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

In the Matter of the Accusation Against:

CONVERSIO HEALTH LLC AND INTEGRATED HEALTH CONCEPTS INC., dba CONVERSIO HEALTH, JAMES M. HOXTER, CEO, Original Pharmacy Permit No. PHY 51610, & Sterile Compounding Permit No. LSC 99934;

and

TIMOTHY JAMES WALSH, Registered Pharmacist License No. RPH 42653,

Respondents

Agency Case No. 6932

OAH No. 2020110299

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 August 18, 2021.

It is so ORDERED on July 19, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BUNTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
MATTHEW A. KING
Deputy Attorney General
State Bar No. 265691
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6303
Facsimile: (916) 731-2126
E-mail: Matthew.King@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **CONVERSIO HEALTH LLC AND INTEGRATED HEALTH CONCEPTS INC., DBA CONVERSIO HEALTH, JAMES M. HOXTER, CEO** **720 Aerovista Place, Ste. D** **San Luis Obispo, CA 93401** **Original Permit No. PHY 51610** **Sterile Compounding Permit No. LSC 99934,** **and** **TIMOTHY JAMES WALSH** **371 Broad Street** **San Luis Obispo, CA 93405** **Registered Pharmacist License No. RPH 42653** Respondents.	Case No. 6932 OAH No. 2020110299 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT TIMOTHY JAMES WALSH 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 Matthew Rodriquez, Attorney General of the State of California, by Matthew A. King, Deputy Attorney General.

2. On or about August 7, 1989, the board issued Registered Pharmacist License Number RPH 42653 to Timothy James Walsh (respondent). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2023, unless renewed.

3. Respondent was the Pharmacist-in-Charge of respondent Conversio Health LLC and Integrated Health Concepts, doing business as Conversio Health, from March 12, 2018 to February 4, 2020.

4. Respondent is represented in this proceeding by attorney Natallia Mazina of Mazina Law, whose office is located at 100 Pine Street Suite 1250, San Francisco, CA 94111-5235.

JURISDICTION

5. Accusation No. 6932 was filed before the board, and is currently pending against respondent. The Accusation and all other statutorily required documents were properly served on respondent on August 31, 2020. Respondent timely filed his Notice of Defense contesting the Accusation.

6. A copy of Accusation No. 6932 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6932. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

///

///

8. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his 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.

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

CULPABILITY

10. Respondent understands and agrees that the charges and allegations in Accusation No. 6932, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License.

11. For the purpose of resolving the 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 Accusation, and that respondent hereby gives up his right to contest those charges.

12. Respondent agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the board's imposition of discipline as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the board. Respondent understands and agrees that counsel for complainant and the staff of the board may communicate directly with the board regarding this stipulation and settlement, without notice to or participation by respondent or his counsel. By signing the stipulation, respondent understands and agrees that they may not withdraw his 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 his 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 Registered Pharmacist License Number RPH 42653 issued to respondent is revoked. However, the revocation is stayed and respondent is placed on probation for three (3) years on the following terms and conditions:

1. **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
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves

respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

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

2. **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.

3. **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.

4. **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 his 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.

///

5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Reporting of Employment and Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 6932 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of each of his employer(s), and the name(s) and telephone number(s) of all of his direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) his direct supervisor, (b) his pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6932, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in

writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 6932, and the terms and conditions imposed thereby.

If respondent works for or is employed by or through an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 6932, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a Pharmacist's License is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

///

///

///

8. **Restrictions on Supervision and Oversight of Licensed Facilities**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. **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 $7,245.60. Respondent shall make said payments as follows: within 30 days of the effective date of the Decision and Order.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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.

10. **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.

11. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Pharmacist's License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Pharmacist's License shall be considered a violation of probation.

If respondent's Pharmacist's License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all

terms and conditions of this probation not previously satisfied.

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

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may relinquish his license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the 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. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any 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, including any outstanding costs.

13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the board or its designee.

If respondent does not practice as a pharmacist in California for the minimum number of 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 least: the date(s), location(s), and hours of last practice; the reason(s) for the

interruption or reduction in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be 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. The board or its designee may post a notice of the extended probation period on its website.

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, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, 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 Accusation No. 6932 shall be deemed true and correct as to respondent.

15. **Completion of Probation**

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

///

16. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Natallia Mazina, Esq. I understand the stipulation and the effect it will have on my Registered Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

TIMOTHY JAMES M. WALSH
Respondent

I have read and fully discussed with my client, respondent Timothy James Walsh, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

NATALLIA MAZINA, ESQ.
Attorney for Respondent

///

///

///

16. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Natallia Mazina, Esq. I understand the stipulation and the effect it will have on my Registered Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 4.27.21

TIMOTHY JAMES M. WALSH
Respondent

I have read and fully discussed with my client, respondent Timothy James Walsh, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: April 28, 2021

NATALLIA MAZINA, ESQ.
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,

MATTHEW RODRIQUEZ
Acting Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

MATTHEW A. KING
Deputy Attorney General
Attorneys for Complainant

LA2020600264
64166028.docx
Jz(4/15/21)

ENDORSEMENT

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

DATED: April 28, 2021

Respectfully submitted,

MATTHEW RODRIQUEZ
Acting Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

MATTHEW A. KING
Deputy Attorney General
Attorneys for Complainant

LA2020600264
64166028.docx
Jz(4/15/21)

Exhibit A

Accusation Number 6932

XAVIER BECERRA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
MATTHEW A. KING
Deputy Attorney General
State Bar No. 265691
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6303
Facsimile: (916) 731-2126
E-mail: Matthew.King@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against: **CONVERSIO HEALTH LLC AND INTEGRATED HEALTH CONCEPTS INC., DBA CONVERSIO HEALTH; JAMES M. HOXTER, CEO** **720 Aerovista Place, Ste. D** **San Luis Obispo, CA 93401** **Original Permit Number No. PHY 51610** **Sterile Compounding Permit Number No. LSC 99934**, **and** **TIMOTHY JAMES WALSH** **371 Broad Street** **San Luis Obispo, CA 93405** **Registered Pharmacist License Number No. RPH 42653** Respondents.	Case No. 6932 **ACCUSATION**

PARTIES

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

2. On or about September 30, 2013, the Board issued Original Permit Number PHY 51610 to Conversio Health LLC and Integrated Health Concepts Inc., doing business as

Conversio Health (Respondent Conversio Health). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2021, unless renewed. James M. Hoxter has been the Chief Executive Officer since September 30, 2013.

3. On or about March 20, 2014, the Board issued Sterile Compounding Permit Number LSC 99934 to Respondent Conversio Health. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2021, unless renewed.

4. On or about August 7, 1989, the Board issued Registered Pharmacist License Number RPH 42653 to Timothy James Walsh (Respondent Walsh). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2021, unless renewed.

5. Respondent Walsh was the Pharmacist-in-Charge of Respondent Conversio Health from March 12, 2018 to February 4, 2020.

JURISDICTION

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

7. Section 4300 of the Code states in pertinent part that "[e]very license issued may be suspended or revoked."

8. 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

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

9. Section 4126.5 of the Code states, in pertinent part:

(a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control. During a proclaimed state of emergency, "another pharmacy" as used in this paragraph shall include a mobile pharmacy, as described in subdivision (c) of Section 4062.

10. Section 4169 of the Code 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.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

11. 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:

…

(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.

12. Section 4306.5 of the Code states in pertinent part:

(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.

13. Section 4307 of the Code states in pertinent part:

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

(1) Where a probationary license is issued or where an existing license is placed

on probation, this prohibition shall remain in effect for a period not to exceed five years.

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

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

14. Health and Safety Code section 111255 states:

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

15. Health and Safety Code section 111330 states:

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

16. Health and Safety 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.

17. Health and Safety Code section 111445 states:

It is unlawful for any person to misbrand any drug or device.

18. Health and Safety Code section 111450 states:

It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

19. United States Code, title 21, section 352 states in pertinent part:

A drug or device shall be deemed to be misbranded—

(a) False or misleading label.

(1) If its label is false or misleading in any particular.

…

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

REGULATORY PROVISIONS

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

(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

…

(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.

(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.

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

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

(1) The master formula document.

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

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

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

(E) The quantity of each ingredient used in compounding the drug preparation.

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

(I) The final quantity or amount of drug preparation compounded for dispensing.

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

and procedures.

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

…

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

22. California Code of Regulations, title 16, section 1735.4 states:

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

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(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.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and

dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a)–(c).

23. California Code of Regulations, title 16, section 1751.4 states in pertinent part:

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

24. California Code of Regulations, title 16, section 1751.7 states in pertinent part:

(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing

that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

25. California Code of Regulations, title 16, section 1751.8 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:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and

containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(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; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

COST RECOVERY

26. 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.

///

///

///

///

///

///

DEFINITIONS

27. Section 4022 of the Code 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.

28. Albuterol 1.25 mg/ Ipratropium 0.5 mg ("Drug #1"), an oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

29. Albuterol 2.5 mg/ Ipratropium 0.75 mg ("Drug #2"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

30. Albuterol 3.75 mg/ Ipratropium 0.75 mg ("Drug #3"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

31. Albuterol 1.25 mg/ Ipratropium 0.5 mg/ Budesonide 0.25 mg ("Drug #4"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

32. Albuterol 2.5 mg/Ipratropium 0.75 mg/ Budesonide 0.25 mg ("Drug #5"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

33. Albuterol 2.5 mg/ Ipratropium 0.75 mg/ Budesonide 0.5 mg ("Drug #6"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

34. Albuterol 2.5 mg/ Budesonide 0.5 mg ("Drug #7"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

35. Albuterol 2.5 mg/ Ipratropium 0.75 mg/ Triamcinolone 0.5 mg ("Drug #8"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

36. Budesonide 0.4 mg ("Drug #9"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

37. Formoterol 12 mcg/ Budesonide 0.5 mg ("Drug #10"), oral inhalation medication, is a dangerous drug. (Bus. & Prof. Code, § 4022.)

38. Formoterol Fumarate 3.4 mg/10 ml stock solution ("Drug #11") is not an oral inhalation medication. It must be diluted before dispensing and is classified as a dangerous drug. (Bus. & Prof. Code, § 4022.)

39. "Compounding" is defined as "any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription: (1) [a]ltering the dosage form or delivery system of a drug[;] (2) [a]ltering the strength of a drug[;] (3) [c]ombining components or active ingredients[;] (4) [p]reparing a drug product from chemicals or bulk drug substances." (Cal. Code Regs., tit. 16, § 1735, subd. (a).)

40. "Compounding Aseptic Isolator (CAI)" is defined as "a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent." (Cal. Code Regs., tit. 16, § 1735.1, subd. (g).)

41. "Controlled cold temperature" means "2 degrees to 8 degrees Celsius (35 degrees to 46 degrees Fahrenheit)." (Cal. Code Regs., tit. 16, § 1735.1, subd. (h).)

42. "Non-sterile-to-sterile batch" is defined as "any compounded drug preparation containing two or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient. (Cal. Code Regs., tit. 16, § 1735.1, subd. (v).)

43. "Primary Engineering Control (PEC)" is defined as "a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots,

compounding aseptic isolators, and compounding aseptic containment isolators." (Cal. Code Regs., tit. 16, § 1735.1, subd. (ab).)

44. "Quality" is defined as "the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document." (Cal. Code Regs., tit. 16, § 1735.1, subd. (ae).)

FACTUAL ALLEGATIONS

45. On or about November 12, 2019, Respondents notified the Board of a recall of all compounded inhalation medication within expiry. As a result of the recall notification, the Board initiated an investigation into the recalled prescriptions and Respondents' compounding practices.

46. Respondents assigned lot numbers to compounded drug preparations using the following convention. The first six digits of the lot number represented the month, day, and year when the compounded drug preparation was prepared. The date was followed by a hyphen and then a number representing the sequential batch number mixed that day. For example, "1" would indicate the first batch of any drug mixed on a given day. Following the sequential batch number was a solidus and a number representing the bag from which the batch was mixed. For example, "1" would indicate the batch was prepared from the first bag. If more than one bag was used to make a batch, the end of the range was indicated after a hyphen (in place of an en dash) followed by the batch number, a solidus, and a number representing the total number of bags mixed.

052219-1/1-1/3

05 22 19 - 1 / 1 - 1 / 3

(*Date*) (*Batch*) (*Bag*) (*To*) (*Batch*) (*Bag*)

In the above example, the drug lot was prepared on May 22, 2019 from the first batch of any drug mixed that day, and the batch was taken from three bags that were mixed.

///

///

///

///

A. Respondents Established Beyond Use Dates For Sterile Compounded Drug Preparations in Excess of Three Days at Controlled Cold Temperature

47. California Code of Regulations, title 16, section 1735.2, subdivision (i), specifies that a drug preparation must 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.

48. For sterile compounded drug preparations, the beyond use date may not exceed the beyond use date assigned for sterility in California Code of Regulations, title 16, section 1751.8. If a sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients entirely within an International Standards Organization (ISO) Class 5 Primary Engineering Control (PEC) located in an ISO Class 7 cleanroom with an ante-area, or if it is compounded entirely within a compounding aseptic isolator (CAI), then regardless of intervening sterilization of any ingredient or the preparation, the beyond use date cannot be more than 24 hours at controlled room temperature, three days at controlled cold temperature, or 45 days in solid frozen state.

49. From approximately April 23, 2019 through September 17, 2019, Respondents assigned a beyond use date to 40 lots of compounded drugs that exceeded the legal beyond use date for a compounded drug preparation prepared with non-sterile ingredients using aseptic manipulations in an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area, or else compounded within a CAI, as more particularly alleged in the table below.

	Lot No.	**Date Compounded**	**Number Made**	**Beyond Use Date**
Drug #1. Albuterol 1.25 mg / Ipratropium 0.5 mg				
1.	061019-2/1-2/5	6/10/2019	10,000 ml 5,670 vials	12/7/2019 180 days
2.	081419-2/1-2/4	8/14/2019	8,000 ml 3,715 vials	2/10/2020 180 days

	Lot No.	Date Compounded	Number Made	Beyond Use Date
3.	090519-1/1-1/4	9/5/2019	8,000 ml 3,945 vials	3/3/2020 180 days
Drug #2. Albuterol 2.5 mg / Ipratropium 0.75 mg				
4.	052319-2/1-2/10	5/23/2019	20,000 ml 9,355 vials	11/19/2019 180 days
5.	061119-1/1-1/10	6/11/2019	20,000 ml 9,440 vials	12/8/2019 180 days
6.	071619-1/1-1/10	7/16/2019	20,000 ml 9,370 vials	1/12/2020 180 days
Drug #3. Albuterol 3.75 mg / Ipratropium 0.75 mg				
7.	052419-1/1-1/2	5/24/2019	6,000 ml 1,940 vials	11/20/2019 180 days
8.	082219-1/1-1/3	8/22/2019	9,000 ml 2,920 vials	2/18/2020 180 days
Drug #4. Albuterol 1.25 mg / Ipratropium 0.5 mg/ Budesonide 0.25 mg				
9.	073019-2/1	7/30/2019	9,000 ml 2,920 vials	11/27/2019 120 days
Drug #5. Albuterol 2.5 mg / Ipratropium 0.75 mg /Budesonide 0.25 mg				
10.	061119-3/1-3/2	6/11/2019	6,000 ml 2,010 vials	9/9/2019 90 days
11.	082219-2/1-2/4	8/22/2019	12,000 ml 3,815 vials	1/19/2020 150 days
Drug #6. Albuterol 2.5 mg / Ipratropium 0.75 mg /Budesonide 0.5 mg				
12.	062619-3/1-3/2	6/26/2019	6,000 ml 2,020 vials	10/24/2019 120 days
13.	070319-2/1-2/3	7/3/2019	9,000 ml 3,045 vials	10/31/2019 120 days
14.	080819-1/1-1/4	8/8/2019	12,000 ml 4,070 vials	1/5/2020 150 days

	Lot No.	Date Compounded	Number Made	Beyond Use Date
15.	052219-1/1-1/3	5/22/2019	9,000 ml 2,475 vials	11/18/2019 180 days
16.	070319-3/1-1/3	7/3/2019	9,000 ml 3,035 vials	12/30/2019 180 days
17.	082919-1/1-1/3	8/29/2019	9,000 ml 2,960 vials	2/25/2020 180 days
Drug #8. Albuterol 2.5 mg / Ipratropium 0.75 mg/ Triamcinolone 0.5 mg				
18.	081219-2	8/12/2019	2,000 ml 600 vials	11/30/2019 150 days
Drug #9. Budesonide 0.4 mg				
19.	071019-2/1-2/2	7/10/2019	6,000 ml 1,940 vials	11/7/2019 120 days
20.	080619-2/1-2/5	8/6/2019	15,000 ml 5,250 vials	1/3/2020 150 days
21.	082819-1/1-1/4	8/28/2019	12,000 ml 3,315 vials	1/25/2020 150 days
Drug #10. Formoterol 12 mcg / Budesonide 0.5 mg				
22.	051719-1/1-1/6	5/17/2019	18,000 ml 4,940 vials	11/13/2019 180 days
23.	052019-1/1-1/6	5/20/2019	18,000 ml 4,765 vials	11/16/2019 180 days
24.	052019-2/1-2/6	5/20/2019	18,000 ml 4,965 vials	11/16/2019 180 days
25.	062019-1/1-1/6	6/20/2019	18,000 ml 5,075 vials	12/17/2019 180 days
26.	062019-2/1-2/5	6/20/2019	18,000 ml 5,175 vials	12/17/2019 180 days
27.	062419-2/1-2/6	6/24/2019	18,000 ml 5,085 vials	12/21/2019 180 days
28.	070119-1/1-1/6	7/1/2019	18,000 ml 5,015 vials	12/28/2019 180 days

	Lot No.	Date Compounded	Number Made	Beyond Use Date
29.	080119-1/1-1/6	8/1/2019	18,000 ml 5,095 vials	1/28/2020 180 days
30.	080119-2/1-2/6	8/1/2019	18,000 ml 4,965 vials	1/28/2020 180 days
31.	090319-1/1-1/6	9/3/2019	18,000 ml 3,360 vials	3/1/2020 180 days
32.	090319-2/1-2/6	9/3/2019	18,000 ml 5,150 vials	3/1/2020 180 days
33.	090319-3/1-3/6	9/3/2019	18,000 ml 5,195 vials	3/1/2020 180 days
34.	090419-1/1-1/6	9/4/2019	18,000 ml 5,095 vials	3/2/2020 180 days
35.	091719-1/1-1/6	09/17/2019	18,000 ml 4,980 vials	3/15/2020 180 day
Drug #11. Formoterol Fumarate stock solution 3.4 mg/10 ml				
36.	042319-3/1-3/2	4/23/2019	6,000 ml	12/31/2019 252 days
37.	052419-3/1-3/2	5/24/2019	6,000 ml	3/11/2020 292 days
38.	061319-2/1-2/2	6/13/2019	6,000 ml	3/11/2020 272 days
39.	0712/19-2/1-2/2	7/12/2019	6,000 ml	3/31/2020 263 days
40.	080719-1/1-1/2	8/7/2019	6,000 ml	3/31/2020 237 days

B. Respondents Established Beyond Use Dates for 14 Drugs That Exceeded The Beyond Use Date of One of the Ingredients

50. California Code of Regulations, title 16, section 1735.2, subdivision (i)(2)(A), specifies that a drug preparation must 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. For sterile compounded drug preparations, the beyond use date

may not exceed the shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation.

51. From approximately May 17, 2019 through September 17, 2019, Respondents established a beyond use date for 14 lots of a compounded drug (*viz*., Formoterol 12 mcg/Budesonide 0.5 mg [Drug #10]), which exceeded the beyond use date of one of the compounded drug's ingredients (*viz*., Formoterol Fumarate stock solution 3.4 mg/10 ml [Drug #11]), as more particularly alleged in the table below.

No.	**Drug #10 Lot No**.	**Date Compounded**	**Amount**	**Assigned Beyond Use Date of Drug #10**	**Beyond Use Date of Ingredient, Drug #11**
1.	051719-1/1-1/6	5/17/2019	18,000 ml 4,940 vials	11/13/2020	4/26/2019 Lot 042319-3
2.	052019-1/1-1/6	5/20/2019	18,000 ml 4,765 vials	11/16/2020	4/26/2019 Lot 042319-3
3.	052019-2/1-2/6	5/20/2019	18,000 ml 4,965 vials	11/16/2020	4/26/2019 Lot 042319-3
4.	062019-1/1-1/6	6/20/2019	18,000 ml 5,075 vials	12/17/2019	5/27/2019 Lot 052319-3
5.	062019-2/1-2/5	6/20/2019	18,000 ml 5,175 vials	12/17/2019	5/27/2019 Lot 052419-3
6.	062419-2/1-2/6	6/24/2019	18,000 ml 5,085 vials	12/21/2019	5/27/2019 Lot 052419-3
7.	070119-1/1-1/6	7/1/2019	18,000 ml 5,015 vials	12/28/2019	6/16/2019 Lot 061319-2
8.	080119-1/1-1/6	8/1/2019	18,000 ml 5,095 vials	1/28/2020 180 days	7/15/2019 Lot 071219-2
9.	080119-2/1-2/6	8/1/2019	18,000 ml 4,965 vials	1/28/2020 180 days	7/15/2019 Lot 071219-2
10.	090319-1/1-1/6	9/3/2019	18,000 ml 3,360 vials	3/1/2020 180 days	8/10/2019 Lot 080719-1
11.	090319-2/1-2/6	9/3/2019	18,000 ml 5,150 vials	3/1/2020 180 days	8/10/2019 Lot 080719-1

No.	Drug #10 Lot No.	Date Compounded	Amount	Assigned Beyond Use Date of Drug #10	Beyond Use Date of Ingredient, Drug #11
12.	090319-3/1-3/6	9/3/2019	18,000 ml 5,195 vials	3/1/2020 180 days	8/10/2019 Lot 080719-1
13.	090419-1/1-1/6	9/4/2019	18,000 ml 5,095 vials	3/2/2020 180 days	8/10/2019 Lot 080719-1
14.	091719-1/1-1/6	09/17/2019	18,000 ml 4,980 vials	3/15/2020 180 day	8/10/2019 Lot 080719-1

C. Respondents Did Not Support Extended Beyond Use Dates with Tests and Studies

52. California Code of Regulations, title 16, section 1735.2, subdivision (i)(3)(A)–(C), permits a pharmacist and pharmacy to extend the beyond use date of a sterile compounded drug preparation only if the beyond use date is supported by a 1) method suitability test; 2) container closure integrity test; and 3) stability studies.

53. From approximately April 23, 2019 through August 28, 2019, Respondents established an extended beyond use date for 20 lots of sterile compounded drug preparations without supporting the extended beyond use date with a 1) method suitability test; 2) container closure integrity test; and 3) stability studies. Respondents had at least one of the required types of supporting evidence for an extended beyond use date for some of the sterile compounded drug preparations, but they did not have all three types of required supporting evidence to establish an extended beyond use date for any of the sterile compounded drug preparations, as more particularly alleged in the table below.

Lot No.		Date Compounded	Method Suitability Test	Container Closure Integrity Test	Stability Studies
Drug #2. Albuterol 2.5 mg / Ipratropium 0.75 mg					
1.	052319-2/1-2/10	5/23/2019	No	No	No

Lot No.		Date Compounded	Method Suitability Test	Container Closure Integrity Test	Stability Studies
2.	061119-1/1-1/10	6/11/2019	No	No	No
3.	071619-1/1-1/10	7/16/2019	No	No	No
Drug #3. Albuterol 3.75 mg / Ipratropium 0.75 mg					
4.	052419-1/1-1/2	5/24/2019	No	No	No
5.	082219-1/1-1/3	8/22/2019	No	No	No
Drug #4. Albuterol 1.25 mg / Ipratropium 0.5 mg/ Budesonide 0.25 mg					
6.	073019-2/1	7/30/2019	No	Yes	Yes
Drug #5. Albuterol 2.5 mg / Ipratropium 0.75 mg /Budesonide 0.25 mg					
7.	061119-3/1-3/2	6/11/2019	No	No	No
8.	082219-2/1-2/4	8/22/2019	No	No	No
Drug #6. Albuterol 2.5 mg / Ipratropium 0.75 mg /Budesonide 0.5 mg					
9.	062619-3/1-3/2	6/26/2019	Yes	No Because Test Failed On 3-8-2019	Yes
10.	070319-2/1-2/3	7/3/2019	Yes	No Because Test Failed On 3-8-2019	Yes
11.	080819-1/1-1/4	8/8/2019	Yes	No Because Test Failed On 3-8-2019	Yes
Drug #8. Albuterol 2.5 mg / Ipratropium 0.75 mg / Triamcinolone 0.5 mg					
12.	081219-2	8/12/2019	Yes	No Because Test Failed On 3-8-2019	Yes
Drug #9. Budesonide 0.4 mg					
13.	071019-2/1-2/2	7/10/2019	No	No Because Test Failed On 3-8-2019	Yes
14.	080619-2/1-2/5	8/6/2019	No	No Because Test Failed On 3-8-2019	Yes
15.	082819-1/1-1/4	8/28/2019	No	No Because Test	Yes

Lot No.		Date Compounded	Method Suitability Test	Container Closure Integrity Test	Stability Studies
				Failed On 3-8-2019	
Drug #11. Formoterol Fumarate stock solution 3.4 mg/10 ml					
16.	042319-3/1-3/2	4/23/2019	No	No	No
17.	052419-3/1-3/2	5/24/2019	No	No	No
18.	061319-2/1-2/2	6/13/2019	No	No	No
19.	071219-2/1-2/2	7/12/2019	No	No	No
20.	080719-1/1-1/2	8/7/2019	No	No	No

D. Respondents Did Not Ensure the Quality of Compounded Drug Preparations

54. California Code of Regulations, title 16, section 1735.2, subdivision (g), makes the pharmacist performing or supervising compounding 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 the label instructions for storage and handling are followed after the preparation is dispensed.

55. California Code of Regulations, title 16, section 1735.1, subdivision (ae), defines "quality" to mean the absence of harmful levels of contaminants, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

56. From approximately May 22, 2019 through August 22, 2019, Respondents failed to ensure the quality of ten lots of compounded drug preparations. In the case of each of the ten lots, Respondents used a STyLUX ST0.2 Irradiated Filter which has a bubble point greater than or equal to 44 pounds per square inch (psi) in water. Respondents tested the integrity of the filter in each of the ten lots using a bubble point test, which in every case yielded a failing result of less than 44 psi, indicating a compromised filter. Instead of documenting each failed test as a failed

test, Respondents documented them as passing tests, as more particularly alleged in the table below.

	Drug and Lot	Outcome of Test	Compounding Pharmacist
Drug #1. Albuterol 1.25 mg / Ipratropium 0.5 mg			
1.	061019-2/1-2/5	Bubble point log shows: PSI 40 (failed)	Respondent Walsh
Drug #2. Albuterol 2.5 mg / Ipratropium 0.75 mg			
2.	052319-2/1-2/10	Bubble point log shows: PSI 43 (Failed)	Respondent Walsh
3.	061119-1/1-1/10	Bubble point log shows: PSI 40 (Failed)	Respondent Walsh
4.	071619-1/1-1/10	Bubble point log shows: PSI 40 (Failed)	Respondent Walsh
Drug #3. Albuterol 3.75 mg / Ipratropium 0.75 mg			
5.	082219-1/1-1/3	Bubble point log shows: PSI 42 (Failed)	Respondent Walsh
Drug #7. Albuterol 2.5 mg / Budesonide 0.5 mg			
6.	052219-1/1-1/3	Bubble point log shows: PSI 43 (failed)	Respondent Walsh
Drug #8. Albuterol 2.5 mg / Ipratropium 0.75 mg / Triamcinolone 0.5 mg			
7.	081219-2	Bubble point log shows: PSI 40 (failed)	C.A.
Drug #9. Budesonide 0.4 mg			
8.	080619-2/1-2/5	Bubble point log shows: PSI 43 (Failed)	H.B.
Drug # 10. Formoterol 12 mcg / Budesonide 0.5 mg			
9.	062019-2/1-2/5	Bubble point log: PSI 43 (Failed)	Respondent Walsh
10.	080119-1/1-1/6	Bubble point log: PSI 43 (failed)	Respondent Walsh

///

57. Respondent Walsh was the pharmacist who compounded or supervised the compounding of eight of the affected lots where the bubble test failed. Respondent Walsh was responsible for the quality of the failed lots.

E. Respondents Failed to Maintain Compounding Log Information in a Single Document

58. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2), requires that for each compounded drug preparation, pharmacy records shall include a compounding log consisting of *a single document* containing all of the following:

a. Name and Strength of the compounded drug preparation.

b. The date the drug preparation was compounded.

c. The identity of any pharmacy personnel engaged in compounding the drug preparation.

d. The identity of the pharmacist reviewing the final drug preparation.

e. The quantity of each ingredient used in compounding the drug preparation.

f. The manufacturer, expiration date and lot number of each component.

g. A pharmacy-assigned unique reference or lot number for the compounded drug product 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.

i. The final quantity or amount of drug preparation compounded for dispensing.

j. Documentation of quality reviews and required post-compounding process and procedures.

59. Respondents failed to have a compounding log consisting of a *single document* containing all of the required information in the case of 40 compounding logs. The 40 affected compounded drug lots for which Respondents failed to have compliant compounding drug logs are more particularly alleged in the table in paragraph 49 above.

///

///

F. Respondents Failed to Document the Identity of the Pharmacist Reviewing the Final Drug Preparation in Compounding Logs

60. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(D), requires that for each compounded drug preparation, pharmacy records must include a compounding log consisting of a single document that identifies the identity of the pharmacist reviewing the final drug preparation.

61. Respondents failed to document the identity of the pharmacist reviewing the final drug preparation with respect to 40 lots of compounded drug preparations. The 40 affected compounded drug lots are more particularly alleged in the table in paragraph 49 above.

G. Respondents Failed to Document Quality Reviews and Post-Compounding Processes and Procedures in Compounding Logs

62. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(J), provides that for each compounded drug preparation, pharmacy records must include a compounding log consisting of a single document containing documentation of quality reviews and required post-compounding process and procedures.

63. Respondents failed to document quality reviews and post-compounding processes and procedures with respect to 40 lots of compounded drug preparations, as more particularly alleged in the table below. Quality reviews in certain instances were missing one or more of the following: the filter integrity test, end product sterility data and/or visual inspections. Post-compounding process and procedures in certain instances were missing one or more of the following items: information concerning the required quarantine prior to the completion of sterility testing, quarantine release, and/or drug storage prior to being pumped into the final container. The 40 affected compounded drug lots are more particularly alleged in the table in paragraph 49 above.

///

///

///

///

H. Respondents Failed to Document the Expiration Date of Each Component in Compounding Logs

64. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F), provides that for each compounded drug preparation, pharmacy records must include a compounding log consisting of a single document containing the manufacturer, expiration date and lot number of each component.

65. From approximately June 20, 2019 through June 24, 2019, Respondents failed to document in compounding logs pertaining to three preparations of Formoterol 12 mcg/Budesonide 0.5 mg (Drug #10) the expiration date of a component, namely, Formoterol Fumarate stock solution 3.4 mg/10 ml (Drug #11), as more particularly alleged in the table below.

No.	Drug #11 Lot	Active Pharmaceutical Ingredient Used	Expiration Date Documentation of Drug #11
Drug #10. Formoterol 12 mcg / Budesonide 0.5 mg			
1.	062019-1/1-1/6	Formoterol Fumarate Stock Solution 3.4 mg/10 ml (Drug #11) Store Lot 052419-3/2	No Expiration Date Documented for Formoterol Fumarate Stock Solution 3.4 mg/10 ml (Drug #11)
2.	062019-2/1-2/5	Formoterol Fumarate Stock Solution 3.4 mg/10 ml (Drug #11) Store Lot 052419-3/2	No Expiration Date Documented for Formoterol Fumarate Stock Solution 3.4 mg/10 ml (Drug #11)
3.	062419-2/1-2/6	Formoterol Fumarate Stock Solution 3.4 mg/10 ml (Drug #11) Store Lot 052419-3/2	No Expiration Date Documented for Formoterol Fumarate Stock Solution 3.4 mg/10 ml (Drug #11)

I. Respondents Failed to Complete a U.S. Pharmacopeia (USP) 71 Sterility Test and Failed to Quarantine Drugs Before Dispensing from Non-Sterile-To-Sterile Compounded Drug Preparations

66. California Code of Regulations, title 16, section 1751.7, subdivision (e)(1), requires batch-produced sterile drug preparations compounded from one or more non-sterile ingredients to be subject to documented end product testing for sterility and pyrogens. In addition, drug preparations compounded from one or more non-sterile ingredients must be quarantined until end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing must be conducted in accordance with USP chapter 71, and pyrogen testing must confirm acceptable levels of pyrogens pursuant to USP chapter 85 limits prior to release of the drug preparation from quarantine for dispensing. The requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing applies regardless of any sterility or pyrogen testing that may have been conducted on an ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations. As oral inhalation medications, Drug #1, Drug #2, Drug #3, Drug #4, Drug #5, Drug #6, Drug #7, Drug #8, Drug #9, and Drug #10 were exempt from testing for pyrogens. However, all of the compounded drug preparations (*viz.*, Drug #1–Drug #11) were required to be tested for sterility and quarantined until documented testing established sterility.

67. From approximately April 23, 2019 through September 17, 2019, Respondents dispensed 40 non-sterile-to-sterile compounded drug preparations without subjecting them to documented end product testing for sterility (and, as applicable to Drug #11, pyrogens), and without quarantining the drug preparations until end product testing confirmed sterility (and, as applicable to Drug #11, acceptable levels of pyrogens). The 40 affected compounded drug lots are more particularly alleged in the table in paragraph 49 above.

///

///

///

///

J. Respondents Misbranded Dangerous Drugs

68. Health and Safety Code section 111330 states that any drug or device is misbranded if its labeling is false or misleading in any particular. Health and Safety Code section 111440 makes it unlawful for a person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded. Health and Safety Code section 111445 makes it unlawful for a person to misbrand any drug or device. Health and Safety Code section 111450 makes it unlawful for any person to receive in commerce any drug that is misbranded or to deliver or proffer for delivery any misbranded drug. United States Code, title 21, section 352, subdivisions (a)(1) and (f), deem a drug to be misbranded if it contains a false or misleading label, inadequate directions for use, or lack of drug warnings.

69. From approximately April 23, 2019 through August 7, 2019, Respondents manufactured a misbranded drug when they 1) prepared four lots of Formoterol Fumarate stock solution 3.4 mg/10 ml (Drug #11) and 2) assigned a beyond use date of greater than three days when stored at cold temperature without having supporting studies and tests to justify an extended beyond use date. The affected lots are more particularly alleged in the table below.

No.	**Lot**	**Date Made**	**Amount Prepared**	**Beyond Use Date On Label**	**Correct Beyond Use Date**
Drug #11. Formoterol Fumarate Stock Solution 3.4 mg/10 ml					
1.	042319-3/1-3/2	4/23/19	6,000 ml	12/31/2019	4/26/2019
2.	061319-2/1-2/2	6/13/19	6,000 ml	3/11/2020	6/16/2019
3.	071219-2/1-2/2	7/12/19	6,000 ml	3/31/2020	07/15/2019
4.	080719-1/1-1/2	8/7/19	6,000 ml	3/31/2020	08/10/2019

///

///

///

70. Respondents sold, delivered, held, or offered for sale a misbranded drug when from approximately May 28, 2019 through October 30, 2019, Respondents dispensed to patients in California and elsewhere 408 prescriptions for Formoterol 12 mcg/ Budesonide 0.5 mg (Drug #10), which prescriptions were compounded in part from expired Formoterol Fumarate Stock Solution 3.4 mg/ 10 ml (Drug #11).

K. Respondents Failed to Label a Compounded Drug Preparation

71. California Code of Regulations, title 16, section 1735.4, subdivision (a)(4), requires that for each compounded drug preparation a label must be affixed to the container prior to dispensing that contains at least the beyond use date for the drug preparation. An additional requirement, contained in subdivision (d), is that prior to dispensing drug preparations that are compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the labeling requirements of subdivisions (a) through (c), the unit-dose container must be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, the active ingredients, strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date without regard to minimum font size requirements.

72. On or about May 24, 2019, Respondents failed to label Formoterol Fumarate stock solution 3.4 mg/10 ml (Drug #11), lot number 052419-3/1-3/2, with a beyond use date.

L. Respondents Adulterated Formoterol 12 mcg/ Budesonide 0.5 mg

73. Health and Safety Code section 111255 provides that a drug is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. From approximately May 17, 2019 through September 17, 2019, Respondents adulterated 14 lots of the compounded drug preparation Formoterol 12 mcg/ Budesonide 0.5 mg (Drug #10) when they produced and prepared the drug lots with expired Formoterol Fumarate stock solution 3.4 mg/10 ml (Drug #11), as more particularly alleged in the table in paragraph 51 above.

///

///

///

M. Respondents Sold Adulterated Formoterol 12 mcg/ Budesonide 0.5 mg

74. Section 4169, subdivision (a), of the Code prohibits a person from selling or transferring dangerous drugs that the person knew or reasonably should have known were adulterated. Respondents violated said section in that between approximately May 28, 2019 through October 30, 2019, Respondents sold and transferred to patients in California and elsewhere 408 prescriptions for Formoterol 12 mcg/ Budesonide 0.5 mg (Drug #10), which was compounded in part from expired Formoterol Fumarate Stock Solution 3.4 mg/ 10 ml (Drug #11).

N. Respondents Furnished a Dangerous Drug to an Unlicensed Entity

75. Section 4126.5, subdivision (a), of the Code provides that a pharmacy may furnish a dangerous drug only to specific people, including, as relevant here, a wholesaler from whom the dangerous drug was acquired or a licensed wholesaler acting as a reverse distributor. On or about September 5, 2019, Respondents prepared Albuterol 1.25 mg/ Ipratropium 0.5 mg (Drug #1), lot number 090519-1/1-1/4, but because the filter used during compounding failed the bubble point test, Respondents furnished the drug lot to D.S.I. for destruction on or about September 24, 2019. While Respondents correctly realized that the failed bubble point test required the drug lot to be destroyed, Respondents violated the Pharmacy Law when they furnished the drug lot to D.S.I., which was neither a wholesaler from which Respondents acquired the drug lot or a licensed wholesaler acting as a reverse distributor.

O. Respondents Failed to Maintain Records of Disposition

76. Section 4081, subdivision (a), of the Code requires that all records of manufacture, sale, acquisition, receipt, shipment or disposition of dangerous drugs be at all times during business hours be open to inspection by authorized officers of the law, including Board inspectors. Respondents violated this section because on or about September 24, 2019, Respondents furnished Albuterol 1.25 mg/Ipratropium 0.5 mg (Drug #1), lot number 090519-1/1-1/4 to D.S.I. for destruction, but all times thereafter, and subsequent to a lawful Board request, Respondents were unable to produce an adequate record of disposition for lot number 0901519-1/1-1/4.

///

FIRST CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Failure to Correctly Assign Beyond Use Date)

77. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1735.2, subdivision (i), and section 1751.8. From approximately April 23, 2019 through September 17, 2019, Respondents assigned a beyond use date to 40 lots of compounded drugs that exceeded the legal beyond use date for a compounded drug preparation prepared with non-sterile ingredients using aseptic manipulations in an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area, or else compounded within a CAI. Complainant realleges paragraphs 47 through 49.

SECOND CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Failure to Assign a Correct Beyond Use Date Based On Expiration of Ingredients)

78. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1735.2, subdivision (i)(2)(A). From approximately May 17, 2019 through September 17, 2019, Respondents established a beyond use date for 14 lots of a compounded drug (*viz*., Formoterol 12 mcg/Budesonide 0.5 mg [Drug #10]), which exceeded the beyond use date of one of the compounded drug's ingredients (*viz*., Formoterol Fumarate stock solution 3.4 mg/10 ml [Drug #11]). Complainant realleges paragraphs 50 through 51.

///

THIRD CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Failure to Support an Extended Beyond Use Date)

79. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that Respondents violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1735.2, subdivision (i)(3)(A)–(C). From approximately April 23, 2019 through August 28, 2019, Respondents established an extended beyond use date for 20 lots of sterile compounded drug preparations without supporting the extended beyond use date with a 1) method suitability test; 2) container closure integrity test; and 3) stability studies. Complainant realleges paragraphs 52 through 53.

FOURTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Failure to Ensure Quality of Compounded Drug Products)

80. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that Respondents violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, sections 1735.2, subdivision (g) and 1735.1, subdivision (ae). From approximately May 22, 2019 through August 22, 2019, Respondents failed to ensure the quality of ten lots of compounded drug preparations. In each case, Respondents used a STyLUX ST0.2 Irradiated Filter with a bubble point greater than or equal to 44 psi in water. Each bubble test yielded a failing result of less than 44 psi, indicating a compromised filter. Instead of documenting each failed test as a failed test, Respondents documented them as passing tests. Complainant realleges 54 through 57.

FIFTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Compounding Logs: Failure to Have Log Information In a Single Document)

81. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1735.3, subdivision (a)(2). Respondents failed to have a compounding log consisting of a single document containing all of the required information in the case of 40 compounding logs. Complainant realleges paragraphs 58 through 59.

SIXTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Compounding Logs: Failure to Identify Compounding Pharmacist)

82. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(D). Respondents failed to document the identity of the pharmacist reviewing the final drug preparation with respect to 40 lots of compounded drug preparations. Complainant realleges paragraphs 60 through 61.

///

///

///

///

///

///

SEVENTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Compounding Logs: Failure to Document Quality Reviews and Required Post-Compounding Process and Procedures)

83. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that Respondents violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(J). Respondents failed to document quality reviews and post-compounding processes and procedures with respect to 40 lots of compounded drug preparations. Quality reviews in certain instances were missing one or more of the following: the filter integrity test, end product sterility data and/or visual inspections. Post-compounding process and procedures in certain instances were missing one or more of the following items: information concerning the required quarantine prior to the completion of sterility testing, quarantine release, and/or drug storage prior to being pumped into the final container. Complainant realleges paragraphs 62 through 63.

EIGHTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Compounding Logs: Failure to Provide Expiration Date of Each Component)

84. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F). From approximately June 20, 2019 through June 24, 2019, Respondents failed to document in compounding logs pertaining to three preparations of Formoterol 12 mcg/Budesonide 0.5 mg (Drug #10) the expiration date of a

component, namely, Formoterol Fumarate stock solution 3.4 mg/10 ml (Drug #11). Complainant realleges paragraphs 64 through 65.

NINTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Failure to Complete USP 71 Sterility Test Before Releasing Drug from Quarantine)

85. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1751.7, subdivision (e)(1). From approximately April 23, 2019 through September 17, 2019, Respondents dispensed 40 non-sterile-to-sterile compounded drug preparations (Drug #1–Drug #11) without subjecting them to documented end product testing for sterility (and, as applicable to Drug #11, pyrogens), and without quarantining the drug preparations until end product testing confirmed sterility (and, as applicable to Drug #11, acceptable levels of pyrogens). Complainant realleges paragraphs 66 through 67.

TENTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Manufacture and Sale of Misbranded Drugs)

86. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for unprofessional conduct in that they violated statues regulating dangerous drugs and attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: Health and Safety Code sections 111330, 111440, 111445, 111450 and United States Code, title 21, section 352, subdivisions (a)(1) and (f). From approximately April 23, 2019 through August 7, 2019, Respondents manufactured a misbranded drug when they 1) prepared four lots of Formoterol Fumarate stock solution 3.4 mg/10 ml and 2)

assigned a beyond use date of greater than three days when stored at cold temperature without having supporting studies and tests to justify an extended beyond use date. Respondents then sold, delivered, held, or offered for sale a misbranded drug when from approximately May 28, 2019 through October 30, 2019, Respondents dispensed to patients in California and elsewhere 408 prescriptions for Formoterol 12 mcg/ Budesonide 0.5 mg (Drug #10), which prescriptions were compounded in part from expired Formoterol Fumarate Stock Solution 3.4 mg/ 10 ml (Drug #11). Complainant realleges paragraphs 68 through 70.

ELEVENTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Failure to Label a Compounded Drug Preparation)

87. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: California Code of Regulations, title 16, section 1735.4, subdivisions (a)(4) and (d). On or about May 24, 2019, Respondents failed to label Formoterol Fumarate stock solution 3.4 mg/10 ml (Drug #11), lot number 052419-3/1-3/2, with a beyond use date. Complainant realleges paragraphs 71 through 72.

///

///

///

///

///

///

///

///

///

TWELFTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Adulteration of Formoterol 12 mcg/ Budesonide 0.5 mg)

88. Respondents are subject to disciplinary action under Code section 4301, subdivision (j), for unprofessional conduct in that they violated statues regulating dangerous drugs, to wit: Health and Safety Code section 111255. From approximately May 17, 2019 through September 17, 2019, Respondents adulterated 14 lots of the compounded drug preparation Formoterol 12 mcg/ Budesonide 0.5 mg (Drug #10) when they produced and prepared the drug lots with expired Formoterol Fumarate stock solution 3.4 mg/10 ml (Drug #11). Complainant realleges paragraph 73.

THIRTEENTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Sale of Adulterated Formoterol 12 mcg/ Budesonide 0.5 mg)

89. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: section 4169, subdivision (a), of the Code. Between approximately May 28, 2019 through October 30, 2019, Respondents sold and transferred to patients in California and elsewhere 408 prescriptions for Formoterol 12 mcg/ Budesonide 0.5 mg (Drug #10), which was compounded in part from expired Formoterol Fumarate Stock Solution 3.4 mg/ 10 ml (Drug #11). Complainant realleges paragraph 74.

///

///

///

///

///

FOURTEENTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Furnishing Danger Drugs to Unlicensed Reverse Distributor)

90. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: section 4126.5, subdivision (a). On or about September 5, 2019, Respondents prepared Albuterol 1.25 mg/ Ipratropium 0.5 mg (Drug #1), lot number 090519-1/1-1/4, but because the filter used during compounding failed the bubble point test, Respondents furnished the drug lot to D.S.I. for destruction on or about September 24, 2019. While Respondents correctly realized that the failed bubble point test required the drug lot to be destroyed, Respondents violated the Pharmacy Law when they furnished the drug lot to D.S.I., which was not a wholesaler from which Respondents acquired the drug lot, nor a licensed wholesaler acting as a reverse distributor, nor a person to whom Respondents were otherwise lawfully able to furnish drugs. Complainant realleges paragraph 75.

FIFTEENTH CAUSE FOR DISCIPLINE

(As to Respondents Conversio Health and Walsh)

(Failure to Maintain Record of Disposition of Dangerous Drugs)

91. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for unprofessional conduct in that they violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of or conspired to violate a provision of Pharmacy Law or 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, to wit: section 4081, subdivision (a), of the Code. On or about September 24, 2019, Respondents furnished Albuterol 1.25 mg/Ipratropium 0.5 mg (Drug #1), lot number 090519-1/1-1/4 to Daniels SharpSmart Inc. for destruction, but all times thereafter, and subsequent to a lawful Board

request, Respondents were unable to produce an adequate record of disposition for lot number 0901519-1/1-1/4. Complainant realleges paragraph 76.

SIXTEENTH CAUSE FOR DISCIPLINE

(As to Respondent Walsh Only)

(Inappropriate Exercise of Education, Training or Experience)

92. Respondent Walsh is subject to disciplinary action under Code sections 4301 and 4306.5 for unprofessional conduct, in conjunction with California Code of Regulations, title 16, sections 1735.2, subdivision (g), and 1735.1, subdivision (ae), in that Respondent Walsh committed acts or omissions that involved, in whole or in part, the inappropriate exercise of his education, training or experience as a pharmacist. In particular, from approximately May 22, 2019 through August 22, 2019, Respondents failed to ensure the quality of ten lots of compounded drug preparations. Respondent Walsh was the pharmacist who compounded or supervised the compounding of eight of the affected lots for which a bubble test returned a failing result. Complainant realleges paragraphs 54 through 57.

DISCIPLINE CONSIDERATIONS

93. To determine the degree of discipline, if any, to be imposed on Respondent Walsh, Complainant alleges that on or about September 12, 2017, in a prior action, the Board of Pharmacy issued Citation Number CI 2016 71909 and ordered Respondent to pay a fine of $1,000. The Citation is now final.

OTHER MATTERS

94. Pursuant to section 4307 of the Code, if while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control, Respondent Walsh had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 51610 or Sterile Compounding Permit Number No. LSC 99934, issued to Respondent Conversio Health, is revoked or placed on probation, then Respondent Walsh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee for a period not to exceed five years if Pharmacy Permit Number PHY 51610 or Sterile Compounding

Permit Number No. LSC 99934 is placed on probation, or, if Pharmacy Permit Number PHY 51610 or Sterile Compounding Permit Number No. LSC 99934 is revoked, the prohibition shall continue until reinstatement.

95. Pursuant to section 4307 of the Code, if discipline is imposed on Pharmacist License Number RPH 42653 issued to Respondent Walsh, then Respondent Walsh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five years if Pharmacist License Number RPH 42653 is placed on probation; or, 2) if the pharmacist license is revoked, the prohibition shall continue until the license is reinstated.

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 Original Permit Number PHY 51610, issued to Conversio Health LLC and Integrated Health Concepts Inc., doing business as Conversio Health;

2. Revoking or suspending Sterile Compounding Permit Number LSC 99934, issued to Conversio Health LLC and Integrated Health Concepts Inc., doing business as Conversio Health;

3. Revoking or suspending Registered Pharmacist License Number RPH 42653, issued to Timothy James Walsh;

4. Prohibiting Timothy James Walsh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for a period not to exceed five years if Pharmacist License Number RPH 42653 is placed on probation, or, if Pharmacist License Number RPH 42653 is revoked, the prohibition shall continue until the license is reinstated;

5. Prohibiting Timothy James Walsh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee if, while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control, he had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 51610 or Sterile Compounding Permit Number LSC 99934 is revoked or placed on probation, in which case the prohibition shall last for a period not to exceed

five years if Pharmacy Permit Number PHY 51610 or Sterile Compounding Permit Number LSC 99934 is placed on probation, or, if Pharmacy Permit Number PHY 51610 or Sterile Compounding Permit Number LSC 99934 is revoked, the prohibition shall continue until reinstatement;

6. Ordering Conversio Health LLC and Integrated Health Concepts Inc., doing business as Conversio Health, and Timothy James Walsh to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 8/22/2020

Anne Sodergren

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

LA2020600264
34245136.docx