where compounded drugs preparations were stored, failed to have policies and procedures in place for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy as set forth in paragraph 49 above, and incorporated by reference herein as though fully set forth.

FOURTH CAUSE FOR DISCIPLINE

(Prescription Labeling Requirements)

82. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code section 4301(o) and 4076(a)(11)(A), in that Respondent MSP filled prescriptions

which were missing the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, as set forth in paragraph 48 above, and incorporated by reference herein as though fully set forth..

FIFTH CAUSE FOR DISCIPLINE

(Labeling of Compounded Prescriptions)

83. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code section 4301(o) and C.C.R., title 16, 1735.4(a)(2), in that Respondent MSP filled prescriptions for patients RM and MO with labels that were missing a name (brand or generic), strength, volume, or weight of each active ingredient, the date compounded, and the lot number or pharmacy reference number as set forth in paragraph 52-55 above, and incorporated by reference herein as though fully set forth.

SIXTH CAUSE FOR DISCIPLINE

(Expired Medications)

84. Complainant incorporates by reference paragraphs 50-53 above, as though fully restated herein.

85. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code sections 4342(a), 4169(a)(2), C.C.R., title 16, 1735.2 (*I*)(1), and Health and Saf. Code section 111295, in that Respondent MSP held the following adulterated medications as part of the pharmacy's active shelves:

a. 54 dropper bottles of histamine Subl Sol 1:10,000 containing an active expired ingredient (Histamine Phosphate USP-Lot:69) with a certificate of analysis with an expiration date of February 2007.

b. 3 expired compounded preparations

c. 12 expired medications

d. 7 compounding ingredients, active and inactive, which lacked manufacturer's expiration date with unknown dates of receipt.

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SEVENTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements)

86. Complainant incorporates by reference paragraphs 52, 54, and 72 above, as though fully restated herein.

87. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) and C.C.R., title 16, 1735.2 (g) and (i)(1)(A-F), in that Respondent MSP compounded prescriptions with incorrect beyond use date to non-sterile compound preparations and/or extended the beyond use date without complying with the standards in CCR 1735.2(i)(3)(A-F) as follows:

a. Respondent MSP compounded prescription No. Rx439853 for patient MO with a one year beyond use date without supporting documents for extending past the 180-day period.

b. Respondent MSP compounded "Lot 111-188, histamine Subl Sol 1:10,000" using an expired active ingredient and with a Certificate of Analysis with an expiration date of February 2007.

c. Respondent MSP compounded prescription No. Rx439819 for patient KM using an expired active ingredient and with a Certificate of Analysis with an expiration date of February 2007.

EIGHTH CAUSE FOR DISCIPLINE

(Prohibited Act / Misbranded)

88. Complainant incorporates by reference paragraphs 55-75 above, as though fully restated herein.

89. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code section 4301(o), Code section 4169(a)(1), and Health and Saf. Code section 111440, subdivision (a), and C.C.R., title 16, 1735.3(c), in that Respondent MSP, violated pharmacy law for obtaining/purchasing and dispensing and/or compounded misbranded drugs as follows:

a. Obtained or purchased Vergo 16mg /Serc 16mg, a dangerous drug unapproved by the Food and Drug Administration from an unlicensed entity. Between January 1, 2015, and February

8,2 017, MSP dispensed 150,752 tablets of Vergo 16mg / Serc 16mg under the generic name of betahistine.

b. Obtained or purchased Sulfanilamide 99+%, a product unapproved by the Food and Drug Administration from and unlicensed entity. Between January 1, 2015, and January 21, 2017, MSP dispensed 690 prescriptions compounded with Sulfanilamide 99+%.

NINTH CAUSE FOR DISCIPLINE

(Adulterated Drugs and Devices)

90. Complainant incorporates by reference paragraphs 55-75 above, as though fully restated herein.

91. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) and Health and Saf. Code sections 111295 and 111305, in that Respondent MSP purchased, held and/or dispensed the following adulterated drugs:

a. On, or about February 10, 2015, Sulfanilamide, 99+%, a product unapproved by the Food and Drug Administration, was purchased from an unlicensed entity. Between January 1, 2015, and February 10, 2017, MSP dispensed 690 compounded prescriptions containing Sulfanilamide 99+%.

b. Between January 1, 2015, and February 8, 2017, Vergo 16mg / Serc 16mg, a product unapproved by the Food and Drug Administration, was purchased from an unlicensed entity. Between January 1, 2015, and February 8, 2017, MSP dispensed 150,752 tablets of Vergo 16mg or Serc 16mg.

TENTH CAUSE FOR DISCIPLINE

(Records of Acquisitions and Disposition)

92. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code section 4301(o) by and through Code section 4081(a) and C.C.R., title 16, 1718, in that Respondent MSP failed maintain a current inventory and records of acquisition and disposition of dangerous drugs as it could not account for the following overages of dangerous drugs between April 1, 2015, and February 8, 2017:

a. 450 tablets of Bystolic 10mg

b. 345 capsules of Nexium DR 40mg

c. 219 tablets of Zetia 10mg

ELEVENTH CAUSE FOR DISCIPLINE

(Furnishing Dangerous Drugs Without a Prescription)

93. Respondent MSP is subject to disciplinary action for unprofessional conduct under section Code section 4059 (a) and 4063, in that Respondent MSP dispensed multiple times the following prescriptions without a prescriber's authorization:

a. Viagra 100mg (Rx 430321) to patient RG was dispensed 7 times

b. Viagra 100mg (Rx 434280) to patient RG was dispensed 9 times

Respondent Green

TWELFTH CAUSE FOR DISCIPLINE

(License Required)

94. Respondent Green is subject to disciplinary action under Code section 4110(a), by and through Code section 4301, subdivision (o), in that on February 10, 2017, during an inspection at MSP, it was determined that MSP was operating a pharmacy whose owner, Samuel Miller, was deceased, and without a new pharmacy license being issued to the new owner, Barbara Miller. Respondent Green, was the Pharmacist-in-Charge and was operating MSP without a valid temporary permit or temporary license.

THIRTEENTH CAUSE FOR DISCIPLINE

(Compounding Facilities and Equipment)

95. Respondent Green is subject to disciplinary action for unprofessional conduct under section Code section 4301(o), C.C.R., title 16, section 1714(b), 1735.5(c)(9), 1735.6(a), and 1735.3(b) in that Respondent Green failed to monitor, maintain and document daily the refrigerator and freezer temperatures where compounded drugs preparations were stored, failed to ensure that MSP had policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy as set forth in paragraph 49 above, and incorporated by reference herein as though fully set forth.

FOURTEENTH CAUSE FOR DISCIPLINE

(Labeling of Compounded Prescriptions)

96. Respondent Green is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) and C.C.R., title 16, 1735.4(a)(2), in that Respondent Green, acting as Pharmacist-in-Charge, had permitted prescription No. RX438047 for patient RM, to be labeled inadequately, as more thoroughly described in paragraphs 54-55 above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Incorrect Beyond Use Date to a Non-Sterile Compound)

97. Respondent Green is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) and C.C.R., title 16, 1735.2 (g) and (i)(1)(A-F), in that Respondent Green, while acting as Pharmacist-in-Charge, verified compound Lot 111-188 and compound Lot 111-187, using an expired active ingredient and assigned a an incorrect beyond use date to a non-sterile compound (180 days) and/or extended the beyond use date without complying with the standards set forth in CCR 1735.2(g)(i-vi), as more thoroughly described in paragraphs 53-54 above, and incorporate by reference herein as though fully set forth.

SIXTEENTH CAUSE FOR DISCIPLINE

(Misbranded)

98. Complainant incorporates by reference paragraphs 55-75 above, as though fully restated herein.

99. Respondent Green is subject to disciplinary action for unprofessional conduct under section Code section 4301(j), Code section 4169(a)(1), and Health and Saf. Code section 111440, subdivision (a), and CCR 1735.3(c), in that Respondent Green, while acting as Pharmacist-in-Charge, violated pharmacy law as follows:

a. Obtained or purchased Vergo 16mg /Serc 16mg, a dangerous drug unapproved by the Food and Drug Administration from an unlicensed entity. MSP dispensed 148,988 tablets of Vergo 16mg / Serc 16mg under the generic name of betahistine.

b. Obtained or purchased Sulfanilamide 99+%, a product unapproved by the Food and Drug Administration from and unlicensed entity. Between January 1, 2015, and January 31, 2017, MSP dispensed 687 prescriptions compounded with Sulfanilamide 99+%.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Adulterated Drugs and Devises)

100. Complainant incorporates by reference paragraphs 55-75 above, as though fully restated herein.

101. Respondent Green is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) and Health and Saf. Code sections 111295 and 111305, in that Respondent Green, while acting as Pharmacist-in-Charge, at MSP, obtained, purchased, or dispensed the following adulterated drugs:

a. On, or about February 10, 2015, Sulfanilamide, 99+%, a product unapproved by the Food and Drug Administration, was purchased from an unlicensed entity. Between January 1, 2015, and January 31, 2017, MSP dispensed 687 prescriptions compounded with Sulfanilamide 99+%.

b. Between January 1, 2015, and January 31, 2017, Vergo 16mg / Serc 16mg, a product unapproved by the Food and Drug Administration, was purchased from an unlicensed entity. Between January 1, 2015, and January 1, 2017, MSP dispensed 148,988 tablets of Vergo 16mg or Serc 16mg.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Records of Acquisition and Disposition)

102. Respondent Green is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) by and through Code section 4081(a) and CCR 1718, in that Respondent Green, while acting as Pharmacist-in-Charge, at MSP, failed to account for the following overages of dangerous drugs between April 1, 2015, and February 8, 2017:

a. 450 tablets of Bystolic 10mg

b. 345 capsules of Nexium DR 40mg

c. 219 tablets of Zetia 10mg

NINETEENTH CAUSE FOR DISCIPLINE

(Furnishing Dangerous Drugs Without a Prescription)

103. Respondent Green is subject to disciplinary action for unprofessional conduct under section Code section 4059 (a) and 4063, in that Respondent Green, while acting as Pharmacist-in-Charge, at MSP, dispensed multiple times the following prescriptions without a prescriber's authorization:

a. Viagra 100mg (Rx 430321) to patient RG was dispensed 7 times

b. Viagra 100mg (Rx 434280) to patient RG was dispensed 9 times

Respondent Leano

TWENTIETH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

104. Respondent Leano is subject to disciplinary action under CCR 1714, subdivisions (d) and (e), by and through Code section 4301, subdivision (o), in that on February 8, 2017, during an inspection at MSP, Respondent Leno was determined to be in possession of the pharmacy's key, which was not maintained in a tamper evident container, and accessed the pharmacy using the key.

Respondent Fox

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Incorrect Beyond Use Date to a Non-Sterile Compound)

105. Complainant incorporates by reference paragraphs 52, 54, and 72 above, as though fully restated herein.

106. Respondent Fox is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) and CCR 1735.2 (i)(1)(a-f) for giving an incorrect beyond use date to a non-sterile compound (180 days) and/or extending the beyond use date without complying with the standards set forth in CCR 1735.2(g)(i-vi), .

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TWENTY-SECOND CAUSE FOR DISCIPLINE

(Labeling of Compounded Prescriptions)

107. Complainant incorporates by reference paragraphs 52 through 72 above, including all subparts, as though fully restated herein.

108. Respondent Fox is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) and CCR 1735.4(a)(2), in that Respondent Fox filled and verified a prescription for patient MO and prescription for patient RM, with labels missing the following required items:

a. The name (brand or generic), strength, volume, or weight of each active ingredient;

b. The date compounded;

c. The lot number or pharmacy reference number;

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Misbranded)

109. Respondent Fox is subject to disciplinary action for unprofessional conduct under section Code section 4301(j) and Health and Saf. Code section 111397, subdivision (a), in that Respondent Fox verified and dispensed prescriptions for Betahistadine, a dangerous drug, and prescriptions using Sulfanilamide, 99+% powder. Both Betahistadine and Sulfanilamide 99+% are unapproved by the Food and Drug Administration and were purchased from unlicensed entities, as more thoroughly set forth in paragraphs 55 through 76, and all subparts above, and incorporated by reference as though fully stated herein.

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Adulterated Drugs and Devises)

110. Respondent Fox is subject to disciplinary action for unprofessional conduct under section Code section 4301(o) and Health and Saf. Code sections 111295 and 111305, in that Respondent Fox verified and dispensed adulterated drugs as defined in Health and Saf. Code section 111260, by filling prescriptions for Betahistine and prescriptions using Sulfanilamide, 99+% powder, as more thoroughly set forth in paragraphs 55-76 above which are incorporated by reference as though fully stated herein.

Respondent Eshaghian

TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements)

111. Respondent Eshaghian is subject to disciplinary action for unprofessional conduct under section Code section 4301(o) and CCR 1735.2 (g) and (i)(1)(a-f) for giving an incorrect beyond use date to a non-sterile compound (180 days) and/or extending the beyond use date without complying with the standards set forth in CCR 1735(i)(1)(A-F), as more thoroughly set forth in paragraphs 52 through 54, and 72 above, which are incorporated by reference as though fully restated herein.

TWENTY-SIXTH CAUSE FOR DISCIPLINE

(Misbranded)

112. Respondent Eshaghian is subject to disciplinary action for unprofessional conduct under section Code section 4301(o) and Health and Saf. Code section 111397, subdivision (a), in that Respondent Eshaghian verified and dispensed prescriptions for Betahistadine, a dangerous drug, and prescription using Sulfanilamide, 99+% powder. Both Betahistadine and Sulfanilamide 99+% are unapproved by the Food and Drug Administration and were purchased from unlicensed entities, as more thoroughly set forth in paragraphs 55 through 76, and all subparts above, and incorporated by reference as though fully stated herein.

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

(Adulterated Drugs and Devises)

113. Respondent Eshaghian is subject to disciplinary action for unprofessional conduct under section Code section 4301(o) and Health and Saf. Code sections 111295 and 111305, in that Respondent Fox verified and dispensed adulterated drugs as defined in Health and Saf. Code section 111260, by filling prescriptions for Betahistine and prescriptions using Sulfanilamide, 99+% powder, as more thoroughly set forth in paragraphs 55-76, and all subparts above.

OTHER MATTERS

114. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 36470 issued to Sambar Corporation dba Medial Square Pharmacy, Sambar Corporation dba

Medical Square 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 36470 is placed on probation or until Pharmacy Permit Number PHY 36470 is reinstated if it is revoked.

115. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 36470 issued to Sambar Corporation dba Medial Square Pharmacy, while Barbara Miller has been a manager, administrator, owner, director, associate, partner, or any other person with management or control and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Barbara Miller 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 36470 is placed on probation or until Pharmacy Permit Number PHY 36470 is reinstated if it is revoked.

116. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 17770 issued to Albert Green, Respondent Green shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 17770 is placed on probation or until Pharmacist License Number RPH 17770 is reinstated if it is revoked.

117. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 76111 issued to Eliane Hannah Eshaghian, Respondent Eshaghian shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 76111 is placed on probation or until Pharmacist License Number RPH 76111 is reinstated if it is revoked.

118. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 28768 issued to Edward Fox, Respondent Fox shall be prohibited from serving as a manager, administrator, owner, member , officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 28768 is placed on probation or until Pharmacist License Number RPH 28768 is reinstated if it is revoked.

DISCIPLINE CONSIDERATIONS

119. On or about January 5, 2016, Respondent MSP was issued Citation No. CI 2014 64466, for violating CCR 1715, failure to complete a Self-Assessment by the Pharmacist-in-Charge. The Citation is now final.

120. On or about May 5, 2017, Respondent MSP was issued Citation No. CI 2016 71491, for violating CCR 1714(b), Operational Standards and Security, and Code section 4081(a), Maintenance of Records. The Citation is now final but Respondent has failed to pay the fine in the amount of $700.00. The underlying facts of the citation are that MSP could not account for the following drug loss from their inventory between December 28,2015 and July 14, 2016:

a. Hydrocodone/APAP 5-325#1000

b. Oxycodone/APAP 5-325#100

c. Oxycodone/APAP 10-325#200

d. Oxycontin XR 10mg#100

121. On or about January 5, 2016, Respondent Green was issued Citation No. CI 2015 68516, for violating CCR 1715, failure to complete a Self-Assessment of the pharmacies compliance with pharmacy claw by the Pharmacist-in-Charge. The Citation is now final and has been completed

122. On or about November 29, 2017, Respondent Green was issued Modified Citation No. CI 2016 75074, for violating CCR 1714(d), Operational Standards and Security, and Code section 4081(a), Maintenance of Records. The Citation is now final and has been completed. The underlying facts are that MSP could not account for the following drug loss from their inventory between December 28,2015 and July 14, 2016:

a. Hydrocodone/APAP 5-325#1000

b. Oxycodone/APAP 5-325#100

c. Oxycodone/APAP 10-325#200

d. Oxycontin XR 10mg#100

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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 Permit Number PHY 36470, issued to Sambar Corporation dba Medical Square Pharmacy, Samuel J. Miller, PRES, Barbara Miller, SEC;

2. Revoking or suspending Pharmacist License Number RPH 17770, issued to Albert Green;

3. Revoking or suspending Pharmacist License Number RPH 76111, issued to Eliane Hannah Eshaghian;

4. Revoking or suspending Pharmacist License Number RPH 28768, issued to Edward Fox;

5. Revoking or suspending Pharmacy Technician Registration Number TCH 10968, issued to Rosalinda S. Leano;

6. Prohibiting Barbara Miller from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 36470 is placed on probation or until Pharmacy Permit Number PHY 36470 is reinstated if Pharmacy Permit Number PHY 36470 issued to Sambar Corporation dba Medical Square Pharmacy is revoked;

7. Prohibiting Albert Green from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 17770 is placed on probation or until Pharmacist License Number RPH 17770 is reinstated if Pharmacist License Number RPH 17770 issued to Albert Green is revoked;

8. Prohibiting Eliane Hannah Eshaghian from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 76111 is placed on probation or until Pharmacist License Number RPH 76111 is reinstated if Pharmacist License Number RPH 76111 issued to Eliane Hannah Eshaghian is revoked;

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9. Prohibiting Edward Fox from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 28768 is placed on probation or until Pharmacist License Number RPH 28768 is reinstated if Pharmacist License Number RPH 28768 issued to Edward Fox is revoked;

10. Ordering Sambar Corporation, dba Medical Square Pharmacy 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;

11. Ordering Albert Green 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;

12. Ordering Eliane Hannah Eshaghian 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;

13. Ordering Edward Fox 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;

14. Ordering Rosalina S. Leano 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;

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

DATED: October 28, 2019

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

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