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

In the Matter of the First Amended Accusation Against:

COUNTY OF SAN MATEO dba
SAN MATEO MEDICAL CENTER
Original Hospital Pharmacy Permit No. HPE 19576,

COUNTY OF SAN MATEO dba
SAN MATEO MEDICAL CENTER
MAIN PHARMACY ROOM 1PH021
Sterile Compounding Permit No. LSE 100358,

and

GARY LYNN HORNE,
Pharmacist License No. RPH 42499,

Respondents.

Agency Case No. 6756

OAH No. 2020100517

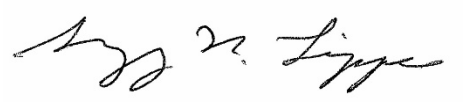
DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on June 23, 2021.

It is so ORDERED on May 24, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

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

In the Matter of the First Amended Accusation Against: **COUNTY OF SAN MATEO dba SAN MATEO MEDICAL CENTER 222 West 39th Avenue-1PH021 San Mateo, CA 94403** **Original Hospital Pharmacy Permit No. HPE 19576,** **COUNTY OF SAN MATEO dba SAN MATEO MEDICAL CENTER MAIN PHARMACY ROOM 1PH021 222 West 39th Avenue-1PH021 San Mateo, CA 94403** **Sterile Compounding Permit No. LSE 100358,** **and** **GARY LYNN HORNE 2934 Esser Ct. Carson City, NV 89703** **Pharmacist License No. RPH 42499** Respondents.	Case No. 6756 OAH No. 2020100517 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO COUNTY OF SAN MATEO DOING BUSINESS AS SAN MATEO MEDICAL CENTER AND SAN MATEO MAIN PHARMACY ROOM 1PH021 ONLY**

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

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Aspasia A. Papavassiliou, Deputy Attorney General.

2. County of San Mateo (Respondent) is represented in this proceeding by Deputy County Counsel Sarah H. Trela, Office of the County Counsel—County of San Mateo, whose address is: Hall of Justice and Records, 400 County Center, 6th Floor, Redwood City, CA 94063-1662.

3. On or about June 1, 1980, the Board of Pharmacy issued Original Hospital Pharmacy Permit Number HPE 19576 to Respondent doing business as San Mateo Medical Center. On or about June 18, 2014, the Board of Pharmacy issued Sterile Compounding Permit Number LSE 100358 to Respondent doing business as San Mateo Medical Center Main Pharmacy Room 1PH021. The Original Hospital Pharmacy Permit and Sterile Compounding Permit were in full force and effect at all times relevant to the charges brought in this First Amended Accusation and will expire on October 1, 2021, unless renewed.

JURISDICTION

4. First Amended Accusation No. 6756 was filed before the Board, and is currently pending against Respondent.[1] The First Amended Accusation and all other statutorily required documents were properly served on Respondent on September 17, 2020. Respondent timely filed its Notice of Defense contesting the First Amended Accusation No. 6756. A copy of First Amended Accusation No. 6756 is attached as exhibit A and incorporated by reference.[2]

[1] The First Amended Accusation against remaining respondent Gary Lynn Horne is being resolved in a separate stipulation as part of a global settlement contingent on all parties' agreement to a settlement.

[2] Causes for Discipline 8, 9, and 10 incorrectly refer to subparts of California Code of Regulations, title 16, section 17535 instead of section 1735. The parties agree that the pleading will be deemed to refer to the correct code section.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 6756. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent understands and agrees that the charges and allegations in First Amended Accusation No. 6756, if proven at a hearing, constitute cause for imposing discipline upon its Original Hospital Pharmacy Permit and Sterile Compounding Permit.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation, and that Respondent hereby gives up its right to contest those charges.

10. Respondent agrees that its Original Hospital Pharmacy Permit and Sterile Compounding Permit are subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

11. If a subsequent Accusation alleging similar violations as alleged in First Amended Accusation No. 6756 is filed against Respondent, then the charges and allegations in First Amended Accusation No. 6756 shall be deemed to be true and correct.

RESERVATION

12. The admissions made by Respondent in this stipulation are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Hospital Pharmacy License No. HPE 19576, issued to County of San Mateo (Respondent) doing business as San Mateo Medical Center, and Sterile Compounding Permit No. LSC 100358 issued to Respondent doing business as San Mateo Medical Center Main Pharmacy Room 1PH021, are revoked. However, the revocations are stayed and Respondent is placed on probation for two (2) years on the following terms and conditions.

1. **Definition of Respondent**

For the purposes of these terms and conditions, "respondent" shall refer to San Mateo County doing business as San Mateo Medical Center and/or San Mateo County doing business as San Mateo Medical Center Main Pharmacy Room 1PH021. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's original pharmacy permit or sterile compounding permit or

which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

3. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

6. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent shall pay to the

board its costs of investigation and prosecution in the amount of $10,000.00. Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

7. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

8. **Status of License**

Respondent shall, at all times while on probation, maintain a current original pharmacy permit and sterile compounding permit with the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

9. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent wish to discontinue business, respondent may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent further stipulates that it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. **Sale or Discontinuance of Business**

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. **Notice to Employees**

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

12. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and all of its officers, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and

regulations governing the practice of pharmacy.[3] The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. **Premises Open for Business**

Respondent shall remain open and engaged in its ordinary business as a hospital pharmacy in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a hospital pharmacy for a minimum of 120 hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a hospital in California for a minimum of 120 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. **Posted Notice of Probation**

Respondent shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation. Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

[3] Respondent's Director of Pharmacy may sign on behalf of all owners and officers.

15. **Violation of Probation**

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall be automatically extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in First Amended Accusation No. 6232 shall be deemed to be true and correct.

16. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

17. **Consultant Pharmacist Review of Pharmacy Operations**

During the period of probation, respondent shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent with state and federal laws and regulations governing the practice of pharmacy. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. During the period of probation, the board or its designee retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent Pharmacy's operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

18. **Remedial Education**

Within ninety (90) days of the effective date of this decision, Respondent shall submit to

the Board or its designee, for prior approval, an appropriate program of remedial education for compounding staff. Specifically, the program of remedial education shall consist of at least six (6) hours of training in sterile compounding. The remedial education shall be completed within one year from the effective date of the decision at Respondent's own expense. At least 50 percent of the remedial education shall be in-person or live webinar. Respondent shall submit to the Board the original transcripts or certificates of completion for the above-required course(s). All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

ACCEPTANCE

On behalf of Respondent County of San Mateo, I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with Deputy County Counsel Sarah H. Trela. I have authority to sign for the county and understand the stipulation and the effect it will have on the county's Original Hospital Pharmacy License, and Sterile Compounding Permit. The county enters into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

For the COUNTY OF SAN MATEO,
dba SAN MATEO MEDICAL CENTER and
dba SAN MATEO MEDICAL CENTER
MAIN PHARMACY ROOM 1PH021
Respondent

I have read and fully discussed with Respondent County of San Mateo, doing business as San Mateo Medical Center and as San Mateo County Medical Center Main Pharmacy Room 1PH021, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

SARAH H. TRELA
Attorney for Respondent

the Board or its designee, for prior approval, an appropriate program of remedial education for compounding staff. Specifically, the program of remedial education shall consist of at least six (6) hours of training in sterile compounding. The remedial education shall be completed within one year from the effective date of the decision at Respondent's own expense. At least 50 percent of the remedial education shall be in-person or live webinar. Respondent shall submit to the Board the original transcripts or certificates of completion for the above-required course(s). All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

ACCEPTANCE

On behalf of Respondent County of San Mateo, I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with Deputy County Counsel Sarah H. Trela. I have authority to sign for the county and understand the stipulation and the effect it will have on the county's Original Hospital Pharmacy License, and Sterile Compounding Permit. The county enters into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agrees to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 3/4/2021

For the COUNTY OF SAN MATEO,
dba SAN MATEO MEDICAL CENTER and
dba SAN MATEO MEDICAL CENTER
MAIN PHARMACY ROOM 1PH021
Respondent

I have read and fully discussed with Respondent County of San Mateo, doing business as San Mateo Medical Center and as San Mateo County Medical Center Main Pharmacy Room 1PH021, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 3/4/2021

SARAH H. TRELA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General

ASPASIA A. PAPAVASSILIOU
Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: March 5, 2021

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General

ASPASIA A. PAPAVASSILIOU
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 6756

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BEFORE THE
BOARD OF PHARMACY
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In the Matter of the Accusation Against**:** **COUNTY OF SAN MATEO dba SAN MATEO MEDICAL CENTER** **222 West 39th Avenue-1PH021** **San Mateo, CA 94403** **Original Hospital Pharmacy Permit No. HPE 19576,** **COUNTY OF SAN MATEO dba SAN MATEO MEDICAL CENTER MAIN PHARMACY ROOM 1PH021** **222 West 39th Avenue-1PH021** **San Mateo, CA 94403** **Sterile Compounding Permit No. LSE 100358,** **and** **GARY LYNN HORNE** **222 West 39th Avenue** **San Mateo, CA 94403** **Pharmacist License No. RPH 42499** Respondents.	Case No. 6756 **FIRST AMENDED** **ACCUSATION**

PARTIES

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

2. On or about June 1, 1980, the Board of Pharmacy issued Original Hospital Pharmacy Permit Number HPE 19576 to San Mateo County doing business as San Mateo Medical Center (Respondent SMMC). On or about June 18, 2014, the Board of Pharmacy issued Sterile Compounding Permit Number LSE 100358 to San Mateo County doing business as San Mateo Medical Center Main Pharmacy Room 1PH021 (Respondent SMMC 1PH021). The Original Hospital Pharmacy Permit and Sterile Compounding Permit were in full force and effect at all times relevant to the charges brought in this First Amended Accusation and will expire on October 1, 2020, unless renewed.

3. On or about March 31, 1989, the Board of Pharmacy issued Pharmacist License Number RPH 42499 to Gary Lynn Horne (Respondent Horne). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this First Amended Accusation and will expire on August 31, 2020, unless renewed.

JURISDICTION

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

5. Section 4300 of the Code states:

> (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.

(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

(1) Medical or psychiatric evaluation.

(2) Continuing medical or psychiatric treatment.

(3) Restriction of type or circumstances of practice.

(4) Continuing participation in a board-approved rehabilitation program.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

(7) Compliance with laws and regulations governing the practice of pharmacy.

(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

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

6. Section 4300.1 of the Code states:

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

STATUTORY PROVISIONS

7. Section 4301 of the Code states:

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:

. . .

(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.

8. Section 4113, subdivision (c) of the Code states:

(c) The 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.

REGULATORY PROVISIONS

9. California Code of Regulations, title 16, section 1751.8, subdivision (d)(1) states:

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

. . .

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed;

10. California Code of Regulations, title 16, section 1735.1 states, in pertinent part:

. . .

(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

. . .

(e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

. . .

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

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

. . .

(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.

(2) For sterile compounded drug preparations, 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 sterile compounded drug product preparation,

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

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

(D) The beyond use date assigned for sterility in section 1751.8.

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subdivision may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

. . .

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

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

. . .

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

. . .

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

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72)

hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

. . .

(J) Documentation of quality reviews and required post-compounding process and procedures.

13. California Code of Regulations, 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.

. . . .

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

. . .

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

14. California Code of Regulations, title 16, section 1735.6, states, in pertinent part:

. . .

(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) (A) For sterile compounding, each BSC or CACI shall be externally exhausted.

(B) For nonsterile compounding, a BSC, a CACI, or other containment

ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted. For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

. . .

15. California Code of Regulations, title 16, section 1735.7, subdivision (a) states:

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

16. California Code of Regulations, title 24, section 1250.4 states:

The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

. . .

2. Have non-porous and cleanable surfaces, walls, floors and floor coverings.

. . .

17. Code of Federal Regulations, title 21, section 1304.04, subdivision (f)(1) states:

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant[.]

18. Code of Federal Regulations, title 21, section 1304.11, subdivision (a) states:

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the

possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

19. Code of Federal Regulations, California Code of Regulations, title 21, section 1304.04, subdivision (f)(1) states:

> (f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:
>
> (1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant[.]

COST RECOVERY

20. Section 125.3 of the Code states, 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.

FACTUAL ALLEGATIONS

21. Respondent Horne has been the pharmacist-in-charge (PIC) of Respondent SMMC since on or about June 27, 2006, and the PIC of Respondent SMMC 1PH021 since on or about June 18, 2014.

22. The Board inspected SMMC on September 3, 2018. Respondent Horne assisted the investigators.

23. During the course of their inspections, the inspectors discovered that between approximately June 1, 2018, and September 13, 2018, Respondents had assigned beyond use dates to 109 compounded sterile preparations that exceeded 12 hours from when the preparations were compounded. The preparations had been compounded in an area that did not meet clean room requirements. At the time of the inspection, Respondent SMMC only had a segregated sterile compounding area and the preparations were compounded with aseptic manipulations.

24. The inspectors discovered that between approximately June 1, 2018 and September 13, 2018, Respondents failed to document the beyond use dates for at least 127 compounded sterile preparations on Respondent SMMC's compounding log.

25. The inspectors discovered that Respondents' compounding logs were incomplete because they lacked the lot, manufacturer, and expiration date for all ingredients used in at least 55 compounded sterile preparations.

26. The inspectors discovered that several of the compounding logs were also missing a pharmacy-assigned unique reference or lot number for at least 46 compounded sterile preparations.

27. The inspectors discovered that Respondents' compounding logs did not include complete documentation of quality reviews and post-compounding process and procedures for at least 100 compounded sterile preparations.

28. The inspectors discovered that Respondents failed to document any annual review of Respondent SMMC's policies and procedures by the PIC.

29. The inspectors discovered that Respondents failed to maintain documentation demonstrating that pharmacy personnel involved in compounding preparations had the skills and training needed to properly and accurately perform their assigned responsibilities. Respondents failed to maintain documentation that pharmacy personnel involved in compounding preparations had received training in all aspects of policies and procedures. Specifically, Respondents had failed to document if environmental services staff had received training related to garbing, meaning training on the proper clothing to wear.

30. The inspectors discovered that Respondents had failed to maintain Respondent SMMC's controlled substance Schedule II inventory separate from its controlled substance Schedule III-V inventory. Respondent SMMC had comingled its controlled substance Schedule II inventory with its controlled substance Schedule III-V inventory.

31. The inspectors discovered that Respondents' biennial inventory taken on or about June 27, 2017, did not indicate if the inventory was taken at the opening or closing of the business.

32. The inspectors discovered that the areas in front of the compounding aseptic isolator, biological safety cabinet, and sink had mats that were not smooth or easily cleanable.

33. On or about September 23, 2019, the Board conducted an annual inspection for the renewal of the sterile compounding permit of Respondent SMMC 1PH021 and found that Respondents were still engaging in violations of pharmacy law.

CAUSES FOR DISCIPLINE BASED ON 2018 INSPECTION

FIRST CAUSE FOR DISCIPLINE
(Incorrect Assignment of Beyond Use Date)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1751.8, subd. (d)(1))

34. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action because between June 1, 2018, and September 13, 2018, Respondents compounded sterile preparations and assigned the preparations beyond use dates that exceeded 12 hours from when the preparations were compounded for at least 109 compounded sterile preparations. (Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1751.8, subd. (d)(1)).) The circumstances are explained in paragraphs 21 to 23, above.

SECOND CAUSE FOR DISCIPLINE
(Incomplete Compounding Records)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1735.3)

35. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action because they failed to keep complete compounding records, as set forth in paragraphs 21 to 22, and 24 to 27, above. (Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1735.3.) The violations are as follows:

a. **Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(H)**: Respondents kept incomplete compounding logs that failed to include the beyond use dates for at least 127 compounded sterile preparations on Respondents' compounding log.

b. **Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(F)**: Respondents kept incomplete compounding logs that lacked the lot, manufacturer, and expiration date for all ingredients used in at least 55 compounded sterile preparations.

c. **Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(G)**: Respondents kept incomplete compounding logs that did not include a pharmacy-assigned unique reference or lot number for at least 46 compounded sterile preparations.

d. **Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(J)**: Respondents kept incomplete compounding logs that did not include the complete documentation of quality reviews and post-compounding process and procedures for at least 100 compounded sterile preparations.

THIRD CAUSE FOR DISCIPLINE
(Incomplete Policies and Procedures)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1735.5, subd. (c)(7))

36. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action because Respondents did not have documentation to reflect the annual review of the policies and procedures by the PIC. (Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1735.5, subd. (c)(7).) The circumstances are explained in paragraphs 21, 22, and 28, above.

FOURTH CAUSE FOR DISCIPLINE
(Incomplete Training Records)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1735.7, subd. (a))

37. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action because Respondents failed to maintain documentation of whether environmental services staff had received training related to garbing, meaning training on the proper clothing to wear. (Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1735.7, subd. (a).) The circumstances are explained in paragraphs 21, 22, and 29, above.

FIFTH CAUSE FOR DISCIPLINE
(Failure to Comply with the Code of Federal Regulations—Controlled Substance Inventory)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Code Fed. Regs., tit. 21, §§ 1304.04/1304.11)

38. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action because Respondents failed to comply with the Code of Federal Regulations regarding their controlled substance inventory, as set forth in paragraphs 21, 22, 30, and 31, above. (Bus. &

Prof. Code, §§ 4301, subd. (o)/4113; Code Fed. Regs., tit. 21, §§ 1304.04, subd. (f)(1), 1304.11, subd. (a).) The violations are as follows:

a. **Code Fed. Regs., tit. 21, § 1304.04, subd. (f)(1)**: Respondents failed to maintain a controlled substance Schedule II inventory separate from their controlled substance Schedule III-V inventory. Respondents comingled their controlled substance Schedule II inventory with its controlled substance Schedule III-V inventory.

b. **Code Fed. Regs., tit. 21, § 1304.11, subd. (a)**: Respondents' biennial inventory taken on or about June 27, 2017, did not indicate if the inventory was taken at the opening or closing of business.

SIXTH CAUSE FOR DISCIPLINE
(Floor Mats in Compounding Area Insufficiently Cleanable)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 24, § 1250.4)

39. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action because Respondents had mats that were not smooth or easily cleanable in the areas in front of the compounding aseptic isolator, biological safety cabinet, and sink. (Bus. & Prof. Code, §§ 4301, subd. (o)/4113Cal. Code Regs., tit. 24, § 1250.4.) The circumstances are explained in paragraph 32, above.

CAUSES FOR DISCIPLINE BASED ON 2019 INSPECTION

SEVENTH CAUSE FOR DISCIPLINE
(Incorrect Assignment of Beyond Use Date)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1751.8, subd. (d)(1))

40. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action for incorrect assignment of beyond use date because between on or about March 6, 2019, through on or about September 23, 2019, Respondents incorrectly assigned beyond use dates that exceeded 12 hours for 79 sterile medications (Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 1751.8, subd. (d)(1)). Moreover, Respondents compounded the preparations in an area that failed to meet the definition of a clean room under California Code of Regulations, title 16, section 1735.1, subdivision (e)(2).

EIGHTH CAUSE FOR DISCIPLINE
(Failure to Follow Written Policies and Procedures)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 17535.5, subd. (a))

41. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action for failure to follow written policies and procedures because between March 6, 2019, and September 23, 2019, Respondents assigned beyond use dates exceeding 12 hours for at least 79 sterile compounded preparations compounded in a Biological Safety Cabinet in a segregated compounding area, when Respondents' written policies and procedures required a beyond use date of 12 hours or less for those preparations (Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 17535.5, subd. (a)).

NINTH CAUSE FOR DISCIPLINE
(Failure to Maintain Sterile Compounding Records)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 17535.3, subd. (a)(2))

42. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action for failure to maintain sterile compounding records because a review of the compounding logs dated from March 6, 2019 through September 23, 2019, revealed missing items required on compounding logs for compounded sterile products (Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 17535.3, subd. (a)(2)). The compounding logs were incomplete as follows:

- 12 compounding logs were missing the strength of the compound;
- three compounding logs were missing the date the drug was compounded;
- four compounding logs were missing the identity of the person compounding;
- one compounding log was missing the manufacturer, lot number and/or expiration date of each component used; and
- 24 compounding logs were missing the beyond use date or beyond use date and time.

TENTH CAUSE FOR DISCIPLINE
(Compounding Hazardous Drugs in Environment Failing to Meet Requirements)
(Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 17535.6, subd. (e))

43. Respondent SMMC's Pharmacy License, Respondent SMMC 1PH021's Sterile

Compounding Permit, and Respondent Horne's Pharmacist License are subject to disciplinary action for compounding hazardous drugs in an environment failing to meet pressure, venting and air change requirements (Bus. & Prof. Code, §§ 4301, subd. (o)/4113; Cal. Code Regs., tit. 16, § 17535.6, subd. (e)). Specifically, between on or about March 6, 2019, through on or about September 23, 2019, the pharmacy compounded 193 compounded sterile products in a biological safety cabinet not externally vented, in a room not physically separated from other activities, with no evidence of pressure differential, and with no evidence of a minimum of 12 air changes per hour. In aggravation, this was a repeat finding from the 2017 and 2018 inspections.

PRAYER

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

1. Revoking or suspending Original Hospital Pharmacy Permit Number HPE 19576, issued to San Mateo County doing business as San Mateo Medical Center;

2. Revoking or suspending Sterile Compounding Permit Number LSC 100358, issued to San Mateo County doing business as San Mateo County Medical Center Main Pharmacy Room 1PH021;

3. Revoking or suspending Pharmacist License Number RPH 42499, issued to Gary Lynn Horne;

4. Ordering San Mateo County and Gary Lynn Horne to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 9/11/2020

Anne Sodergren

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

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